PHARM TECH

PHARMACY TECHNICIAN Certification Review and Practice Exam

4th Edition

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PREFACE

Pharmacy Technician Certification Review and Practice Exam, 4th edition, is a self-study guide that is designed to be a companion book to the *Manual for Pharmacy Technicians, 5th edition*; however, it can be used alone in preparation for national certification exams.

The fourth edition is expanded to cover all areas of the current exam offered by the Pharmacy Technician Certification Board (PTCB), and it includes educational standards of the 2019 ASHP Accreditation Standard for Pharmacy Technician Programs.

New expanded areas include:

- New calculations preparation questions
- Medication safety
- Inventory management
- Billing and information systems
- Two new practice exams containing over 200 questions

Certification is becoming increasingly important for pharmacy technicians, especially in light of their roles and responsibilities in the changing practice of pharmacy. As pharmacy rapidly evolves, qualified and credentialed pharmacy technicians are playing a critical role in pharmaceutical care. Many states as well as many employers are now requiring certification as a minimum requirement. Technicians often deem certification important personally so they can show employers they have the necessary skills to meet the minimum standard of the profession. Certification demonstrates the technician's commitment to the profession.

Pharmacy has changed the way pharmaceutical care is practiced and continues to change, adding more responsibility and tasks to what technicians do and are expected to do in the future. Pharmacists need time to provide care for patients, which has resulted in an increase in pharmacist technicians' assigned duties. Roles for technicians now include medication therapy management, medication reconciliation, immunizations, informatics, and tech-check-tech to name a few.

As with all editions of this review manual, it is not intended to be used as a single source for preparation for the certification exam. To ensure a successful outcome, technicians should use this in conjunction with other study materials recommended by the testing organizations.

All the best for a successful career,

Barbara Lacher

May 2019

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I would like to acknowledge ASHP and their continued support of pharmacy technicians as a profession. ASHP has long supported the education of pharmacy technicians not only in publishing, but in accreditation of educational programs. ASHP has taken an active role in helping the profession create a definition of entry level and advanced technicians in practice. Under the leadership of ASHP and other organizations, we are hopeful of one day having pharmacy technicians follow the same professional path as pharmacists as they enter the profession.

CHAPTER 1

PREPARING FOR THE EXAM AND TAKING THE TEST



Learning Outcomes

After completing this chapter, you will be able to

- Discuss basic study and review skills for objective tests.
- List basic strategies for taking objective tests.
- Define common trouble areas in taking objective tests and describe how to manage them.
- Recognize test anxiety and define common relaxation techniques.

You are not alone if you face upcoming examinations with dread and anxiety. Most people do. But exams serve a purpose. They are intended to test your knowledge, not your patience and endurance. Tests are helpful to others who are attempting to determine your understanding and knowledge of specific areas. Tests also help you to understand what areas you are competent in and what areas require focus in terms of your own learning and development.

This chapter reviews preparation tips and test-taking strategies. It concludes with a section on how to deal with the anxiety most of us feel prior to an examination.

TYPES OF EXAMINATIONS

There are two basic types of examinations. The first is the *objective* examination. Objective examinations include multiple-choice, true/false, and matching questions. Objective examinations are designed to test your ability to recognize, rather than recall, facts and information. The second type is the *essay* examination. Essay examinations are tests for which respondents give long, written answers. They provide the opportunity for respondents to organize their knowledge, integrate materials, and express themselves. The two kinds of tests require different skill sets. Because your exam will be objective multiple choice, this chapter focuses on techniques to help you perform at your best on this type of examination.

MULTIPLE-CHOICE QUESTIONS

A multiple-choice question usually begins with an incomplete sentence or question, known as a *stem.* The stem is followed by a series of choices for completing the sentence or answering the question, known as *responses.* The responses are usually lettered *a*, *b*, *c*, and *d.* Typically, there are four, sometimes five, responses to choose from. You complete the sentence or answer the question by choosing the correct or best response. For example, a typical multiple-choice question will look like this:

(Stem) The capital of Illinois is:

(Responses)

a. Springfield
b. Chicago
c. Rockford
d. St. Louis

Generally, the directions are to pick the one best response. However, the directions vary, so read the directions and the stem carefully. You may be instructed to pick the incorrect option or to pick more than one option. There are also questions that present the stem as a complete statement. Key words to note in the stem are the subject of the question and any qualifiers or adjectives that further define the best answer.

PREPARATION FOR OBJECTIVE EXAMS

You may be fresh out of the classroom with recent experience in preparing for and taking objective exams, or you might not have taken an exam in quite some time. Whatever the case, it's always useful to review good study skills. This section reviews some basic study and test preparation techniques.

The first step is to go to the Pharmacy Technician Certification Board — PTCB.org — and complete all the necessary steps in registering to take the exam. Next, check all the pre-requisite requirements. Once you have registered to take the exam and completed the preparation, make sure you look at the *What to Bring* section. Double check the date, time, and place of the exam. Mark your calendar and be sure to find the location in advance. You do not want to be late for the exam because you got lost. Estimate how long it will take you to get to the test center. You may even want to do a test drive. Find out where parking is available, or make a trial run on public transportation.

Be sure you understand the scope of the exam. In other words, how long is it and what material will it cover? What materials, if any, can you bring with you?

EXAM PREPARATION BASICS

Time Management

Every busy person needs a schedule. But planning your study schedule, you first need a thorough understanding of how you study. Answer these basic questions about yourself:

- When is the best time of day for me to study?
- How do I best learn?

If you are unsure of the answers to these questions, you may want to monitor yourself for a week. Develop a time chart and follow your activities. Are there any times of the day when you are more productive than others? Think about how you learn, too. What tasks help you learn? Do you learn best by doing or by reading? Some people find reading aloud to be a helpful memorization technique. This kind of self-knowledge will guide you in developing your study schedule. Even though family and work responsibilities may take most of your time, try to use your most productive time of the day for your studies.

Work Habits

Get Organized

Design a workplace to be productive. Find a place that allows you to work efficiently with a minimum number of distractions. Also ensure that you have enough space to spread your work out, if required. Organize your workspace so that you have quick and easy access to everything you need.

Make a "To Do" List

Keep a running list of all projects and assignments that are due. This will help ensure that you don't forget about

any major obligations. An article on time management recommends creating three lists[1]:

1. ***Daily to-do list***—all of the tasks that need to be completed that day, such as homework due tomorrow.
2. ***Projects to-do list***—all of the projects you have and when they are due. This list should be used to create the daily to-do list and should be reviewed several times a week.
3. ***Long-term to-do list***—the projects that you would like to or need to work on sometime in the future, but for which there are not currently any assigned deadlines. This list should be reviewed about once a week to see if you can move any of these projects to the projects to-do list. Spending as little as 1 hour a week working on these long-term projects can lead to meaningful progress over time.

Prioritize

Often times, you will have many things you are working on simultaneously. Take time each day to prioritize what needs to be done first and work on items in that order. It is tempting to start on the easier things or the ones you are most interested in first. However, if it is at the expense of missing an important deadline, it will make your future stressful. Be mindful of deadlines and work first on things that have the earliest due dates.

Eliminate Distractors

Create an area with few distractions so you can concentrate. Toward that end, the following is suggested:

- *Attach a "do not disturb" sign* if you are working in a room with a door. This lets others know not to bother you and will help to minimize unwanted interruptions.
- *Stay in the zone.* When people are talking around you, avoid getting pulled into the discussion, especially if it is not relevant to your work.
- *Stay focused on the task at hand.*
- *Consider using earplugs or headphones* if you have to work in shared areas. This helps to minimize the chance that you will be distracted by a nearby conversation.

Avoid Procrastination

Nearly everyone has procrastinated at some point in time. However, most will testify that it caused more harm than good in the long run. Putting off an unpleasant task is human nature, but those who muster the self-discipline to see the task through will ultimately be successful in the end.

Allocate More Time than You Think You'll Need

A general rule of thumb is that any task will almost always take more time to finish than you think it will. Think in small increments of time. Do not postpone studying because you do not have all afternoon to devote to your studies. Plan and organize small learning tasks that can occur in short blocks of time. It is easier to learn when you break your studies into smaller increments. For example, each of these is an increment: review your notes, generate questions from your notes, and make a question chart (more on that later) or key word list, and define key words. Don't postpone your studies while you wait for that perfect free day. That free day may not come.

Question Charts

One study technique that has been useful in organizing and learning information is a question chart. Question charts help you make connections between information that is new to you and what you already know—an important step in the learning process. For example, if your topic is medication administration, **Table 1-1** gives an example of how to set up your chart.

Make question charts to cover all the main concepts in this review guide. Complete the charts as you read, revising and adding questions as you go, and then use them as study guides.

TABLE 1-1. Sample Question Chart

Medication Administration			
Questions	**Intravenous**	**Oral**	**Topical**
What are the available dosage forms?	Solutions, suspensions	Tablets, capsules, solutions, suspensions, powders	Ointments, creams, patches
What are the advantages of this route of administration?	Quick onset of action	Convenience	Limited systemic route of absorption (ointments and creams only)
What are the disadvantages of this route of administration?	No drug recall, pain at injection site	Slower onset of action, taste, palatability	Inconvenience

Definition of Terms

Make a separate section in your notes for terms and their definitions. Define each term by a key word or phrase. Review those terms every day, and add terms to your list as you read new material. This is an example of one of the small learning tasks discussed earlier.

Group Review

Some people find it helpful to meet with other students to review notes, ask questions, and compare perceptions. This may or may not be helpful to you; it all depends on your personal style. If you study with others, have an organized agenda so that time is not wasted. Listen and learn from your colleagues, but if you are unsure, check your references. Do not take another person's word for something — look it up.

Mock Exams

Use your question charts to make up your own exam, or if you are working with a group of colleagues, write questions for each other. This is often a helpful way to prepare for exams. The practice exam included in this book is a good way to test your comprehension of the material.

Final Review

Suppose the test is tomorrow. Spend your final review time reviewing, reciting, and summarizing your notes. When you are reviewing your term list or mastering your notes, make sure that you review from both directions. Begin first with the most difficult material, or reverse the review process by rearranging your notes, reviewing from back to front, and beginning in the middle. Don't get tied to order. If there is anything you are not certain of, now is the time to look it up and learn it. Recite from your summary sheets.

Personal Preparation

Since you are mentally prepared, prepare yourself physically for your exam. Go to your exam rested. You will not do well if you are so sleepy that you cannot concentrate on the questions. Eat a good breakfast before your exam. It's hard for the mind to concentrate if the body is demanding attention. Your brain functions better with a supply of energy. Also, it is probably not wise to start a new diet, quit smoking, or begin a new exercise regimen until after you complete the exam. Focus your energies on preparing for and taking the exam, not on redesigning your lifestyle.

Prepare emotionally too. Remember that the purpose of this exam is not to fail you or humiliate you, but to assist you professionally. So relax, be prepared, and concentrate. With preparation and strategy on your side, you will perform at your best.

OBJECTIVE EXAMS

You've been preparing for weeks, and now the big test date has finally arrived. This section outlines several steps and strategies that are useful in successfully completing an objective test.

Come Prepared

The first step in successfully taking objective tests is to come prepared. Make sure you follow the guidelines of *What to Bring.* Also, arrive at the test site 30 to 40 minutes early.

Computerized Testing

Computerized testing poses a unique set of problems. People vary in their comfort level when dealing with computer programs. If you are not accustomed to working on a computer, it would be wise to complete a practice exam in that format prior to the actual test, if possible. The Pharmacy Technician Certification Board (PTCB) also offers a free practice exam and sells practice exams on its web page (**www.ptcb.org**). There are also a number of free apps for your phone to help you prepare. Other programs with computerized standardized tests are available commercially.

Computerized tests often employ many of the same types of questions and question formats as paper tests, and you should use most of the same strategies (e.g., reading both the questions and the answers carefully). The PTCB exam allows you to skip items and mark items you want to go back to. It also allows you to go back and change your answer. There is only one correct answer per question and no penalty for guessing. It is important for you to try to pace yourself accordingly. Try to make your best answer in the time available and move on to the next question. An erasable board will be provided to serve as your scratch paper. You should not bring any electronic devices into the testing center, including calculators. You are permitted to use the on-screen calculator or handheld devices provided by the testing center. You will be required to lock all your personal items in a locker during the exam.

Test-Taking Strategies

Some basic strategies are helpful to most people taking objective tests. First, make sure you know how to *navigate through the pages of the exam*. The PTCB has a tutorial for this that can be accessed from their website. You are allowed to mark questions to review later; the exam will prompt you to go back to these questions.

The second step is to *use your time wisely*. Set yourself a schedule. Using your time wisely is dependent on reviewing the test carefully. Be aware of how many and what types of questions you must answer. You should have an idea at what time it will be when you are halfway done with the exam. For example, if you have 2 hours for a test, you should be at least halfway through it by the end of the first hour. Remember to leave extra time for particularly tough questions and for review. Work as rapidly as possible with a reasonable assurance of accuracy. The PTCB allows 2 hours to complete 90 multiple-choice questions.

The third strategy is to *read carefully*. This includes both the directions and the questions. Sections of the exam may vary, so take time to read the directions carefully at the beginning of each new section, and keep those directions in mind while answering the questions. Making careless mistakes because you misunderstood the directions is not an effective test-taking strategy! For example, the directions may read, "select the incorrect response," or "mark the two best answers."

Part of reading carefully involves reading the questions as they are, not as you would like them to be. In other words, don't look for answers you have memorized. Answer the question. Many people find it helpful to mark the key words in the stem so they do not forget them or misinterpret them. Also look for and mark the question words. This will help you answer the question as written. Some common question words are *what*, *how*, *when*, and *define*.

A fourth strategy is to *leave your assumptions at home*. You should not anticipate or assume trick questions. For example, you may know the correct answer is *d,* but you feel you have already answered too many questions with *d*. Take the question at face value and mark the answer you think is correct. Also, do not assume that methods or procedures you use at work are necessarily the correct ones. "Because that's the way we do it around here" may not be based on fact or best practice.

Going through the test at least two or even three times is another strategy for successful test taking. Go through the test completely the first time and answer all the "easy" questions that you are sure of. While you are doing the first run-through, mark the questions you need to come back to by marking the square in the top left of the page that says "review later." By answering all the easy questions first, you can be assured that you have answered the questions you know. This strategy also builds confidence. In the stem of one question, you may also find an answer to another question.

On the second run through, answer the questions that you are unsure of by considering all the alternatives and eliminating the options you know are inappropriate or incorrect. Relate the remaining options to the stem and balance them against each other. Use the information obtained from other questions to help you.

On the third run through, look at the remaining questions. If it is in your best interest to guess, do so. Always guess if your chances of gaining points are greater than your chances of losing points. Use the following strategies for intelligent guessing:

- The most general option is often the correct one because it allows for exceptions. If three of the four options are specific in nature and one is more general, choose the more general option.
- The correct choice is most often a middle value. If the options range in value (e.g., from high to low or from big to small), then eliminate the extreme values and choose from the middle values.
- The longest option is often the correct one. If three options are much shorter than the fourth, then choose the longest answer.
- When two options have opposite meanings, then the correct answer is usually one of them.
- Look for grammatical agreement between the stem and the answers. For example, if the stem uses a singular verb tense, then the answer should also be singular. Eliminate the answers that don't produce grammatically correct sentences. Most multiple-choice questions are designed as sentence completions.
- Do not leave questions blank; they will be marked wrong.

TROUBLE AREAS IN OBJECTIVE EXAMS

A couple of areas are problematic for most people taking objective exams. The first problem area deals with specific determiners. There are positive- and negative-specific determiners. Positive-specific determiners include *all, every, everybody, everyone, always, all the time, invariably, will certainly, will definitely, will absolutely,* and *the best.* Negative-specific determiners include *none, not one, nobody, no one, never, at no time, will certainly not, will definitely not, will absolutely not, the worst,* and *impossible.* When specific determiners like these are included in an option, that option is *usually incorrect.* These words make statements absolute, and there are few absolutes in the world.

However, some specific determiners are associated with correct statements. Look for more general terms such as *often, perhaps, seldom, generally, may,* and *usually.* Life more often reflects statements that use these kinds of words, rather than the absolute terms presented in the previous paragraph. When you are reading the question, circle the specific determiner so you keep careful track of them. Don't ignore them when answering the question.

The second problem area deals with negative terms. It is more difficult to interpret statements that contain negatives than it is to interpret statements without negatives. Here's an example of a double-negative statement: "Donald works well with patients. Therefore it is not untrue to say that he may be a good pharmacy technician." Cross out the *not* and the *un-* and reread the statement. It means the same thing but is easier to understand. Negatives include words such as *no, not, none,* and *never,* and prefixes such as *il-, un-,* and *im-*. Negative prefixes are particularly difficult because they are easily overlooked when reading a statement. Underline negatives in the question so you do not overlook them when answering the question.

Another common trouble area in objective tests is "all or none of the above" questions. One way to confirm the choice of "all of the above" is to find two correct answers among the options. For example, if you are confident that two of the four options are correct, then choosing "all of the above" is a pretty safe bet. Similarly, if you find one that is definitely incorrect, the "all of the above" must be ruled out.

The last type of question that is usually problematic for test takers is the best choice option. The options presented may not contain the correct answer, but possibilities from which you choose the best option. Another way of thinking of it is to consider the correct option as the least problematic. Select your answer by a process of elimination.

Mental Blocks

You know you know the material. You've been answering questions—and all of a sudden, you can't seem to think. You have a mental block. One useful technique is to think of the multiple-choice question as a series of true and false statements. In other words, make statements or complete sentences out of each option and then ask yourself if the statement is true or false. This change in perspective may help you to answer a difficult question or just refresh your thinking. However, keep your time limitations in mind and don't spend too much time on any one question. Skip difficult questions and come back to them, or take a quick 1-minute mental break to refresh yourself.

Final Review

Always plan on saving time to review your test before submitting it. Check your math if any of the questions required calculations. Contrary to popular belief, research has shown that test takers generally increase their scores when they review their answers and make changes. Make changes thoughtfully, though. When changing an answer, be sure you have considered the reasons why you answered the questions the way you did in the first place.

Finally, don't let other test takers distract you; concentrate on what you are doing. Do not be concerned if other people are finishing the exam before you. They may be finishing early because they simply are not as prepared as you are and cannot answer all the questions. There is little relationship between the amount of time spent on a test and the test scores.

TEST ANXIETIES

At the beginning of this chapter, we discussed how many people face taking an exam with dread and anxiety. It has been estimated that half of the nation's students suffer test anxiety, and one-quarter of them are significantly hampered by it. You may feel faint at heart, apprehensive, nervous, nauseated, dizzy, or even have heart palpitations. Some people describe it as "my mind goes blank." Some amount of test anxiety is normal, so you just need to learn how to make it work for you. The first step is to recognize that some anxiety is natural; it serves as a primary motivator in your performance.

There are three components of test anxiety. The first one is *fear of failure*. Nobody likes to fail, but remember to keep it in perspective. Tests just measure and assess one aspect of your life. Passing or failing a test reflects your performance in one area at one particular time. The second component of test anxiety is the *pressure of time*. You have a limited amount of time to accomplish a task and to accomplish it as accurately as possible. We all feel the pressure of time in many situations aside from testing. The third component is the *logistics of taking the exam*. You must read the instructions, follow them, understand the questions, and select the correct answer. Generally, the higher the stakes, the more anxiety you may feel, particularly if the competition is intense.

If your anxiety is moderate, several relaxation techniques are helpful in calming your nerves. Physical relaxation is one technique. First, sit comfortably with both feet on the floor and your hands resting on your thighs. Release all your body tension, close your eyes, and count backward from 10 to 1. Count only on each exhalation and breathe very deeply from the abdomen.[2]

Another physical technique is to clench your hands tightly for 5 to 10 seconds and then slowly relax your hands. Repeat this process throughout the muscles in your entire body. Complete your relaxation exercise by taking a deep breath and tensing your entire body, then relaxing it.

Now that your body is relaxed, try to relax your mind too. One popular technique is imagining yourself in a peaceful setting. Envision a pleasing situation, such as lying on a favorite beach, sitting in your backyard with the sun shining, or taking a walk in a park or along the lake. When you are feeling particularly stressed, imagine peaceful images.

At all costs, avoid fear-generating thoughts. Do not focus on the negative consequences; instead, focus on the positive outcomes of your examination.

These are just a few simple techniques that may help you relax so that you can do your best. For some,

however, test anxiety is so severe that it prevents them from performing at their best. If you experience severe anxiety, you may benefit from personal counseling.

CONCLUSION

Now that the exam is over, you deserve a reward. Be kind to yourself. However, do spend a few minutes to review what worked for you and what didn't. Think about your preparation. Did you allow yourself enough time? Did you understand what was important to study and learn and what were minor details? How about the test itself? Did you glance over the test, run through it several times, and save time for review and checking your answers? One of the most important lessons in life is to learn from your experiences, so evaluate your performance and learn how you can make it better. You may register and take this examination again if you need to. Most likely, there will be other exams in your life.

This chapter presented an overview of objective tests, basic study skills, and test-taking strategies. It also presented some simple techniques for relaxation to refresh you. But remember, no matter how effective the strategies, there is no substitute for thorough preparation. Begin your preparation early, be organized, use small increments of time, break your studying down into small tasks, and relax.

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CHAPTER 2

PHARMACY CALCULATIONS REVIEW



Learning Outcomes

After completing this chapter, you will be able to

- Explain why it is important to follow a standardized approach when using math in pharmacy.
- Convert between fractions, decimals, and percentages.
- Convert between different systems of measurement.
- Perform and check key pharmacy calculations, including the calculations needed to interpret prescriptions and those involving patient-specific information.

This chapter reviews the fundamentals of calculations and how those calculations are applied in pharmacy. For additional review and practice problems, see Chapter 12, Pharmacy Calculations, in *Manual for Pharmacy Technicians, 5th Edition.*

KINDS OF NUMBERS

Arabic numbers is the system of notation that is preferred in pharmacy practice. This is the system we are most familiar with, consisting of the numbers 0, 1, 2, 3, 4, 5, 6, 7, 8, and 9. From these numbers, fractions and decimal numbers are written.

Roman numerals consist of a numbering system using letters to represent numbers. Roman numerals are used to designate numbers and are often used in prescription writing to designate quantities to be dispensed or the number of a unit of medication the patient is to take. Roman numerals are used in prescription writing because they are more difficult to alter in the case of controlled substances. The following rules apply to the Roman numbering system:

- When a Roman numeral of equal or lesser value is placed after one of equal or greater value, the value of the numerals is added.
- A numeral cannot be repeated more than three times.

- When a Roman numeral of lesser value is placed before a numeral of greater value, the value of the first numeral is subtracted from the numeral of greater value.

Roman Numeral	Numeric Value
ss	1/2
I or i	1
V or v	5
X or x	10
L or l	50
C or c	100

Examples: IX = 10 – 1 = 9
iii = 3
XL = 50 – 10 = 40

REVIEW OF BASIC MATHEMATICAL FUNCTIONS INVOLVING FRACTIONS

All fractions must be converted to a common denominator when adding and subtracting. When multiplying and dividing, however, this conversion is not necessary. When working with fractions, the answer should be expressed as the smallest reduced fraction (i.e., if the answer is 6/8, it should be reduced to 3/4).

Addition

The following steps are necessary to add these fractions:

$$3/4 + 7/8 + 1/4$$

1. Convert all fractions to common denominators:
   $3/4 \times 2/2 = 6/8$
   $1/4 \times 2/2 = 2/8$
2. Add: $6/8 + 7/8 + 2/8 = 15/8$
3. Reduce to the smallest fraction: $15/8 = 1\ 7/8$

Subtraction

The following steps are necessary to subtract these fractions:

$$7/8 - 1/4$$

1. Convert the fractions to common denominators:
   $1/4 \times 2/2 = 2/8$
2. Subtract: $7/8 - 2/8 = 5/8$

Multiplication

The following steps are necessary to multiply these fractions:

$$1/6 \times 2/3$$

When multiplying and dividing fractions, it is not necessary to convert to common denominators.

1. Multiply the numerators: $1 \times 2 = 2$
2. Multiply the denominators: $6 \times 3 = 18$
3. Express the answer as a fraction: 2/18
4. Reduce the fraction: $2/18 = 1/9$

Division

The following steps are necessary to divide these fractions:

$$1/2 \div 1/4$$

Once again, it is not necessary to convert to common denominators.

To divide two fractions, the first fraction must be multiplied by the inverse (or reciprocal) of the second fraction.

1. Invert the second fraction: 1/4 becomes 4/1.
2. Multiply: $1/2 \times 4/1 = 4/2$
3. Reduce to lowest fraction: $4/2 = 2$

Converting Fractions to Decimal Numbers

To convert a fraction to a decimal number, the numerator is simply divided by the denominator.

For example, 1/2 = 1 divided by 2 = 0.5

Converting Mixed Numbers to Decimal Numbers

The process of converting mixed numbers to decimal numbers involves the following two steps:

1. Write the mixed number as a fraction.

   Method: Multiply the whole number and the denominator of the fraction. Add the product (result) to the numerator of the fraction, keeping the same denominator.

   Example: 2 3/4 = [(2 × 4) + 3]/4
   = 2 times 4 plus 3 over 4
   = 11/4

2. Divide the numerator by the denominator.

   Example: 11/4 = 11 divided by 4
   = 2.75

An alternate method involves the following three steps:

1. Separate the whole number and the fraction.

   Example: 2 3/4 = 2 and 3/4

2. Convert the fraction to its decimal counterpart.

   Example: 3/4 = 3 divided by 4 = 0.75

3. Add the whole number to the decimal fraction.

   Example: 2 plus 0.75 = 2.75

Converting Decimal Numbers to Mixed Numbers or Fractions

The process of converting decimal numbers to mixed numbers involves the following two steps:

1. Write the decimal number over 1, dividing it by 1. (Remember that dividing any number by 1 does not change the number.)

   Example: 3.5 = 3.5/1

2. Move the decimal point in both the numerator and denominator an equal number of places to the right. The number of places the decimal point needs to be moved is determined by the number of digits following the decimal point in the numerator.

   Example: Because there is only one digit following the decimal point in 3.5, move the decimal point one place to the right in both the numerator and the denominator: 3.5/1 = 35/10. The number will remain the same as long as the same steps are taken with the numerator and the denominator. *Remember that the decimal point of a whole number always follows the last digit.*

3. Simplify the fraction.

   Example: 35/10 = 7/2 = 3 1/2

Medication errors can occur when decimals are used incorrectly or misinterpreted. Sloppy handwriting, stray pen marks, and poor quality faxed copies can lead to misinterpretation. Decimal point errors can lead to medication underdoses or overdoses.

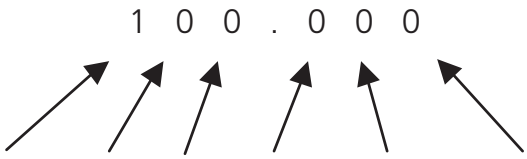


FIGURE 2–1. Numbers to the left of the decimal point represent whole numbers, and numbers to the right of the decimal point represent quantities less than 1.

Rules Governing Use of Decimals

1. Decimals should only be used when absolutely necessary. For example, five milligrams should be written as 5 mg, not 5.0 mg; the decimal point and **trailing zero** are not necessary. Use of a trailing zero in this example could be misinterpreted as 50 mg.

2. Only zeros serving as place holders should be included after the decimal. For example, if you wish to write seven and five hundredths, it should be written as 7.05 with no zeros following the last significant digit (in this case, the 5).

3. A decimal point should not appear without a number before it. If you wish to write one-half milligram, it should be written as **0.5** mg, not **.5** mg. This is referred to as proper use of a **leading zero.** Failure to use a leading zero in this example could lead someone to mistakenly read the number as **5** mg rather than **0.5** mg.

Percentages

Percentage (%) means "by the hundred" or "in a hundred." Percents are just fractions, but fractions with a set denominator. The denominator is always one hundred (100).

Example: "50%" means "50 in a hundred" or "50/100" or "1/2"

Converting Percentages to Fractions

To convert a percentage to a fraction, one would write the number preceding the percent sign over 100 and simplify the resulting fraction.

Example: 25% = 25/100 = 1/4

Converting Fractions to Percentages

Percentage means "by the hundred" or "in a hundred." Percents are fractions with a denominator of 100.

To convert a fraction to a percentage, one must take the following steps to convert the fraction to one in which the denominator is a hundred. This is easiest when the fraction is in the form of a decimal.

1. Write the fraction in its decimal form.

   Example: 3/4 = 3 divided by 4 = 0.75

2. Write the decimal over 1.

   Example: 0.75/1

3. To obtain 100 as the denominator, move the decimal point two places to the right. To avoid changing the value, move the decimal point two places to the right in the numerator as well.

   Example: 0.75/1 = 75/100

4. Because we already know that "out of a hundred" or "divided by a hundred" is the same as percent, we can write 75/100 as 75%.

Concentration Expressed as a Percentage

- *Percent weight-in-weight* (w/w) is the grams of a drug in 100 grams of the product.
- *Percent weight-in-volume* (w/v) is the grams of a drug in 100 milliliters (mL) of the product.
- *Percent volume-in-volume* (v/v) is the milliliters of drug in 100 mL of the product.

These concentration percentages will be discussed in detail a little later in this chapter.

Ratio and Proportion

A **ratio** shows the relationship between two items. For example, when calculating a dose, a ratio can be used to show the number of milligrams in the dose required per one kilogram of patient weight, which is written as mg/kg and read as "milligrams per kilogram." Two ratios with the same units can be combined to create a **proportion**, or a statement of equality between two ratios.

Example:

Ratio: Diphenhydramine 12.5 mg/5 mL means there are 12.5 mg of diphenhydramine in every 5 mL of cough syrup. If we wanted to determine how many mg of diphenhydramine were in 10 mL of cough syrup, we could set up a proportion.

5 g of dextrose in 100 mL of water (this solution is often abbreviated "D5W").

Therefore: 5 g of dextrose in 100 mL of a D5W solution equals 50 g of dextrose in 1,000 mL of a D5W solution;

or

5 g/100 mL = 50 g/1,000 mL

If three of the variables of a proportion are known, one can easily solve for the fourth variable. For example, if the standard dose of a medication is 4 mg per kg of patient weight, and the patient weighs 70 kg, we can set up a proportion to determine how many mg of the drug are needed for this patient:

Example:

$$\frac{4 \text{ mg}}{1 \text{ kg}} = \frac{x \text{ mg}}{70 \text{ kg}}$$

"*x*" represents the unknown value (in this case, the number of mg of the drug) that you will find when you solve this problem.

Step 1: Cross-multiply

$$\frac{4 \text{ mg}}{1 \text{ kg}} \times \frac{x \text{ mg}}{70 \text{ kg}}$$

4 mg × 70 kg = 1 kg × x mg

Step 2: Divide both sides of the equation by 1 kg, so that you isolate the unknown "x" on one side of the equation. Then you can solve for x.

$$\frac{4\ mg \times 70\ kg}{1\ kg} = \frac{1\ kg \times x\ mg}{1\ kg}$$

The kg units on the numerator and denominator cancel each other out, and any amount divided by one is equal to that amount.

$$\frac{4\ mg \times 70\ \cancel{kg}}{\cancel{1\ kg}} = \frac{\cancel{1\ kg} \times x\ mg}{\cancel{1\ kg}}$$

Therefore the equation becomes:

4 mg × 70 = *x* mg

x = 280 mg

Problem Solving by the Ratio and Proportion Method

The ratio and proportion method is an accurate and simple way to solve certain problems. To use this method, the technician should learn how to arrange the terms correctly and must know how to multiply and divide.

There is more than one way to write a proportion. The most common is the following:

Term #1/Term #2 = Term #3/Term #4

This expression is read, "*Term #1 is to Term #2 as Term #3 is to Term #4.*"

By cross-multiplying, the proportion can now be written as follows:

(Term #1) × (Term #4) = (Term #2) × (Term #3)

Example 1: How many grams of dextrose are in 10 mL of a solution containing 50 g of dextrose in 100 mL of water (D50W)?

The following steps are necessary to solve this problem:

1. Determine which is the *known* ratio and which is the *unknown* ratio. In this example, the known ratio is "50 g of dextrose in 100 mL of solution." The unknown ratio is "*X* g of dextrose in 10 mL of solution."
2. Write the unknown ratio (terms #1 and #2) on the left side of the proportion. Be sure that the unknown term is on the top. *X* g/10 mL = Term #3/Term #4
3. Write the known ratio (terms #3 and #4) on the right side of the proportion. The units of both ratios must be the same—the units in the numerators and the units in the denominators must match. In this case, that means grams in the numerator and milliliters in the denominator. If units of the numerators or the denominators differ, then a conversion to the same units must be completed.

   X g/10 mL = 50 g/100 mL
4. Units of the numerators or the denominators differ, then a conversion to the same units must be completed.

   X g/10 mL = 50 g/100 mL
5. Cross multiply.

   X g × 100 mL = 50 g × 10 mL
6. Divide each side of the equation by the known number on the left side of the equation. This will leave only the unknown value on the left side of the equation:

   X g = 50 g × 10 mL/100 mL
7. Simplify the right side of the equation to solve for X grams:

Answer: X g = 5 g

Example 2: The technician needs to prepare a 500-mg chloramphenicol dose in a syringe. The concentration of chloramphenicol solution is 250 mg/mL. How many milliliters should be drawn up into the syringe?

The following steps are necessary to solve this problem:

1. Determine the known and unknown ratios.
   Known: 1 mL/250 mg
   Unknown: *X* mL/500 mg
2. Write the proportion:
   X mL/500 mg = 1 mL/250 mg
3. Cross multiply:
   X mL × 250 mg = 1 mL × 500 mg
4. Divide:
   X mL = 1 mL × 500 mg/250 mg
5. Simplify:
   X mL = 2 mL

Answer: Draw up 2 mL in the syringe to prepare a 500-mg dose of chloramphenicol.

UNITS OF MEASURE

Metric System

The metric system is based on the decimal system, in which everything is measured in multiples or fractions of 10.

Standard Measures

The standard measure for length is the *meter.*

The standard measure for weight is the *gram.*

The standard measure for volume is the *liter.*

Prefixes

The prefixes below are used to describe multiples or fractions of the standard measures for length, weight, and volume.

Latin Prefixes

Latin prefixes denote fractions.

micro- (mc): 1/1,000,000 = 0.000001

milli- (m): 1/1,000 = 0.001

centi- (c): 1/100 = 0.01

deci- (d): 1/10 = 0.1

Greek Prefixes

Greek prefixes denote multiples.

deca- (da): 10

hecto- (h): 100

kilo- (k): 1,000

mega- (M): 1,000,000

Prefixes with Standard Measures

Length

The standard measure is the meter (m).

1 kilometer (km)	= 1,000 meters (m)
0.001 kilometer (km)	= 1 meter (m)
1 millimeter (mm)	= 0.001 meter (m)
1,000 millimeters (mm)	= 1 meter (m)
1 centimeter (cm)	= 0.01 meter (m)
100 centimeters (cm)	= 1 meter (m)

Volume

The standard measure is the liter (L).

1 milliliter (mL)	= 0.001 liter (L)
1,000 milliliters (mL)	= 1 liter (L)
1 microliter (mcL)	= 0.000001 liter (L)
1,000,000 microliters (mcL)	= 1 liter (L)
1 deciliter (dL)	= 0.1 liter (L)
10 deciliters (dL)	= 1 liter (L)

Weight

The standard measure is the gram (g).

1 kilogram (kg)	= 1,000 grams (g)
0.001 kilogram (kg)	= 1 gram (g)
1 milligram (mg)	= 0.001 gram (g)
1,000 milligrams (mg)	= 1 gram (g)
1 microgram (mcg)	= 0.000001 gram (g)
1,000,000 micrograms (mcg)	= 1 gram (g)

Oral solid medications are usually expressed in mg or g. Liquid medications are usually expressed in mL or L. When filling medication orders, it is critically important that the technician pays careful attention to the units to prevent medication errors and potential patient harm. If a dose or volume is not available commercially,

the correct amount must be compounded or measured. Doing so may require converting between units of the metric system.

Each move of the decimal to the left or to the right represents an increase or decrease. As long as you know the order of prefixes, and the magnitude represented, you can easily convert from one unit to another.

Another way to convert between units would be to multiply the units by their corresponding conversion factor. A ***conversion factor*** is a fraction that represents the number of parts present in each unit. For example, 1 gram = 1000 milligrams. Therefore, this conversion factor can be represented as $\frac{1\ g}{1{,}000\ mg}$. This conversion factor can be used to convert milligrams into grams.

Example: Convert 65 milligrams (mg) to grams (g).

$$65\ \cancel{mg} \times \frac{1\ g}{1{,}000\ \cancel{mg}} = 0.065\ g$$

Note: The milligram units will cancel out, leaving grams in the final answer.

APOTHECARY SYSTEM

The apothecary system was originally developed in Greece for use by physicians and pharmacists. This system has historical significance for the profession of pharmacy, but the metric system is replacing it. The Joint Commission (TJC) recommends that healthcare providers avoid using apothecary units because they are largely unfamiliar and often confused with metric units. There has been a decrease in the use of the apothecary system in hospitals, but apothecary units are still used in community pharmacy.

The most common apothecary measure appearing today is the *grain*. One grain may represent 65 milligrams (a 5-grain aspirin tablet is equal to 325 mg) or one grain may represent 60 milligrams (a 1-grain thyroid tablet is the same as 60 mg of thyroid).

POP QUIZ!

How many milligrams are in a 1¼-grain low-dose aspirin?

Avoirdupois System

The ***avoirdupois system*** is a French system of mass that includes ounces and pounds. In the United States, this is the system of mass commonly utilized, in which 1 pound equals 16 ounces. Assume this conversion when performing pharmacy calculations unless otherwise stated.

Household System

The ***household system*** is the most commonly used system of measuring liquids in outpatient settings. Prescribers frequently refer to teaspoons or tablespoons when writing prescriptions.

The term ***drop*** is used commonly; however, caution should be used when working with this measure, especially with potent medications. The volume of a drop depends not only on the nature of the liquid but also on the size, shape, and position of the dropper. To accurately measure small amounts of liquid, use a 1-mL syringe (with milliliter markings) instead of a dropper. Eye drops are an exception to this rule; they are packaged in a manner to deliver a correctly sized droplet.

Equivalencies between Systems

The systems that have been described lack a close relationship among their units. For this reason, the preferred system of measuring is the *metric system*. The tables of weights and measures below give the approximate equivalencies used in practice (**Table 2-1**).

Using the proportion method, you can convert from household to metric units.

TABLE 2-1. Common Conversions

Converting Measures of Length		
Metric		**Household**
2.54 cm	=	1 inch

Converting Measures of Mass		
Metric		**Avoirdupois**
1 kg	=	2.2 pounds (lb)
454 g	=	1 lb
28.4 g (usually rounded to 30 g)	=	1 ounce (oz)

Converting Measures of Volume		
Metric		**Household**
5 mL	=	1 teaspoon (tsp)
15 mL	=	1 tablespoon (T)
30 mL	=	1 fluid ounce (fl oz)
473 mL (usually rounded to 480 mL)	=	1 pint

Converting Within the Household System	
1 cup	8 fluid ounces
2 cups	1 pint
2 pints	1 quart
4 quarts	1 gallon

Converting Temperature	
Metric	**Household System**
degrees Celsius (°C)	degrees Fahrenheit (°F)

Example:

How many mL in 2.5 teaspoonfuls?

Set up a proportion starting with the conversion you know.

$$\frac{5 \text{ mL}}{1 \text{ tsp}} = \frac{x \text{ mL}}{2.5 \text{ tsp}}$$

To solve for *x*, use the 2-step process of cross-multiplying and dividing to isolate *x* so that you can solve for *x:* 5 mL × 2.5 tsp = 1 tsp × *x* mL

$$\frac{5\ mL \times 2.5\ tsp}{1\ tsp} = \frac{1\ tsp \times x\ mL}{1\ tsp}$$

5 mL × 2.5=*x* mL

x=12.5 mL

Temperature Conversion

Temperature is measured in the number of degrees centigrade (°C), also known as degrees Celsius, or the number of degrees Fahrenheit (°F). The following equation shows the relationship between degrees centigrade and degrees Fahrenheit:

$$[9(^{\circ}C)] = [5(^{\circ}F)] - 160^{\circ}$$

Time Conversion

It is also important to know how to convert between the 12-hour and 24-hour clock because many institutions refer to medication administration by the 24-hour clock. The 24-hour clock, also known as military time, does not include am or pm to designate hours of the day. Instead, the hours represent the number of hours and minutes since midnight and range from 0–23. It is reported without a colon separating hours and minutes (example: 2130 = 9:30 pm).

Example: Convert 4:15 pm to the 24 hour clock.

12 + 4 = 16 hours in the 24 hour clock

Note: 4 PM is 4 hours past 12 noon

4:15 pm = 1615 in the 24 hour clock

PATIENT-SPECIFIC CALCULATIONS

As science progresses, we are learning more about medications and how they work in the body. Researchers are also discovering how medications target specific sites and how their safety or efficacy may differ from one patient to the next. Some medications may be administered at a common dose across all patient types, while doses of other medications must be calculated based on factors specific to the individual patient to be safe and effective. Three examples of patient-specific calculations that may influence drug dosing include:

1. Body surface area
2. Ideal body weight
3. Body mass index

Although some of the calculations may be confusing or cumbersome, such as body surface area, *nomograms*—graphical representation of the key variables in the calculation—are available to use and provide a quick and easy way to determine the result.

Determining Body Surface Area

The ***square meter surface area*** (body surface area) is a measurement that is used instead of kilograms to estimate the amount of medication a patient should receive. ***Body surface area*** (BSA) takes into account the patient's weight and height. BSA is always expressed in meters squared (m^2) and is frequently used to dose chemotherapy agents.

The following equation is used to determine BSA. When using the equation below, units of weight (W) should be kilograms (kg), and height (H) should be centimeters.

For example, a man weighing 150 lbs (68.2 kg) and standing 5′10″ (177.8 cm) tall has a BSA of 1.8 m^2.

BSA values are frequently used to calculate doses of chemotherapeutic agents. There are several similar equations that are used, such as the *Mosteller formula*, which is:

$$\text{BSA } (m^2) = \sqrt{\frac{[height\ (cm) \times weight\ (kg)]}{3{,}600}}$$

Ideal Body Weight

Ideal body weight (IBW) is an estimate of how much a patient should weigh based on his or her height and gender. IBW is expressed as kg.

DOSAGE CALCULATIONS

Basic Principle

The technician should always look for what is being asked:

- Number of doses
- Total amount of drug
- Size of a dose

Given any two of the above, the technician can solve for the third.

Number of doses, total amount of drug, and size of dose are related in the following way:

Number of doses =
Total amount of drug/Size of dose

This proportion can also be rearranged as follows:

Total amount of drug =
(number of doses) × (size of dose)

or

Size of dose =
Total amount of drug/Number of doses

Dosage calculations can be based on weight, BSA, or age.

Calculating Dose Based on Weight

Certain medications require patient-specific dosing. Depending on the medication, BSA or weight-based dosing may be employed. For example, pediatric dosing is frequently determined by the weight of the child. If diphenhydramine syrup is dosed 5 mg/kg per day, and the child weighs 43 lbs, how many mg should the child receive in one day?

1. Convert all necessary values to the appropriate units.

$$\frac{2.2\ lb}{1\ kg} = \frac{43\ lb}{x\ kg}$$

$$x\ kg = \frac{43\ lb \times 1\ kg}{2.2\ lb} = 19.5\ kg$$

2. Set up a proportion with the available information, and solve for *x*.

$$\frac{5\ mg}{1\ kg} = \frac{x\ mg}{19.5\ kg}$$

$$x\ mg = 5\ mg \times 19.5 = 97.5\ mg$$

Dose (in mg) = [dose per unit of weight (in mg/kg)] × [weight of patient (in kg)]

Dose/day (in mg/day) = [dose/kg per day (in mg/kg per day)] × [weight of patient (in kg)]

To find the size of each dose—The technician should divide the total dose per day by the number of doses per day, as illustrated in the following formula:

Size of Dose = Total amount of drug/Number of doses

Calculating Dose Based on BSA

BSA is expressed as *meters squared* (m^2). To calculate the amount of a dose on the basis of BSA: The technician should simply multiply the BSA in m^2 times the dose per m^2 as provided in the order or other labeling.

Day's Supply

Part of the dispensing process is to ensure that a patient receives a sufficient quantity of the medication to last for the desired duration. To determine the ***day's supply***, evaluate the dosing regimen to determine how much medication per dose, then how many times the dose is given each day, and then for how many days the medication will be given.

Example:

Metoprolol 50 mg po twice daily for 30 days (25 mg tablets available)

- The dose is 50 mg, which will require 2 of the 25-mg tablets. The dose is given twice daily, which will require 2 tablets × 2 = 4 tablets per day.
- The medication regimen will last 30 days, so 4 tablets per day × 30 days = 120 tablets.

Calculating the quantity needed of an oral medication is fairly straightforward, but calculating topical products may be a bit more challenging. For eye drops, the drops per mL may vary, depending on the viscosity of the drops.

Example:

Betaxolol ophthalmic solution 2 drops in each eye twice daily for 10 days (5-mL dropper bottle available; assume 1 mL = 20 drops for this ophthalmic solution, which is a common estimate for many ophthalmic solutions).

1. The patient will take 4 drops twice daily for a total of 8 drops per day.
2. The patient will use 8 drops per day for 10 days for a total of 80 drops.
3. Set up a proportion to determine mL needed per day.

   8 drops per day = 20 drops

   x mL per day = 1 *mL*

   20 × *x mL* = 8 × *1 mL*

   x = 0.4 *mL* per day

   The patient is taking the medication for 10 days so 0.4 mL × 10 days = 4 mL total volume needed to fill the prescription.

4. Determine if the available product will provide a sufficient quantity of medication. Because the total volume of the dropper vial is 5 mL and this prescription calls for 4 mL, one unit would be dispensed to fill the prescription. It is acceptable for the patient to receive slightly more volume than the calculated amount in case he or she has difficulty applying the drops and accidentally misses applying the medication in their eyes.

Calculating 24-Hour Supply of Medication

Patients who are in the hospital setting are often given medications in quantities based on a 24-hour supply of the medication. This is because many patients may only stay a few days in the hospital and often do not require a full 30-day prescription of medication as discussed above.

Example: Ciprofloxacin 500 mg PO BID (by mouth twice daily)

Ciprofloxacin is available in 500-mg tablets.

To determine how many tablets are needed to fulfill a 24-hour supply of this order, multiply the available tablets by the number of times a day the patient is receiving this medication (in this case, twice). Therefore one (1) tablet × 2 times daily = 2 tablets needed to fulfill this medication order.

VERIFYING DRUG ENFORCEMENT ADMINISTRATION NUMBERS

When receiving a prescription for a controlled substance, the prescriber will need to document their Drug Enforcement Administration (DEA) number on the prescription. This assigned number is specific to a certain prescriber and consists of two letters:

- The first letter is either A, B, F, M, or X
- The second letter is the first initial of the prescriber's last name) followed by seven numbers.

(See Chapter 3 in the *Manual for Pharmach Technicians, 5th edition*, Pharmacy Law, Regulations, and Standards, for more information.)

Below is an example DEA number and how to verify its validity:

Example: Dr. Thomas Jones: AJ564123

1. Check that the letters of the DEA number match the prescriber's last name ("A" for type of practitioner, "J" for the first initial of Dr. Jones' last name.)
2. Next, add the 1st, 3rd, and 5th numbers in the DEA: 5 + 4 + 2 = 11
3. Next, add the 2nd, 4th, and 6th numbers in the DEA: 6 + 1 + 3 = 10
4. Next, multiply the result of your second response (the sum of 2nd, 4th, and 6th numbers) by 2

   10 × 2 = 20
5. Finally, add the result of #2 and #4 in this process: 11 + 20 = 31. The second number in this response (in this case, "1"), should match the last number of the DEA. In this case, these numbers do not match; therefore, this is not a valid DEA number.

CONCENTRATION AND DILUTION

Some pharmacy mixtures are created by adding two solids together. When this occurs, the percentage strength is measured in weight in weight (w/w) or grams of drug/100 grams of mixture. This measurement is mainly used when compounding ointments and creams. When mixtures are created by adding two liquids together, the percentage strength is measured in volume in volume (v/v) or mL/100 mL. When mixtures are created by adding a solid to a liquid, the percentage strength is measured in weight/volume (w/v) or grams per 100 mL (**Table 2-2**).

Concentration Expressed as a Percentage

The concentration of one substance in another may be expressed as a percentage or a ratio strength. As stated earlier in this chapter, concentrations expressed as percentages are determined using one of the following formulas:

TABLE 2-2. Standard Intravenous Solutions

Solution	Also Known As	Also Written As	Contains
NS	Normal saline	0.9% NaCl (sodium chloride)	0.9 g NaCl/100 mL water
1/2 NS	Half normal saline	0.45% NaCl	0.45 g NaCl/100 mL water
1/4 NS	Quarter normal saline	0.225% NaCl	0.225 g NaCl/100 mL water
D5W	Dextrose 5% in water	5% dextrose in water	5 g dextrose/100 mL water
D10W	Dextrose 10% in water	10% dextrose in water	10 g dextrose/100 mL water
D5NS	Dextrose 5% in normal saline	5% dextrose in 0.9% NaCl	5 g dextrose and 0.9 g NaCl/100 mL water

1. Percent weight-in-weight (w/w) is the grams of a drug in 100 grams of the product.
2. Percent weight-in-volume (w/v) is the grams of a drug in 100 mL of the product.
3. Percent volume-in-volume (v/v) is the milliliters of drug in 100 mL of the product.

Example 1:

0.9% sodium chloride (w/v) = 0.9 g of sodium chloride in 100 mL of solution.

Example 2:

5% dextrose in water (w/v) = 5 g of dextrose in 100 mL of solution.

Example 3:

How many grams of dextrose are in 1 L of D5W?

The following steps of the ratio and proportion method are necessary to solve this problem:

Known ratio: D5W means 5 g/100 mL

Unknown ratio: *X* g/1 L

1. Write the proportion:
   X g/1 L = 5 g/100 mL
2. It is not time yet to cross-multiply. First, convert the denominator of either term so both are the same. Because we know that 1 L = 1,000 mL, the unlike terms should be converted as follows:
   X g/1,000 mL= 5 g/100 mL
3. Now that the units are both in the same order and the units across from each other are the same, cross-multiply:
   X g × 100 mL = 5 g × 1,000 mL
4. Divide:
   X g = 5 g × 1,000 mL/100 mL
5. Simplify:
   X g = 50 g

   There are 50 g of dextrose in 1 L of D5W.

Here are a few suggestions for solving concentration and dilution problems:

1. Calculate the number of grams in 100 mL of solution first. That is the *known* side of the ratio.
2. Calculate the number of grams in the volume requested in the problem by setting up a ratio.
3. Check to make sure the units are in the same order in the ratio.
4. Make sure the units that are across from each other in the ratio are the same.
5. After arriving at the answer, convert it to the requested units.

Concentration Expressed as a Ratio Strength

The concentrations of very weak solutions are sometimes expressed as **ratio strengths**. Ratio strengths are usually expressed as 1:something, where the units of the ratio are g per mL. For example, lidocaine plus epinephrine is a combination product that is available in concentrations of 0.5%/1:200,000, 1%/1:100,000, and 2%/1:100,000. The first number represents the percent of lidocaine, and the second number represents the amount of epinephrine. This type of expression has caused medication errors, especially for medications ordered in mL, because 1000 and 10,000 look alike, and

people have assumed that only one concentration is available.

To solve a problem utilizing a medication that is labeled by ratio strength, first convert the ratio to a standard fraction.

Example: Epinephrine is available in three concentrations: 1:1,000 (read "one to one thousand"); 1:10,000; and 1:200.

A concentration of 1:1,000 means there is 1 g of epinephrine in 1,000 mL of solution.

What does a 1:200 concentration of epinephrine mean?

It means 1 g of epinephrine in 200 mL of solution.

What does a 1:10,000 concentration of epinephrine mean?

It means 1 g of epinephrine in 10,000 mL of solution.

The pharmacy technician can use this definition of ratio strength to set up the ratios needed to solve problems.

Example: 500 mL of a 1:2,500 solution of potassium permanganate is ordered. How many grams of potassium permanganate will need to be weighed to make the solution?

1 gram/2,500 mL = x grams/500 mL

X = 0.2 g

Dilutions Made from Stock Solutions

Stock solutions are concentrated solutions used to prepare various dilutions of the original stock solution. To prepare a solution of a desired concentration: The technician must calculate the quantity of stock solution that must be mixed with diluent to prepare the final product.

Example: A medication order is received for gentamicin 120 mg in 100 mL of normal saline.

Gentamicin is available as a 40 mg/mL 20-mL multidose vial.

How many mL of are needed to prepare one dose?

Step 1: Set up a proportion, beginning with the strength of the multidose vial solution. Make sure the units are consistent.

$$\frac{40 \text{ mg}}{1 \text{ mL}} = \frac{120 \text{ mg}}{x \text{ mL}}$$

Step 2: Use the two-step process of cross-multiplying and then dividing to isolate and solve for the unknown *x*.

x mL × 40 mg = 120 mg × 1 mL

$$x = \frac{120\ mg}{40\ mg} = 3\ mL$$

Draw up 3 mL of gentamicin 40 mg/mL and add this amount to a 100-mL minibag of NS to obtain 120 mg of gentamicin in 100 mL of NS.

When working with electrolytes (e.g., potassium, calcium, magnesium), you will encounter milliequivalents (mEq). A milliequivalent is a measure of mass that considers the molecular weight (MW) and ionic charge, or valence, of an electrolyte. Vials containing electrolytes usually express concentrations in both mEq and mg.

Calculations involving milliequivalents are like calculations using units or milligrams as units of measure. Be sure to always check to see that you are using matching units in your equations.

Example: Potassium acetate is available in a concentration of 40 mEq/20 mL. If you need to give a dose of 5 mEq of potassium IV, how much potassium do you need?

Step 1: Start with the given concentration of potassium and set up an equation to determine the volume of the needed potassium:

$$\frac{40 \text{ mEq}}{20 \text{ mL}} = \frac{5 \text{ mEq}}{x \text{ mL}}$$

Step 2: This equation can be simplified to:

$$\frac{2 \text{ mEq}}{1 \text{ mL}} = \frac{5 \text{ mEq}}{x \text{ mL}}$$

Step 3: Cross-multiply:

2 mEq × *x* mL = 1 mL × 5 mEq

Step 4: Divide both sides of the equation by 2 mEq to isolate *x*.

$$\frac{2\ mEq \times x\ mL}{2\ mEq} = \frac{1\ mL \times 5\ mEq}{2\ mEq}$$

When you divide both sides of the equation by 2 mEq, the mEq units cancel out, and you are left with this equation:

$$x\ mL = \frac{5}{2}$$

x mL = 2.5 mL of potassium acetate solution needed

2.5 mL of potassium concentrate will provide 5 mEq of potassium.

Example: A 10% NaCl stock solution is available. The technician needs to prepare 200 mL of a 0.5% NaCl solution. How many milliliters of the stock solution does the technician need to make this preparation? How much more water does the technician need to add to produce the final product? The following steps are necessary to solve this problem:

1. Calculate how many grams of NaCl are in the requested final product.

   X g NaCl/200 mL soln = 0.5 g NaCl/100 mL soln

   Therefore, 200 mL of 0.5% NaCl solution contains 1 g of NaCl.

2. Calculate how many milliliters of the stock solution will contain the amount calculated in step 1 (i.e., 1 g):

   Remember, 10% means the solution contains 10 g/100 mL.

   X mL/1 g = 100 mL/10 g

   X mL = 10 mL

   The first part of the answer is 10 mL of stock solution.

3. Calculate how much water is needed to finish preparing the solution.

   Keep in mind the following formula:

   (final volume) – (stock solution volume) = (volume of water)

   Therefore, for the problem "200 mL – 10 mL = 190 mL of water," the second part of the answer is 190 mL of water.

Pediatric Formulations

Often, pediatric patients will require much smaller doses than adult patients that are a small fraction of an adult dose and are commonly based on the weight of the patient (i.e., mg/kg/day or mg/kg/dose). Because of the need for much smaller dosing in this patient population, many calculations related to preparing pediatric medications will involve dilution and/or weight-based dosing calculations. Independent double-checks on calculating pediatric calculations can help minimize errors.

Alligation Method

At times, the desired concentration of a product is not readily available, but concentrations above and below the desired concentration are available. The ***alligation method*** will help to determine how many parts of each strength should be mixed together to prepare the desired strength. The easiest way to visualize an alligation is to set up a tic-tac-toe board, as shown in **Figure 2-2.**

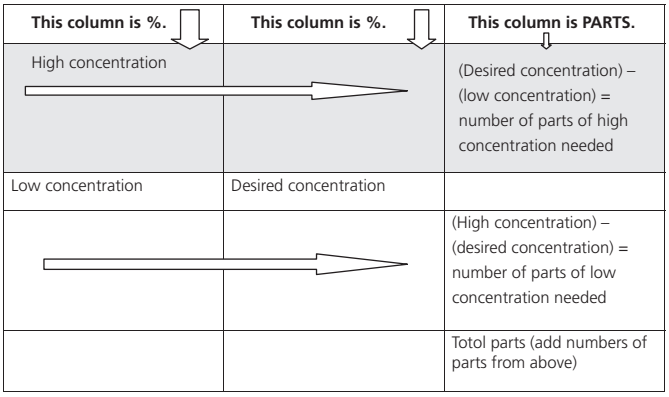


FIGURE 2-2. Alligation method.

This method helps to determine how many parts of each strength should be mixed together to prepare the desired strength.

Example:

You have an order for 550 mL of a 25% solution. You have a 45% solution and a 10% solution available. How many mL of the 45% solution will you need to mix with the 10% solution to prepare the amount of 25% solution that you need?

To set up the alligation, enter the high concentration (45%) in the top left corner, the desired concentration (25%) in the center box, and the low concentration (10%) in the lower left box. Subtract the low concentration (10%) from the desired concentration (25%) and place in the top right corner (15 parts). Subtract the desired concentration from the high concentration (45%) and place in the lower right box (20 parts). Add the two values in the right column (15 + 20) to determine the total parts (35).

%	%	Parts
45%		15 parts of high concentration
	25%	
10%		20 parts of high concentration
		35 parts total (550 mL)

Therefore the equation will start with that information:

$$\frac{15\ parts}{35\ parts} = \frac{x\ mL}{550\ mL}$$

Using the two-step process of cross-multiplying and dividing to isolate *x*:

$$x = \frac{15\ parts \times 550\ mL}{35\ parts} = 235.7\ mL\ of\ the\ 45\%\ solution$$

Knowing that the total is 550 mL, you can subtract the amount of the 45% (235.7 mL) from the total to calculate the amount of the 10% solution needed.

$$550\ mL - 235.7\ mL = 314.3\ mL\ of\ 10\%\ solution\ needed$$

It is helpful to double check your work and calculate it both ways.

Remember, if the product does not contain an active ingredient, its concentration is 0%. Similarly, if the product is pure active ingredient, its concentration is 100%.

Another method to solve similar problems uses the equation below:

$$C_1V_1 = C_2V_2$$

C represents concentration, V represents volume, and the subscript numbers represent two different solutions.

Example: You have an order for 5 mL of a 70% ethanol solution. You only have 98% ethanol. How many mL of the 98% solution will you add to sterile water to make 5 mL of the 70% ethanol solution?

$$C_1V_1 = C_2V_2$$

$$98\%_{conc\ of\ 98\%\ soln}\ X_{volume\ needed\ of\ 98\%\ soln} = 70\%_{conc\ of\ 70\%\ soln}\ 5_{volume\ desired\ of\ 70\%\ soln}$$

$$98x = 70 \times 5\ mL$$

$$x = \frac{70\% \times 5\ mL}{98\%} = 3.6\ mL$$

So, you would add 3.6 mL of the 98% solution with enough sterile water to make 5 mL of the 70% solution.

POP QUIZ!

In the formula $C_1V_1 = C_2V_2$, what does V_2 represent?

CHEMOTHERAPY CALCULATIONS

Accurate pharmacy calculations are critically important in the oncology setting, where extremely potent medications used to eliminate cancerous cells (chemotherapy) are administered to patients and can cause patient harm or death or undertreatment if miscalculations occur. A system of double-checks is in place in most institutions that compound chemotherapy to ensure accurate calculations and medication preparation prior to patient administration.

Example: A medication order is received for amifostine 200 mg/m² IV over 3 minutes once daily 15–30 minutes prior to radiation therapy. The patient is a 79-year-old man weighing 157 lbs and standing 6′ tall. He has a BSA of 1.9 m². What is the dose of amifostine for this patient?

The easiest way to solve this problem is to set up a proportion:

$$\frac{200\ mg}{m^2} = \frac{x\ mg}{1.9\ m^2}$$

$$x = \frac{200\ mg \times 1.9\ m^2}{1\ m^2} = 380\ mg$$

Amifostine is available in a 500 mg/10-mL vial. How much volume (mL) is needed to make this dose?

The easiest way to solve the problem is to set up a proportion:

$$\frac{500\ mg}{10\ mL} = \frac{380\ mg}{x\ mL}$$

$$x = \frac{10\ mL \times 380\ mg}{500\ mg} = 7.6\ mL$$

IV Flow Rate Calculations

When working in an institutional setting or home care, it is important to know how to perform calculations related to intravenous (IV) medications. This includes calculating the rate at which a medication should be infused. Use the math concepts practiced above to find the necessary information.

Flow rates for IV solutions being infused by mechanical means or pumps are measured in milliliters per hour. Note that all flow rates are whole numbers, both gtts/min and mL/hr.

Examples:

How many mL per minute will a patient receive if a 500 mL solution is infused over 2 hours?

To solve this problem, set up a proportion:

$$\frac{500\ \text{mL}}{120\ \text{min}} = \frac{x\ \text{mL}}{1\ \text{min}}$$

$$500\ \text{mL} \times 1\ \text{min} = 120\ \text{min} \times x\ \text{mL}$$

$$x = \frac{500\ mL}{120\ min} = 4.2\ mL/min$$

Therefore the rate is 4.2 mL per minute or 4 mL/min.

How many drops per minute will a patient receive if a 250-mL solution is infused over 1 hour and the infusion set delivers 10 drops/mL?

Set up a proportion to determine the mL per minute and then set up a second proportion to determine the number of drops:

$$\frac{250\ \text{mL}}{60\ \text{min}} = \frac{x\ \text{mL}}{1\ \text{min}}$$

$$250\ mL \times 1\ min = 60\ min \times x\ mL$$

$$x = \frac{250}{60} = 4.2\ \text{mL/min}$$

Now determine how many drops this would be by setting up a second proportion:

$$\frac{10\ drops}{1\ mL} = \frac{x\ drops}{4.2\ mL/min}$$

$x = 10 \times 4.2 = 42$ drops per minute

A useful formula for drip (flow) rates is:

$$\frac{\text{Volume (mls)} \times \text{(drop rate in gtts / mL)}}{\text{Time (in minutes)}} = \text{gtts / min}$$

Therefore, in the above example, 250 mL (10 gtts/mL) ÷ 60 min = 42 gtts/min.

What is the infusion rate of an IV fluid being infused by a pump if 1 liter of fluid is to be infused over 24 hours? 1 liter = 1,000 mL so 1,000 mL ÷ 24 hours = 41.67 = 42 mL/hr

$$\frac{200\ mg}{m^2} = \frac{x\ mg}{1.9\ m^2}$$

$$x = \frac{200\ mg \times 1.9\ m^2}{1\ m^2} = 380\ mg$$

POP QUIZ!

How many times can a prescription for methylphenidate be refilled?

POP QUIZ!

If the patient is receiving a 50-mL IVPB over 30 minutes via pump, what is the flow rate?

PRACTICE CALCULATIONS 1

1. Convert XIV to its Arabic equivalent: _____
2. Convert III to its Arabic equivalent: _____
3. Write 2/3 as a decimal fraction: _____
4. Write the fraction form of 0.4: _____
5. Express 42% as a fraction: _____
6. Write 0.45 as a percentage: _____
7. Express 2/5 as a percentage: _____
8. Write the fraction form of 0.65: _____
9. Express XXIV in Arabic numbers: _____
10. Express 1 1/4 in decimal form: _____
11. The standard metric system measure for weight is the _____.
12. The standard metric system measure for length is the _____.
13. The standard metric system measure for volume is the _____.
14. 1 m = _____ km
15. 1 mL = _____ L
16. 1 g = _____ kg
17. 1 mg = _____ g
18. 1 mg = _____ mcg
19. 1 mcg = _____ mg
20. 1 L = _____ mL
21. 1 TBS = _____ tsp
22. 1 fl oz = _____ mL
23. 3 tbsp = _____ mL
24. 15 mL = _____ tsp
25. 6 tsp = _____ tbsp
26. 100 mL = _____ L
27. 2 kg = _____ lb
28. 45 mL = _____ oz
29. 7.5 mL = _____ tsp
30. 1 kg = _____ mcg
31. 1 tsp = _____ mL
32. 5 gr = _____ mg
33. 4 oz. = _____ mL
34. 26 kg = _____ lb
35. 60 mL = _____ fl oz
36. 81 mg = _____ gr
37. 148 mg = _____ g
38. 2 tbsp = _____ tsp
39. 1 fl oz = _____ tbsp
40. 1 gallon = _____ mL
41. 426 mL = _____ liter
42. 20 mL = _____ tsp
43. 45 mL = _____ tbsp
44. 2480 mg = _____ g
45. 1 lb. = _____ g
46. 2.5 L = _____ mL
47. 30 kg = _____ lb
48. 725 mg = _____ g
49. 10 mL = _____ tsp
50. 9 tsp = _____ tbsp
51. 125 mg = _____ mcg
52. 325 mg = _____ grains

53. 176 lb = _____ kg

54. Express the ratio 1:2,000 as a percent

55. 4875 mL = _____ L

56. 4 oz. = _____ g

57. 180 mL = _____ oz.

58. 2.56 g = _____ mcg

59. If a patient is taking ¾ teaspoonful of an antibiotic TID, how long will 150 mL last?

60. A patient is ordered 60 mg of a drug that is available in a concentration of 120 mg/5 mL. How many teaspoonsful will the patient take per dose? If the patient needs a 30 day supply, how much will the pharmacy need to dispense if the patient is taking 60 mg TID?

61. Express 0.05% as a fraction.

62. Express 0.05% as a ratio.

63. If an inhalation solution has 225 mg of drug per container and the container has 300 inhalations, how many micrograms of drug are available in each inhalation?

64. Add 0.5 kg, 1750 mg, 2.2 g, and 830,000 mcg and express your answer in grams.

65. Low-dose aspirin is 81 mg per tablet. A manufacturer has 5 kg of aspirin powder; how many 81-mg tablets can they make?

PRACTICE CALCULATIONS 2

1. RX: Celebrex 200 mg PO BID for arthritis pain; dispense 3 month supply. How many Celebrex 200-mg capsules should be dispensed?

2. A patient is ordered to take 150 mg of tegretol daily for 30 days. The supply on hand is carbamazepine 100 mg/5 mL.
   a. How many milliliters should the patient receive per dose?
   b. How many milliliters should be dispensed?

3. You receive an order for amoxicillin 400 mg BID × 10 days for a child. Your supply is amoxicillin 400 mg/5 mL.
   a. How should the directions on the prescription label read?
   b. How many milliliters must be dispensed?

4. Metformin is available in 500-mg tablets. The prescription reads: "750 mg Q AM & PM."
   a. How many tablets should the patient take per dose?
   b. How many tablets must be dispensed for a 1-month supply?

5. Humulin N 100 units/mL 10-mL vials are available. The patient has a prescription that reads "10 units Q AM and 15 units Q PM." How many days will the vial last?

6. Zofran is available in a 100-mL bottle containing 4 mg/5 mL. The patient is taking 10 mg q 12 hours.
   a. How many mL should this patient take per dose?
   b. What is the estimated days supply (EDS) of the 100-mL bottle?

7. Lamictal has a recommended maintance dose for children of 4.75–7.5 mg/kg/day in two divided doses. You have a prescription for a 60-lb child for Lamictal 100 mg BID; is the ordered dose within the recommended dose?

8. The prescription reads digoxin 0.125 mg daily, and on hand is digoxin 125 mcg. How should the directions on the prescription label read?

9. 4% (w/w) = _____
   12% (w/v) = _____
   0.75% (v/v) = _____

10. Cyclosporin 100 mg/mL is available. You have an order for 140-lb patient for 15 mg/kg; how many mL will the patient need?

11. A suspension of naladixic acid contains 250 mg/5 mL. The syringe contains 20 mL. How many grams of naladixic acid does the syringe contain?

12. How many grams of betamethazsone are in 120 g of 0.1% betamethasone cream?

13. 1/2 NS = _____ g NaCl/_____ mL solution

14. Express 1:5000 as a percent.

15. Express 0.05% as a ratio.

16. The technician has a solution labeled "$D_{10}NS$."
    a. How many grams of NaCl are in 100 mL of this solution?
    b. How many milliliters of this solution contain 10 g dextrose?

17. A syringe is labeled "inamrinone 5 mg/mL, 10 mL." How many milligrams of inamrinone are in the syringe?

18. Neupogen 480 mcg/1.6 mL; how many milligrams are contained in this vial?

19. If 2,400 mg of tobramycin powder is dissolved in 120 mL of water, what is the percent strength of the solution?

20. How many grams of epinephrine are necessary to prepare 20 mL of a 1:1,000 epinephrine solution?

21. Calculate the amounts of boric acid and zinc sulfate in grams to fill the following prescription:

Zinc sulfate	0.1%
Boric acid	1:10
Distilled water qs. ad	100 mL

22. Use the following concentrations to solve the problems:

Gentamicin	80 mg/mL
Magnesium sulfate	50%
Atropine	1:200

    a. 160 mg gentamicin = _____ mL
    b. 10 mg atropine = _____ mL
    c. _____ g magnesium sulfate = 120 mL

23. Heparin 10,000 units/mL solution, patient is ordered 2,500 units. How many milliliters should the patient receive?

24. Patient has Lantus 100 units/mL in 3-mL cartridges. The patient is ordered to use 46 units daily; how many cartridges will the patient need for a 30-day supply?

25. Potassium chloride is supplied in 30-mL vials containing 2 mEq/mL of potassium. An IV order requires 34 mEq of potassium. How many milliliters need to be added?

26. Trileptal 300 mg/5 mL is ordered for a prescription with the directions of 450 mg BID.
    a. How should the directions on the prescription label read?
    b. How many milliliters must be dispensed to provide a 30-day supply?

27. A drug is available in 1 g vials with a concentration of 125 mg/2 mL. If the directions state to add 12.6 mL of diluent, what is the powder volume?

28. A chemotherapy agent is available in a 5 mg/mL solution. The recommended dose is 25 mg/m^2. What should the dose in milliliters be for a child if the child is 0.24 m^2?

29. Amoxicillin is supplied 400 mg/5 mL; based on the recommended dose of 50 mg/kg/day in 3 divided doses, how many milligrams of drug should a 55-lb child receive per dose?

30. How many grams of sodium chloride are in a liter of NS?

31. A patient weighing 60 kg is to receive a drug with a recommended dose of 20 mg/kg/day in two equally divided doses. How many milligrams should the patient receive per dose?

32. A patient has a BSA of 1.15 m^2. The recommended dose of the ordered drug is 20 mg/m^2 in 4 divided doses.
    a. How many micrograms would the patient receive per dose?
    b. How many milligrams would the patient receive per day?

33. A TPN order needs sodium chloride 40 mEq and potassium chloride 10 mEq. Stock solutions are sodium chloride 4 mEq/mL and potassium chloride 2 mEq/mL. How much of each is required to fill the order?

34. You are to add 12 mM of potassium phosphate to a TPN order. Potassium phosphate is available in a 45 mM/15 mL vial. How many milliliters should be added?

35. You have a 2-gram vial of dry powder antibiotic, and you are directed to prepare a 100-mg/mL concentration by adding 18.7 mL of diluent. What is the PV of the powder?

36. How many grams of lidocaine 20% ointment and how many grams of ointment base must be combined to prepare 2 lb of 2.5% lidocaine topical ointment?

37. RX: Diflucan 100-mg scored tablets Sig: iii now, then 3 mg/kg BID X 10 days is ordered. The patient weighs 183 lb; how many tablets must be dispensed?

38. Furosemide oral solution 10 mg/mL is available. A patient is ordered to take 25 mg daily. What volume should the patient take and how many days will a 4-oz bottle last?

39. Midazolam 5 mg/mL is available. A patient is ordered to receive 40 mg every 4 hours as needed. What should the volume of the dose be?

40. Keflex suspension 500 mg PO QID is ordered. The inpatient pharmacy has a 200-mL bottle with a concentration of 250 mg/5 mL available. How many mL must the inpatient pharmacy send up for a 24-hour supply? How many days will the 200 mL bottle last?

PRACTICE CALCULATIONS 3

1. The technician needs to prepare 2 L of 0.25% acetic acid irrigation solution. The stock concentration of acetic acid is 25%.
   a. How many milliliters of stock solution are needed?
   b. How many milliliters of sterile water have to be added?
2. A drug order requires 50 mL of a 2% neomycin solution.
   a. How much neomycin concentrate (1 g/2 mL) is needed to fill the order?
   b. How many milliliters of sterile water need to be added to the concentrate before dispensing the drug?
3. a. Calculate the amount of atropine stock solution (concentration 0.5%) needed to compound the following prescription:

   Atropine sulfate 1:1,000

   Sterile water qs ad 300 mL

   b. How much sterile water has to be added to complete the order?
4. How many tablets have to be dispensed for the following prescription?

   Obecalp ii tablets tid for 14 days
5. If a patient takes one tablespoonful of Maalox TID, ac and hs, how long will a 16-oz bottle last?
6. A patient is receiving a total daily dose of 1 g of acyclovir. How many milligrams of acyclovir is he receiving per dose if he takes the drug five times a day?
7. The recommended dose of erythromycin to treat an ear infection is 50 mg/kg per day given q6h. Answer the following questions regarding this drug:
   a. If a child weighs 15 kg, how much erythromycin should he receive per day?
   b. How much drug will he receive per dose?
8. The recommended dose of sterioid for replacement therapy is 2 mg/m^2 per dose. The drug is administered twice daily. What is the daily prednisone dose for a 1.2-m^2 person?
9. Potassium chloride 20 mEq/liter runs at a rate of 100 mL/hr. How long will the liter bag last? How many mEq of potassium chloride will the patient receive per hour?
10. A child with an opiate overdose needs naloxone. The recommended starting dose is 5–10 mcg/kg. The doctor writes for "0.3 mg naloxone stat." Answer the following questions on the basis of the child's weight of 35 kg:
    a. What range of doses, in mcg, could be used to start therapy in this child?
    b. On the basis of the answer to "a," does 0.3 mg sound like a reasonable dose?
11. An IV fluid is running at 125/hr. How many liter bags will the patient need for 24 hours?
12. A patient has two IVs running: an aminophylline drip at 22 mL/hr and saline at 40 mL/hr. How much fluid is the patient receiving per day from his IVs?
13. Medication: Dopamine 1800 mcg in 500 mL D5W. Patient is to receive 4 mcg/min. How many mL/hr should the patient receive?
14. If a patient is receiving an IV solution containing 20,000 units of heparin in 500 mL D5NS at a rate of 25 mL/hr with a tubing set that delivers 15 gtt/mL. What is the drip rate in gtt/min?
15. A patient is to receive 40 mg of an antibiotic in 25 mL of D5W to run over 60 min. If the nurse uses a 10 gtt/mL tubing set, what is the drip rate in gtt/min?
16. Medication is ordered at 4 mg/kg daily per IV over 1 hour. The patient weighs 195 lb. The drug is available in a 250-mg/2-mL vial.
    a. How many mL of drug is needed?
17. An IV solution is ordered requiring 250 mL of Drug AX 15%. The stock of Drug AX 20% is available.

a. How many milliliters of concentrate are needed?

b. How many milliliters of diluent are needed?

18. You are to prepare 2 oz of folic acid 100 mcg/mL using a stock of folic acid 5 mg/mL.

a. How much folic acid, in milliliters, do you need?

b. How much diluent, in milliliters, do you need?

19. If an IV is running at 100 mL/hr, how many liter bags are needed for 24 hours?

20. How many grams of coal tar must be added to 1 lb of 10% coal tar to make a 15% ointment?

21. 425 grams of sucrose is added to 500 mL of water with a resulting volume of 850 mL; express the concentration of sucrose as a w/w and a w/v product.

22. Retin A 0.025% gel in 2-oz tubes are available; how many milligrams of tretinoin are in the 2-oz tube?

23. A loading dose of an anticonvulsant medication for children is 20 mg/kg and infused at a rate of 0.5 mg/kg per minute; over how many minutes would a dose be administered for a child weighing 50 lb?

24. A physician orders a 5% ophthalmic ointment. How much drug and how much ophthalmic base (in grams) would be needed to prepare a 3-g tube of ointment?

25. A liter of NS contains 9,000 mg of sodium chloride. Express this as a percent.

26. You receive an order for a liter of TPN solution containing 2.5% Liposyn, and the stock is 20%. How much 20% Liposyn do you need?

27. The standard receipe for progesterone vaginal suppositories is:

Progesterone	3.4 g
Polyethylene glycol 3350	22 g
Polyethylene glycol 1000	90 g
Yield	30 Supp.

You are ordered to make 90 suppositories. How many grams of progesterone will you need?

28. The pharmacy receives an order for 500 mL D15W. Using 70% dextrose and sterile water, how much of each will you need?

29. Orders are received for a 1.5 L TPN for an adult; the order reads:

Dextrose	17%
Aminosyn	3%
Liposyn	2.5%
Sterile water	QSAD 1500 mL
Sodium chloride	15 mEq/L
Potassium chloride	15 mEq/L
Potassium phosphate	10 mM/L
Magnesium sulfate	10 mEq//L
MVI	10 mL/day

On hand

Dextrose	70%
Aminosyn	10%
Lipsyn	20%
Sodium chloride	4 mEq/mL
Potassium chloride	2 mEq/mL
Potassium phosphate	3 mM/mL
Magnesium phosphate	4.06 mEq/mL
MVI	10 mL vial

Calculate the amount of each of the stock ingredients and how much sterile water will be needed:

a. Dextrose

b. Aminosyn

c. Liposyn

d. Sodium chloride

e. Potassium chloride

f. Potassium phosphate

g. Magnesium sulfate

h. MVI

i. Sterile water

30. Prepare a 10-mL dilution of dexamethasone with a 1-mg/mL concentration using a 4-mg/mL stock. How much stock and how much water will you need?

ANSWERS TO PRACTICE CALCULATIONS 1

1. 14
2. 3
3. 0.667
4. 2/5
5. 42/100 = 21/50
6. 45%
7. 40%
8. 65/100 = 13/20
9. 24
10. 1.25
11. gram
12. meter
13. liter
14. 0.001 km
15. 0.001 L
16. 0.001 kg
17. 0.001 g
18. 1,000 mcg
19. 0.001 mg
20. 1,000 mL
21. 3 tsp
22. 29.57 (30) mL
23. 45 mL
24. 3 tsp
25. 2 tbsp
26. 0.1 L
27. 4.4 lb.
28. 1 ½ oz.
29. 1 ½ tsp
30. 1,000,000,000 mcg

31. 5 mL
32. 325 mg
33. 120 mL
34. 57.2 lb.
35. 2 oz
36. 1 ¼ grain, assuming 65 mg = 1 grain
37. 0.148 g
38. 6 tsp
39. 2 tbsp
40. 3785 mL
41. 0.426 L
42. 4 tsp
43. 3 tbsp
44. 2.48 g
45. 454 g
46. 2,500 mL
47. 66 lb
48. 0.725 g
49. 2 tsp
50. 3 tbsp
51. 125,000 mcg
52. 5 grains
53. 80 kg
54. 0.05%
55. 4.8 L
56. 120 g
57. 6 oz.
58. 2,560,000 mcg
59. 13 days
60. ½ tsp; dispense 225 mL
61. 1/2,000
62. 1:2,000
63. 0.75 mg = 750 mcg
64. 504.78 g
65. 61,728 81-mg tablets can be made from 5 kg of powder

ANSWERS TO PRACTICE CALCULATIONS 2

1. 180 capsules
2. a. 7.5 mL
   b. 225 mL
3. a. Give one teaspoonful twice a day for 10 days.
   b. 100 mL
4. a. 1½ tablets
   b. 90 tablets
5. 40 days
6. a. 12.5 mL per dose
   b. 4 days
7. Yes the recommended dose for this weight is 60–102 mg per dose.
8. Take one tablet daily.
9. 4 g/100 g
   12 g/100 mL
   0.75 mL/100 mL
10. 9.55 mL
11. 1 gram
12. 0.12 g
13. 0.45 g/100 mL
14. 0.02%
15. 1:2000
16. a. 0.9 g
    b. 100 mL
17. 50 mg
18. 0.48 mg
19. 2%
20. 0.02 g
21. 0.1 g zinc sulfate and 10 g boric acid
22. a. 2 mL
    b. 2 mL
    c. 60 g
23. a. 0.25 mL
24. 5 cartridges
25. 17 mL
26. a. Take 7.5 mL or 1 1/2 teaspoonfuls twice a day.
    b. 450 mL
27. 3.4 mL PV
28. 1.2 mL (which is 6 mg)
29. 416.67 mg/dose
30. 9 grams
31. 600 mg/dose
32. a. 5,750 mcg/dose
    b. 23 mg/day
33. Sodium chloride 10 mL; potassium chloride 5 mL
34. 4 mL
35. 1.3 PV
36. 113.5 g of 20% and 794.5 g of base
37. 53 tablets (2½ tabets per dose X the 10 days plus the 3 stat pills)
38. 2.5 mL per dose; will last 48 days
39. 8 mL
40. 40 mL for 24 hours, 200 mL will last 5 days

ANSWERS TO PRACTICE CALCULATIONS 3

1. a. 20 mL stock solution
   b. 1,980 mL sterile water
2. a. 2 mL stock solution
   a. 48 mL stock solution
3. a. 60 mL stock solution
   b. 240 mL sterile water
4. 84 tablets
5. 8 days
6. 200 mg per dose
7. a. 750 mg per day
   b. 187.5 mg per dose
8. 4.8 mg per day
9. 10 hours; 2 mEq/hr
10. a. Acceptable dosage range: 175–350 mcg
    b. Yes, it falls within the accepted calculated range.
11. 3 bags
12. 1,488 mL per day
13. 66.67 = 67 mL/hr
14. 6.25 = 6 gtt/min
15. 4 gtt/min
16. 2.8 mL
17. a. 187.5 mL concentrate
    b. 62.5 mL diluent
18. a. 1.2 mL folic acid
    b. 58.8 mL diluent
19. 3 one liter bags
20. 26.7 g
21. 425/925 = 45.9% w/w and 425/850 = 50% w/v
22. 15 mg
23. 40 minutes
24. 0.15 g of drug and 2.85 g of base
25. 0.9%
26. 125 mL
27. 10.2g
28. 107 mL of 70%; 393 mL sterile water
29. a. 364.3 mL of 70% dextrose
    b. 450 mL of 10% aminosyn
    c. 187.5 mL of 20% liposyn
    d. 5.625 mL of sodium chloride
    e. 11.25 mL of potassium chloride
    f. 5 mL of potassium phosphate
    g. 3.7 mL magnesium sulfate
    h. 10 mL MVI
    i. 462.623 mL of sterile water

    (Note the order for sodium and potassium additives states/L and you are making 1.5 L.)
30. 2.5 mL stock; 7.5 mL water

CHAPTER 3

PHARMACOLOGY REVIEW



Learning Outcomes

After completing this chapter, you will be able to

- Identify the common drug names for each classification.
- Describe the important actions and/or therapeutic uses for the major classes of drugs.

This chapter applies to all sections of the PTCB exam.

The tables in this chapter should be utilized in assisting you to create monographs for the drugs listed. You should refer to a current top 200 drug list (see Appendix C in the *Manual for Pharmacy Technicians, 5th edition*, or https://clincalc.com/DrugStats) to add to this list as appropriate. It is important for technicians to identify which drug classification a particular drug belongs to. Classification is made easier once the pharmacist is able to recognize prefixes and suffixes.

There are different ways to classify medications: by medical conditions, by body organ systems, or by type of action. Drugs often have actions in more than one part of the body and may be mentioned in several areas.

BODY SYSTEMS

Drugs That Affect the Nervous System

TABLE 3-1. Antiepileptics

Generic Name (Brand Name)	Dosage Forms	FDA-Approved Indications
Brivaracetam (Briviact)	Injection, tablets, solution	Adjunctive to partial onset seizures
Carbamazepine (Tegretol, Tegretol XR)	Capsules, suspension, tablets, extended-release	Tonic-clonic, partial onset seizures
Clobazam (Onfi)	Suspension, tablets	Adjunctive to seizures associated with Lennox–Gastaut syndrome
Clonazepam (Klonopin)	Tablets, orally disintegrating tablets, wafers	Absence, myoclonic seizures
Diazepam (Valium, Diastat)	Injection, rectal gel	Status epilepticus
Divalproex sodium (Depakote, Depakote ER)	Capsules (sprinkle), delayed-release tablets, extended-release tablets	Absence, partial onset seizures
Eslicarbazepine (Aptiom)	Tablets	Partial onset seizures
Ezogabine (Potiga)	Tablets	Partial onset seizures
Fosphenytoin (Cerebyx)	Injection	Status epilepticus, prevention and treatment of seizures during neurosurgery, short-term administration when unable to take oral phenytoin
Gabapentin (Neurontin)	Capsules, solution, tablets	Tonic-clonic, partial onset seizures
Lacosamide (Vimpat)	Tablets, injection, solution	Adjunctive to partial onset seizures
Lamotrigine (Lamictal, Lamictal XR)	Tablets, orally disintegrating tablets, extended-release tablets	Partial onset seizures, tonic-clonic seizures
Levetiracetam (Keppra)	Injection, solution, tablets, extended-release tablets	Adjunctive to partial onset, myoclonic and tonic-clonic seizures
Lorazepam (Ativan)	Injection	Status epilepticus
Oxcarbazepine (Trileptal, Oxtellar XR)	Suspension, extended-release (XR) tablets, tablets	Partial onset seizures
Perampanel (Fycompa)	Suspension, tablets	Partial onset, tonic-clonic seizures
Phenobarbital	Tablets, injection, solution	Generalized tonic-clonic, partial onset seizures
Phenytoin (Dilantin)	Extended-release capsules, chew-tabs, suspension, injection	Generalized tonic-clonic (grand mal), complex partial onset seizures, prevention and treatment during or following neurosurgery, status epilepticus (intravenous)
Pregabalin (Lyrica)	Capsules, solution	Adjunctive to partial onset
Tiagabine (Gabitril)	Tablets	Adjunctive to partial onset
Topiramate (Topamax)	Capsules (sprinkle), tablets	Adjunctive to tonic-clonic, partial onset
Valproic acid (Depakene), valproate sodium (Depacon)	Capsules, syrup, injection	Absence seizures, complex partial onset
Zonisamide (Zonegran)	Capsules	Adjunctive to partial onset seizures

FDA = U.S. Food and Drug Administration.

- The antiepileptic drugs may increase the risk of suicidal thoughts or behavior; therefore, it is important that patients are monitored for unusual changes in mood or behavior. A Food and Drug Administration (FDA)-approved Medication Guide must be dispensed with all prescriptions for antiepileptic drugs warning patients about this potential risk.

TABLE 3-2. Drugs for Parkinson Disease

Classifications and Medications	Available Dosage Forms
Anticholinergics	
Amantadine (Symmetrel)	Tablets, capsules, solution
Benztropine (Cogentin)	Tablets, injection
Trihexyphenidyl (Artane)	Tablets, sustained-release capsules
Carbidopa/levodopa products	
Carbidopa/levodopa (Sinemet, Sinemet CR)	Tablets, ER and CR tablets
Carbidopa/levodopa/entacapone (Stalevo)	Tablets
MAO-B inhibitors	
Rasagiline (Azilect)	Tablets
Selegiline (Eldepryl, Zelapar ODT, Emsam patch)	Capsules, ODT, transdermal patch
COMT inhibitors	
Entacapone (Comtan)	Tablets
Tolcapone (Tasmar)	Tablets
Dopamine agonists	
Apomorphine (Apokyn)	Subcutaneous injection
Bromocriptine (Parlodel)	Tablets, capsules
Pramipexole (Mirapex)	Tablets, ER tablets
Ropinirole (Requip)	Tablets, ER tablets
Rotigotine (Neupro)	Transdermal patch

COMT = catechol-O-methyl transferase, CR = controlled release, ER = extended release, MAO-B = monoamine oxidase B, ODT = orally disintegrating tablet.

TABLE 3-3. Alzheimer Disease Agents

Classifications and Medications	Available Dosage Forms
Cholinesterase inhibitors	
Donepezil (Aricept)	Tablets, orally disintegrating tablets
Galantamine (Razadyne)	Tablets, extended-release tablets, solution
Rivastigmine (Exelon)	Capsules, solution, patch
N-methyl-D-aspartate (NMDA) receptor antagonists	
Memantine (Namenda)	Tablets, oral solution
Memantine/donepezil (Namzaric)	Capsules

TABLE 3-4. Multiple Sclerosis Agents

Medications—Generic (Brand) Names	Available Dosage Forms	Indications
First-generation agents		
Glatiramer acetate (Copaxone)	Sub-Q injection	To reduce the frequency of relapses in relapsing remitting MS
Interferon beta-1a (Avonex, Rebif)	IM, sub-Q injection	Treatment of relapsing forms of MS to slow disease progression and prevent exacerbations
Interferon beta-1b (Betaseron)	Sub-Q injection	Treatment of relapsing forms of MS and to prevent exacerbations
Mitoxantrone (Novantrone)	IV infusion	To reduce neurologic disability and frequency of relapses in secondary, chronic progressive, relapsing remitting MS
Second-generation agents		
Alemtuzumab (Lemtrada)	IV infusion	To reduce relapse rate in relapsing-remitting MS
Daclizumab (Zinbryta)	Sub-Q injection	Treatment of relapsing forms of MS
Dimethyl Fumarate (Tecfidera)	Capsule	Treatment of relapsing forms of MS
Fingolimod (Gilenya)	Capsule	Treatment of relapsing forms of MS
Natalizumab (Tysabri)	IV infusion	Treatment of relapsing forms of MS to delay disease progression and prevent exacerbations; used when an inadequate response or intolerance to other agents
Ocrelizumab (Ocrevus)	IV infusion	Treatment of primary progressive and relapsing MS
Teriflunomide (Aubagio)	Tablets	Treatment of relapsing forms of MS

IM = intramuscular, IV = intravenous, MS = multiple sclerosis, sub-Q = subcutaneous.

Alternative therapies include **monoclonal antibodies (MABs)** such as natalizumab, alemtuzumab, or daclizumab. These medications suppress the immune system, and often have flu-like side effects.

TABLE 3-5. Drugs for Headaches

Classifications and Medications	Available Dosage Forms
Triptans (common suffix)	
Almotriptan (Axert)	Tablets
Eletriptan (Relpax)	Tablets
Frovatriptan (Frova)	Tablets
Naratriptan (Amerge)	Tablets
Rizatriptan (Maxalt)	Tablets, orally disintegrating tablets
Sumatriptan (Imitrex)	Tablets, nasal spray, injection
Zolmitriptan (Zomig)	Tablets, orally disintegrating tablets, nasal spray

Sumatriptan and naproxen (Treximet)	Tablets
Butalbital-containing products	
Butalbital and acetaminophen	Tablets
Butalbital, acetaminophen, caffeine (Fioricet, Esgic)	Tablets
Butalbital, acetaminophen, caffeine, codeine (Fioricet with codeine)	Tablets
Butalbital, aspirin, caffeine (Fiorinal)	Capsules, tablets
Butalbital, aspirin, caffeine, codeine (Fiorinal with codeine)	Capsules
Ergotamine derivatives	
Ergotamine, caffeine (Cafergot, Migergot, Ergomar)	Suppositories, tablets, sublingual tablets
Dihydroergotamine (D.H.E. 45, Migranal)	Injection, nasal spray

TABLE 3-6. Agents to Treat Neuropathic Pain

Classifications and Medications	Available Dosage Forms
Topical agents	
Capsaicin (Zostrix)	Lotion, cream, gel, patch, roll-on stick
Lidocaine (Lidoderm)	Patch
Antidepressants	
Amitriptyline (Elavil)	Tablets
Bupropion (Wellbutrin)	Extended-release tablets, sustained-release tablets, tablets
Duloxetine (Cymbalta)	Capsules
Fluoxetine (Prozac)	Tablets, capsules, oral solution
Nortriptyline (Pamelor)	Capsules, solution
Venlafaxine (Effexor)	Tablets, extended-release tablets and capsules
Antiepileptics	
Carbamazepine (Tegretol)	Tablets, capsules, oral suspension
Divalproex, valproic acid (Depakote, Depakene)	Capsules, tablets, syrup
Gabapentin (Neurontin, Horizant)	Tablets, capsules, oral solution
Lamotrigine (Lamictal)	Tablets
Pregabalin (Lyrica)	Capsules
Topiramate (Topamax)	Tablets, capsules
Miscellaneous agents	
Tapentadol (Nucynta)	Extended-release tablets, tablets
Baclofen	Tablets

TABLE 3-7. Antidepressants

Classifications and Medications	Available Dosage Forms
Tricyclic antidepressants	
Amitriptyline (Elavil)	Tablets
Clomipramine (Anafranil)	Capsules
Desipramine (Norpramin)	Tablets
Doxepin (Sinequan)	Capsules
Imipramine (Tofranil, Tofranil-PM)	Tablets, capsules
Nortriptyline (Pamelor)	Capsules, solution
Protriptyline (Vivactil)	Tablets
Monoamine oxidase inhibitors (MAOIs)	
Isocarboxazid (Marplan)	Tablets
Phenelzine (Nardil)	Tablets
Tranylcypromine (Parnate)	Tablets
Selective serotonin reuptake inhibitors (SSRIs)	
Citalopram (Celexa)	Tablets, solution
Escitalopram (Lexapro)	Tablets, solution
Fluoxetine (Prozac, Sarafem)	Capsules, tablets, solution
Fluvoxamine	Tablets, extended-release capsules
Paroxetine (Paxil, Paxil CR, Pexeva)	Tablets, extended-release tablets, suspension
Sertraline (Zoloft)	Tablets, concentrate
Selective norepinephrine reuptake inhibitors (SNRIs)	
Desvenlafaxine (Pristiq)	Extended-release tablets
Duloxetine (Cymbalta)	Capsules
Levomilnacipran (Fetzima)	Capsules
Venlafaxine (Effexor, Effexor XR)	Tablets, extended-release tablets, extended-release capsules
Miscellaneous agents	
Bupropion (Wellbutrin, Wellbutrin SR, Wellbutrin XL)	Tablets, extended-release tablets
Mirtazapine (Remeron)	Tablets
Nefazodone (Serzone)	Tablets
Trazodone (Desyrel)	Tablets
Vilazodone (Viibryd)	Tablets
Vortioxetine (Trintellix)	Tablets

CR = controlled release, SR = sustained release, XL/XR = extended release.

TABLE 3-8. Drugs for Bipolar Disorder

Classifications and Medications	Dosage Forms
Lithium carbonate (Lithobid)	Capsules, tablets, controlled-release tablets, syrup
Antiepileptics	
Carbamazepine (Tegretol, Equetro)	Capsules, suspension, tablets, extended-release tablets, chewable tablets, extended-release capsules
Divalproex sodium (Depakote)	Capsules (sprinkle), injection, delayed-release tablets, extended-release tablets
Lamotrigine (Lamictal)	Tablets, orally disintegrating tablets
Oxcarbazepine (Trileptal)	Suspension, tablets, extended-release tablets
Atypical antipsychotics	
Aripiprazole (Abilify)	Injection, solution, tablets, orally disintegrating tablets
Olanzapine (Zyprexa)	Injection, tablets, orally disintegrating tablets
Quetiapine (Seroquel, Seroquel XR)	Tablets, extended-release tablets
Risperidone (Risperdal)	Injection, solution, tablets, orally disintegrating tablets
Ziprasidone (Geodon)	Capsules, injection capsules
Olanzapine/fluoxetine (Symbyax)	Capsules

XR = extended release.

TABLE 3-9. Drugs for Anxiety Disorders

Classifications and Medications	Available Dosage Form
Benzodiazepines (suffix–pam)	
Alprazolam (Xanax)	Tablets, oral concentrate solution, extended-release tablets, orally disintegrating tablets
Diazepam (Valium)	Injection, oral concentrate solution, oral solution, tablets
Lorazepam (Ativan)	Tablets, injection, oral concentrate solution
Clonazepam (Klonopin)	Tablets, orally disintegrating tablets, wafers
Chlordiazepoxide (Librium)	Capsules
Nonbenzodiazepine	
Buspirone (BuSpar)	Tablets

TABLE 3-10. Antipsychotics

Classifications and Medications	Available Dosage Forms
Conventional antipsychotics	
Chlorpromazine	Tablets, injection
Fluphenazine	Tablets, injection, oral concentrate, elixir
Haloperidol (Haldol)	Tablets, oral concentrate, injection
Loxapine (Adasuve)	Capsules, inhalation powder
Thioridazine	Tablets
Thiothixene	Capsule
Trifluoperazine	Tablets
Atypical antipsychotics	
Aripiprazole (Abilify, Abilify Maintena)	Tablets, solution, orally disintegrating tablets, long-acting injection
Clozapine (Clozaril, Fazaclo, Versacloz)	Tablets, orally disintegrating tablets, oral suspension
Olanzapine (Zyprexa, Zyprexa Relprevv, Zyprexa Zydis)	Tablets, orally disintegrating tablets, injection
Paliperidone (Invega, Invega Sustenna), Invega Trinza	Extended-release tablets, long-acting injection
Quetiapine (Seroquel, Seroquel XR)	Tablets, extended-release tablets
Risperidone (Risperdal, Risperdal Consta)	Tablets, orally disintegrating tablets, solution, long-acting injection
Ziprasidone (Geodon)	Capsules, injection

XR = extended release.

TABLE 3-11. Sedative and Hypnotic Medications

Classifications and Medications	Available Dosage Forms
Benzodiazepines (suffix–pam)	
Estazolam	Tablets
Flurazepam (Dalmane)	Capsules
Quazepam (Doral)	Tablets
Temazepam (Restoril)	Capsules
Triazolam (Halcion)	Tablets
Other agents (nonbenzodiazepines)	
Eszopiclone (Lunesta)	Tablets
Ramelteon (Rozerem)	Tablets
Zaleplon (Sonata)	Capsules
Zolpidem (Ambien, Ambien CR, Edular, Intermezzo, Zolpmist)	Tablets, extended-release tablets, sublingual tablets, solution

CR = controlled release.

TABLE 3-12. Drugs for ADHD

Classifications and Medications	Available Dosage Forms
Stimulants	
Amphetamine (Evekeo)	Tablets
Dexmethylphenidate (Focalin)	Tablets, extended-release capsules
Dextroamphetamine (Dexedrine)	Tablets, extended-release capsules, solution
Lisdexamfetamine (Vyvanse)	Capsules

TABLE 3-12. (continued)

Classifications and Medications	Available Dosage Forms
Methylphenidate (Ritalin, Metadate, Methylin, Concerta, Daytrana)	Tablets, extended-release tablets, capsules, patch
Mixed amphetamine salts (Adderall, Adderall XR)	Tablets, extended-release capsules
Nonstimulants	
Atomoxetine (Strattera)	Capsules

XR = extended release.

Drugs That Affect the Cardiovascular System

TABLE 3-13. Cholesterol-Lowering Agents

Classifications and Medications	Available Dosage Forms
Bile acid sequestrants	
Cholestyramine (Questran)	Powder, packets
Colestipol (Colestid)	Granules, packets, tablets
Colesevelam (Welchol)	Tablets
HMG-CoA reductase inhibitors (statins) (common ending–statin)	
Atorvastatin (Lipitor)	Tablets
Fluvastatin (Lescol, Lescol XL)	Capsules, extended-release tablets
Lovastatin (Altoprev)	Tablets, extended-release tablets
Pitavastatin (Livalo)	Tablets
Pravastatin (Pravachol)	Tablets
Simvastatin (Zocor)	Tablets
Rosuvastatin (Crestor)	Tablets
Fibrates	
Gemfibrozil (Lopid)	Tablets
Fenofibrate, fenofibric acid (Antara, Fenoglide, Lofibra, Lipofen, Triglide, Trilipix, Tricor)	Tablets, capsules
PCSK-9 inhibitors	
Alirocumab (Praluent)	Injection
Evolocumab (Repatha)	Injection
Miscellaneous and combination agents	
Amlodipine/atorvastatin (Caduet)	Tablets
Ezetimibe (Zetia)	Tablets
Ezetimibe/simvastatin (Vytorin)	Tablets
Niacin/lovastatin (Advicor)	Extended-release tablets
Niacin/simvastatin (Simcor)	Extended-release tablets
Nicotinic acid (Niacin, Niaspan)	Tablets, capsules, extended-release
Omega-3 fatty acids (Lovaza)	Capsules

XL = extended release.

TABLE 3-14. Diuretics

Classifications and Medications	Available Dosage Forms
Thiazide diuretics (suffix–diazide)	
Chlorothiazide (Diuril)	Injection, suspension, tablets
Hydrochlorothiazide (Microzide)	Capsules, tablets
Metolazone (Zaroxolyn)	Tablets
Loop diuretics	
Bumetanide (Bumex)	Injection, tablets
Ethacrynic acid (Edecrin)	Injection, tablets
Furosemide (Lasix)	Injection, solution, tablets
Torsemide (Demadex)	Injection, tablets
Potassium-sparing diuretics	
Eplerenone (Inspra)	Tablets
Spironolactone (Aldactone)	Tablets
Triamterene (Dyrenium)	Capsules
Combination agents	
Aliskiren/HCTZ (Tekturna HCT)	Tablets
Triamterene/HCTZ (Dyazide, Maxzide)	Tablets, capsules
Spironolactone/HCTZ (Aldactazide)	Tablets

HCT/HCTZ = hydrochlorothiazide.

TABLE 3-15. Beta Blockers (suffix–*olol*)

Medications	Cardioselective or Nonselective	Available Dosage Forms
Atenolol (Tenormin)	Cardioselective	Tablets
Bisoprolol	Cardioselective	Tablets
Carvedilol (Coreg, Coreg CR)	Nonselective	Tablets, extended-release (CR) tablets
Labetalol (Trandate)	Nonselective	Tablets, injection
Metoprolol tartrate (Lopressor)	Cardioselective	Injection, tablets
Metoprolol sodium succinate (Toprol-XL)	Cardioselective	Extended-release (XL) tablets
Nadolol (Corgard)	Nonselective	Tablets
Nebivolol (Bystolic)	Cardioselective	Tablets
Propranolol (Inderal LA)	Nonselective	Solution, extended-release (LA) capsules, tablets, injection
Sotalol (Betapace)	Nonselective	Tablets
Combination agents		
Atenolol/chlorthalidone (Tenoretic)	Cardioselective	Tablets
Bisoprolol/HCTZ (Ziac)	Cardioselective	Tablets
Metoprolol/HCTZ (Lopressor HCT)	Cardioselective	Tablets

CR = controlled release, HCT/HCTZ = hydrochlorothiazide, LA = long acting, XL = extended release.

TABLE 3-16. ACE Inhibitors and ARBs

Classifications and Medications	Available Dosage Forms
ACE inhibitors (ACEIs) (suffix–pril)	
Benazepril (Lotensin)	Tablets
Captopril	Tablets
Enalapril, enalaprilat (Vasotec)	Injection, tablets
Fosinopril	Tablets
Lisinopril (Prinivil, Zestril)	Tablets
Moexipril	Tablets
Quinapril (Accupril)	Tablets
Perindopril (Aceon)	Tablets
Ramipril (Altace)	Capsules, tablets
Trandolapril (Mavik)	Tablets
Angiotensin II receptor blockers (ARBs) (suffix–sartan)	
Azilsartan (Edarbi)	Tablets
Candesartan (Atacand)	Tablets
Eprosartan	Tablets
Irbesartan (Avapro)	Tablets
Losartan (Cozaar)	Tablets
Olmesartan (Benicar)	Tablets
Telmisartan (Micardis)	Tablets
Valsartan (Diovan)	Tablets
Combination products	
Amlodipine/olmesartan (Azor)	Tablets
Amlodipine/valsartan (Exforge)	Tablets
Amlodipine/valsartan/HCTZ (Exforge HCT)	Tablets
Benazepril/HCTZ (Lotensin HCT)	Tablets
Candesartan/HCTZ (Atacand HCT)	Tablets
Enalapril/HCTZ (Vaseretic)	Tablets
Irbesartan/HCTZ (Avalide)	Tablets
Lisinopril/HCTZ (Zestoretic)	Tablets
Losartan/HCTZ (Hyzaar)	Tablets
Moexipril/HCTZ (Uniretic)	Tablets
Olmesartan/HCTZ (Benicar HCT)	Tablets
Quinapril/HCTZ (Accuretic)	Tablets
Telmisartan/HCTZ (Micardis HCT)	Tablets
Trandolapril/verapamil (Tarka)	Tablets
Valsartan/HCTZ (Diovan HCT)	Tablets
Valsartan/Sacubitril (Entresto)	Tablets

HCT, HCTZ = hydrochlorothiazide.

TABLE 3-17. Calcium Channel Blockers

Medications	Available Dosage Forms
Amlodipine (Norvasc)	Tablets
Clevidipine (Cleviprex)	Injection
Diltiazem (Cardizem, Tiazac)	Tablets, extended-release capsules and tablets, injection
Felodipine	Tablets
Isradipine	Capsules
Nifedipine (Procardia, Adalat CC)	Capsules, extended-release tablets
Nicardipine (Cardene)	Capsules, sustained-release capsules, injection
Nimodipine (Nymalize)	Capsules, solution
Nisoldipine (Sular)	Extended-release tablets
Verapamil (Calan, Verelan)	Sustained-release caplets, extended-release capsules, injection, tablets
Combination agents	
Amlodipine/atorvastatin (Caduet)	Tablets
Amlodipine/benazepril (Lotrel)	Tablets
Amlodipine/olmesartan/HCTZ (Tribenzor)	Tablets

HCTZ = hydrochlorothiazide.

TABLE 3-18. Antiarrhythmic Agents

Class	Medications	Available Dosage Forms
IA	Disopyramide (Norpace, Norpace CR)	Capsules, extended-release capsules
	Procainamide	Injection
	Quinidine	Tablets, injection
IB	Lidocaine (Xylocaine)	Injection
	Mexiletine	Capsules
IC	Flecainide	Tablets
	Propafenone (Rythmol)	Tablets, capsules
II	Atenolol (Tenormin)	Tablets
	Esmolol (Brevibloc)	Injection
	Metoprolol (Lopressor, Toprol XL)	Tablets, injection
	Propranolol (Inderal)	Tablets, capsules, oral solution, injection
III	Amlodarone (Pacerone, Cordarone)	Tablets, injection
	Dofetilide (Tikosyn)	Capsules
	Dronedarone (Multaq)	Tablets
	Ibutilide (Corvert)	Injection
	Sotalol (Betapace)	Tablets, injection

CR = controlled release, XL = extended release.

Drugs That Affect the Respiratory System

TABLE 3-19. Agents to Treat Asthma and COPD

Classifications and Medications	Available Dosage Forms
Short-acting bronchodilators (SABAs)	
Albuterol (Proventil HFA, Ventolin HFA, ProAir HFA, ProAir RespiClick)	MDI, BAI, nebulizer solution, extended-release tablets, oral liquid
Levalbuterol (Xopenex, Xopenex HFA)	MDI, nebulizer solution
Long-acting bronchodilators (LABAs)	
Arformoterol (Brovana)	Nebulizer solution
Formoterol (Perforomist)	Nebulizer solution
Indacaterol (Arcapta)	DPI
Olodaterol (Striverdi)	SMI
Salmeterol (Serevent)	DPI
Methylxanthines	
Aminophylline	Injection
Theophylline (Theo-24, Elixophyllin, Theochron)	Injection, elixir, extended-release capsules/tablets
Anticholinergics	
Aclidinium (Tudorza)	DPI and BAI
Ipratropium (Atrovent HFA)	MDI, nebulizer solution
Tiotropium (Spiriva Handihaler, Spiriva Respimat)	DPI, SMI
Umeclidinium (Incruse Ellipta)	DPI
Leukotriene modifiers	
Montelukast (Singulair)	Chewable tablets, tablets, granules
Zafirlukast (Accolate)	Tablets
Zileutin (Zyflo, Zyflo CR)	Tablets, extended-release tablets
Combination agents	
Formoterol/budesonide (Symbicort)	MDI
Formoterol/mometasone (Dulera)	MDI
Ipratropium/albuterol (Combivent Respimat, Duoneb)	SMI, nebulizer solution
Salmeterol/fluticasone (Advair, Advair HFA)	DPI, MDI
Tiotropium/olodaterol (Stiolto Respimat)	SMI
Umeclidinium/vilanterol (Anoro Ellipta)	DPI
Vilanterol/fluticasone (Breo Ellipta)	DPI

BAI = breath-actuated inhaler, DPI = dry powder inhaler, MDI = metered-dose inhaler, SMI = soft mist inhaler.

TABLE 3-20. Oral/Inhaled Corticosteroids

Medications	Available Dosage Forms	Comments
Oral corticosteroids		
Prednisone	Solution, intensol, tablets	Bitter taste
Methylprednisolone (Medrol, Solu-Medrol)	Injection, long-acting injection, tablets, dosepak	
Prednisolone (Orapred)	Solution, orally disintegrating tablets, tablets	
Inhaled corticosteroids		
Beclomethasone (QVAR)	BAI	
Budesonide (Pulmicort)	DPI, nebulizer solution	
Ciclesonide (Alvesco)	MDI	
Flunisolide (Aerospan)	MDI	
Mometasone (Asmanex, Asmanex HFA)	DPI, MDI	
Fluticasone Furoate (Arnuity Ellipta)	DPI	
Fluticasone propionate (Flovent HFA, Flovent Diskus)	MDI, DPI	

BAI = breath-actuated inhaler, DPI = dry powder inhaler, MDI = metered-dose inhaler.

TABLE 3-21. Antihistamines

Medications	Available Dosage Forms
Older antihistamines	
Chlorpheniramine (Chlor-Trimeton)	Tablets, solution
Clemastine (Tavist)	Tablets
Diphenhydramine (Benadryl)	Caplets, capsules, solution, strips, syrup, orally disintegrating tablets, chewable tablets, injection
Newer antihistamines	
Azelastine (Astelin)	Intranasal
Cetirizine (Zyrtec)	Solution, syrup, tablets, chewable tablets, orally disintegrating tablets
Desloratadine (Clarinex)	Syrup, tablets, orally disintegrating tablets
Fexofenadine (Allegra)	Suspension, tablets, orally disintegrating tablets
Levocetirizine (Xyzal)	Solution, tablets
Loratadine (Claritin, Alavert)	Capsules, solution, syrup, tablets, chewable tablets, orally disintegrating tablets Intranasal
Olopatadine (Patanase)	Capsules, solution, syrup, tablets, chewable tablets, orally disintegrating tablets Intranasal

TABLE 3-22. Cough and Cold Agents

Classifications and Medications	Available Dosage Forms
Decongestants	
Pseudoephedrine (Sudafed)	Tablets, extended-release tablets, liquid
Phenylephrine (Sudafed PE, Triaminic Cold PE)	Tablets, extended-release tablets, chewable tablets, orally disintegrating strips, liquid, nasal spray/drops
Topical decongestants	
Azelastine/fluticasone (Dymista)	Intranasal spray
Oxymetazoline (Afrin, Dristan, Mucinex, Neo-Synephrine)	Intranasal gel, intranasal spray
Beclomethasone (Beconase AQ)	Intranasal spray
Budesonide (Rhinocort)	Intranasal spray
Ciclesonide (Omnaris)	Intranasal spray
Fluticasone (Flonase, Flonase Sensimist)	Intranasal spray
Mometasone (Nasonex)	Intranasal spray
Flunisolide	Intranasal spray
Triamcinolone (Nasacort)	Intranasal spray
Antitussives	
Dextromethorphan (Delsym, Mucinex DM, Robitussin DM)	Syrup, suspension, orally disintegrating strips, lozenges, tablets
Expectorants	
Guaifenesin (Robitussin, Mucinex)	Granules, syrup, tablets, extended-release tablets

Drugs That Affect the Musculoskeletal System

TABLE 3-23. Osteoporosis Agents

Classifications and Medications	Available Dosage Forms
Calcium supplements	
Calcium carbonate (Caltrate, Os-Cal, Viactiv, Tums)	Tablets, chewable tablets, chews, suspension, powder
Calcium carbonate + vitamin D (Caltrate +D, Os-cal + D, Viactiv + D)	Tablets, chewable tablets, chews
Calcium citrate (Citracal)	Tablets, capsules, powder
Bisphosphonates	
Alendronate (Fosamax)	Tablets, solution
Alendronate/cholecalciferol (Fosamax + D)	Tablets
Ibandronate (Boniva)	Tablets, injection
Risedronate (Actonel, Atelvia)	Tablets
Risedronate/calcium (Actonel and Calcium)	Tablets
Zoledronic acid (Reclast)	Injection
Parathyroid hormone analog	
Teriparatide (Forteo)	Injection
Selective estrogen receptor modulators (SERMs)	
Raloxifene (Evista)	Tablets
Miscellaneous agents	
Calcitonin (Miacalcin, Fortical)	Intranasal
Denosumab (Prolia)	Injection

TABLE 3-24. Nonsteroidal Anti-inflammatory Agents

Medications	Available Dosage Forms
Diclofenac (Flector, Voltaren)	Tablets, gel, delayed-release tablets, patch
Etodolac	Tablets, capsules, extended-release tablets
Flurbiprofen	Tablets
Ibuprofen (Motrin, Advil)	Caplets, capsules, gelcaps, suspension, oral concentrate, drops, tablets, chewable tablets
Indomethacin (Indocin)	Capsules, extended-release capsules, injection, suppository, suspension
Ketorolac	Tablets, injection
Ketoprofen	Capsules, extended-release capsules
Meloxicam (Mobic)	Tablets
Nabumetone	Tablets
Naproxen (Naprosyn, Naprelan, Aleve, Anaprox DS)	Caplets, capsules, gelcaps, suspension, tablets, delayed-release tablets, extended-release tablets
Oxaprozin (Daypro)	Tablets
Piroxicam (Feldene)	Capsules
Sulindac	Tablets
Diclofenac/misoprostol (Arthrotec)	Tablets
COX-2 inhibitors	
Celecoxib (Celebrex)	Capsules

TABLE 3-25. Skeletal Muscle Relaxants

Medications	Available Dosage Forms
Baclofen (Lioresal)	Tablets, intrathecal injection
Carisoprodol (Soma)	Tablets
Chlorzoxazone	Tablets
Cyclobenzaprine	Tablets
Dantrolene (Dantrium)	Tablets, injection
Diazepam (Valium)	Tablets, oral solution, injection
Metaxalone (Skelaxin)	Tablets
Methocarbamol (Robaxin)	Tablets, injection
Orphenadrine	Tablets, injection
Tizanidine (Zanaflex)	Tablets

TABLE 3-26. Opioid Analgesics

Medications	Available Dosage Forms
Alfentanil (Alfenta)	Injection
Buprenorphine (Buprenex, Subutex)	Sublingual tablets, injection
Butorphanol (Stadol)	Injection, nasal spray
Codeine	Tablets
Fentanyl (Sublimaze, Duragesic, Fentora, Actiq, Lazanda)	Injection, patch, buccal tablets, transmucosal lozenge, nasal solution
Hydrocodone Bitartrate (Zohydro)	Extended-release capsules, antiabuse capsules and tablets
Hydromorphone (Dilaudid, Exalgo)	Tablets, solution, injection, suppository, extended-release tablets
Levorphanol	Tablets
Meperidine (Demerol)	Tablets, solution, injection
Morphine (Avinza, Kadian, MS Contin, Oramorph SR, Roxanol)	Tablets, capsules, extended-release tablets, solution, injection, suppository
Nalbuphine	Injection
Oxycodone (Oxaydo, OxyContin)	Tablets, extended-release tablets, solution
Oxymorphone (Opana, Opana ER)	Tablets, solution, extended-release tablets
Remifentanil (Ultiva)	Injection
Sufentanil (Sufenta)	Injection
Tapentadol (Nucynta)	Tablets, extended-release tablets
Tramadol (Ultram)	Tablets, solution, extended-release tablets
Combination products	
Acetaminophen with codeine (Tylenol #3)	Tablets, elixir
Acetaminophen with hydrocodone (Hycet, Lorcet, Lortab, Norco, Vicodin)	Tablets, solution, elixir
Acetaminophen with oxycodone (Percocet, Roxicet)	Tablets, solution
Acetaminophen with tramadol (Ultracet)	Tablets
Buprenorphine with naloxone (Suboxone)	Sublingual tablets
Ibuprofen with hydrocodone (Vicoprofen)	Tablets

ER = extended release.

Drugs That Affect the Endocrine System

TABLE 3-27. Insulins

Insulin Type	Onset of Action	Duration of Action
Rapid-acting		
Aspart (NovoLOG)	15 min	3–4 hr
Glulisine (Apidra)	15 min	3–4 hr
Lispro (AdmeLOG, HumaLOG, HumaLOG Jr, HumaLOG U 200)	15 min	3–4 hr
Short-acting		
Regular (HumuLIN R, HumuLIN R U-500, NovoLIN R, Afrezza)	30–60 min	4–6 hr
Intermediate-acting		
NPH (HumuLIN N, NovoLIN N)	2–4 hr	12–18 hr
Long-acting (basal)		
Detemir (Levemir)	3–4 hr	16-20 hr
Glargine (Basaglar, Lantus, Toujeo)	2–4 hr	24 hr
Degludec (Tresiba, Tresiba U-200)	1 hr	24 hr
Insulin combinations		
Aspart Protamine and Aspart (NovoLOG 70/30)	10–20 min	18–24 hr
Lispro Protamine and Lispro (HumaLOG 50/50, HumaLOG 75/25)	15–30 min	14–24 hr
NPH and Regular (HumuLIN 70/30, NovoLIN 70/30)	30 min	18–24 hr
Long-acting insulin and GLP-1 combinations		
Degludec and Liraglutide (Xultophy)	1 hr	24 hr
Glargine and Lixisenatide (Soliqua)	2–4 hr	24 hr

GLP-1 = glucagon-like peptide-1.

TABLE 3-28. Antidiabetic Agents (Hypoglycemics)

Classifications and Medications	Available Dosage Forms
Sulfonylureas	
Glimepiride (Amaryl)	Tablets
Glipizide (Glucotrol)	Tablets, extended-release tablets
Glyburide (Glynase)	Tablets
Meglitinides (secretagogues)	
Nateglinide (Starlix)	Tablets
Repaglinide (Prandin)	Tablets
Biguanides	
Metformin (Glucophage, Fortamet, Glumetza, Riomet)	Tablets, extended-release tablets, solution
Thiazolidinediones (glitazones)	
Pioglitazone (Actos)	Tablets
Rosiglitazone (Avandia)	Tablets

TABLE 3-28. (continued)

Classifications and Medications	Available Dosage Forms
Alpha-glucosidase inhibitors	
Acarbose (Precose)	Tablets
Miglitol (Glyset)	Tablets
Incretin mimetics	
Albiglutide (Tanzeum)	Injection
Dulaglutide (Trulicity)	Injection
Exenatide (Byetta, Bydureon)	Injection
Liraglutide (Victoza)	Injection
Amylin analog	
Pramlintide (Symlin)	Injection
Dipeptidyl peptidase-4 (DPP-4) inhibitors	
Alogliptin (Nesina)	Tablets
Linagliptin (Tradjenta)	Tablets
Saxagliptin (Onglyza)	Tablets
Sitagliptin (Januvia)	Tablets
Sodium-glucose cotransporter 2 inhibitors (SGLT-2) inhibitors	
Canagliflozin (Invokana)	Tablets
Dapagliflozin (Farxiga)	Tablets
Empagliflozin (Jardiance)	Tablets
Combination agents	
Alogliption/metformin (Kazano)	Tablets
Alogliptin/pioglitazone (Oseni)	Tablets
Canagliflozin/metformin (Invokamet)	Tablets, extended-release tablets
Dapagliflozin/metformin (Xigduo)	Tablets, extended-release tablets
Empagliflozin/linagliptin (Glyxambi)	Tablets
Empagliflozin/metformin (Synjardy)	Tablets
Glipizide/metformin	Tablets
Glyburide/metformin (Glucovance)	Tablets
Linagliptin/metformin (Jentadueto)	Tablets, extended-release tablets
Pioglitazone/glimepiride (Duetact)	Tablets
Pioglitazone/metformin (Actoplus Met)	Tablets, extended-release tablets
Repaglinide/metformin (Prandimet)	Tablets
Rosiglitazone/glimepiride	Tablets
Rosiglitazone/metformin	Tablets
Saxagliptin/metformin (Kombiglyze XR)	Extended-release tablets
Sitagliptin/metformin (Janumet)	Tablets

XR = extended release.

TABLE 3-29. Thyroid Agents

Medications	Available Dosage Forms
Agents to treat hypothyroidism	
Levothyroxine (Synthroid, Levothroid, Levoxyl, Tirosint, Unithroid)	Tablets, injection, capsules
Liothyronine (Cytomel)	Tablets, injection
Liotrix (Thyrolar)	Tablets
Thyroid USP (Armour Thyroid, Nature-throid)	Tablets
Agents to treat hyperthyroidism	
Iodides (SSKI, Lugol's solution)	Solutions
Methimazole (Tapazole)	Tablets
Propylthiouracil (PTU)	Tablets

Drugs That Affect the Gastrointestinal System

TABLE 3-30. Histamine-2 (H_2) Antagonists

Medications	Available Dosage Forms
Cimetidine (Tagamet HB)	Solution, tablets
Famotidine (Pepcid)	Chewable tablets, injection, suspension, tablets
Nizatidine	Capsules, solution, tablets
Ranitidine (Zantac)	Injection, capsules, syrup, tablets

TABLE 3-31. Proton Pump Inhibitors (suffix–*prazole*)

Medications	Available Dosage Forms
Dexlansoprazole (Dexilant)	Capsules
Esomeprazole (Nexium)	Delayed-release capsules, granules for suspension, injection
Lansoprazole (Prevacid)	Delayed-release capsules, delayed-release tablets, orally disintegrating tablets, suspension
Omeprazole (Prilosec)	Delayed-release capsules, granules for suspension, delayed-release tablets
Pantoprazole (Protonix)	Granules for suspension, delayed-release tablets, injection
Rabeprazole (Aciphex)	Delayed-release tablets

TABLE 3-32. Antiemetic Agents

Medications	Available Dosage Forms
Aprepitant (Emend)	Capsules, suspension
Dimenhydrinate (Dramamine)	Injection, tablets, chewable tablets
Fosaprepitant (Emend)	Injection
Meclizine (Antivert, Bonine)	Tablet, chewable tablets
Metoclopramide (Reglan)	Injection, solution, tablets
Prochlorperazine (Compro)	Injection, suppository, tablets
Promethazine (Phenergan)	Injection, suppository, syrup, tablets
Scopolamine (Trans-Derm Scop)	Patch
Trimethobenzamide (Tigan)	Capsules, injection
5-HT$_3$ antagonists	
Dolasetron (Anzemet)	Tablets, injection
Granisetron (Sancuso)	Injection, solution, tablets, patch
Ondansetron (Zofran, Zuplenz)	Injection, solution, tablets, orally disintegrating tablets, film
Palonosetron (Aloxi)	Injection

TABLE 3-33. Agents to Treat Inflammatory Bowel Disease

Classifications and Medications	Available Dosage Forms
Aminosalicylates	
Balsalazide (Colazal, Giazo)	Capsules, tablets
Mesalamine (Apriso, Asacol HD, Canasa, Lialda, Pentasa, Rowasa)	Capsules, suppository, enema, delayed-release tablets
Sulfasalazine (Azulfidine)	Tablets, delayed-release tablets
Immunosuppressive agents	
Azathioprine (Azasan, Imuran)	Injection, tablets
Mercaptopurine (Purinethol, Purixan)	Tablets, oral suspension
Monoclonal antibodies (suffix–mab)	
Adalimumab (Humira)	Injection
Certolizumab (Cimzia)	Injection
Golimumab (Simponi)	Injection
Infliximab (Remicade)	Injection
Natalizumab (Tysabri)	Injection
Ustekinumab (Stelara)	Injection
Vedolizumab (Entyvio)	Injection

TABLE 3-34. Laxatives

Classifications and Medications	Available Dosage Forms
Bulk-forming laxatives	
Methylcellulose (Citrucel)	Caplets, powder
Polycarbophil (FiberCon, Equalactin)	Caplets, tablets, chewable tablets
Psyllium (Metamucil, Konsyl)	Capsules, powder, wafers
Bowel evacuants	
Polyethylene Glycol–PEG (Miralax)	Powder
Stool softeners	
Docusate Calcium (Surfak)	Capsules, liquid
Docusate Sodium (Colace, Correctol)	Capsules, liquid, enema, syrup
Lubricant laxatives	
Magnesium citrate (Citroma)	Solution
Magnesium hydroxide (Phillips Milk of Magnesia)	Suspension, chewable tablets
Mineral Oil (Fleet Mineral Oil Enema, Kondremul)	Liquid, oil (rectal)
Saline laxatives	
Hyperosmotic laxatives	
Glycerin	Suppository
Lactulose (Generlac)	Solution
Stimulant laxatives	
Bisacodyl (Dulcolax)	Enema, suppository, tablets
Senna (Senokot, Ex-Lax)	Liquid, drops, orally disintegrating strips, syrup, tablets, chewable tablets
Combination laxatives	
Senna/docusate sodium (Senokot-S, Peri-Colace)	Tablets

Drugs That Affect the Urinary System

TABLE 3-35. Agents Used to Treat Overactive Bladder Disorder

Medications	Available Dosage Forms
Darifenacin (Enablex)	Extended-release tablets
Fesoterodine (Toviaz)	Extended-release tablets
Oxybutynin (Ditropan, Ditropan XL)	Tablets, syrup, patch, gel, extended-release tablets
Solifenacin (VESIcare)	Tablets
Tolterodine (Detrol, Detrol LA)	Tablets, extended-release tablets
Trospium (Sanctura, Sanctura XR)	Tablets, extended-release capsules

LA = long-acting, XR = extended release.

Drugs That Affect the Other Body Systems

TABLE 3-36. Ophthalmic Agents

Classifications and Medications	Dosage Forms Available
Antibiotic agents	
Azithromycin (AzaSite)	Solution
Besifloxacin (Besivance)	Solution
Ciprofloxacin (Ciloxan)	Solution, ointment
Erythromycin	Ointment
Gatifloxacin (Zymaxid)	Solution
Gentamicin (Gentak)	Solution, ointment
Levofloxacin	Solution
Moxifloxacin (Vigamox)	Solution
Ofloxacin (Ocuflox)	Solution
Sulfacetamide (Bleph-10)	Solution, ointment
Tobramycin (Tobrex)	Solution, ointment
Antibiotic/steroid combinations	
Neomycin/polymyxin/ hydrocortisone	Solution
Neomycin/polymyxin/ dexamethasone (Maxitrol)	Solution, ointment
Tobramycin/dexamethasone (Tobradex)	Solution, ointment
Antiviral agents	
Ganciclovir (Zirgan)	Gel
Trifluridine (Viroptic)	Solution
Antiallergy agents	
Azelastine	Solution
Cromolyn (Crolom)	Solution
Emedastine (Emadine)	Solution
Epinastine (Elestat)	Solution
Ketotifen (Zaditor)	Solution
Naphazoline (Clear Eyes)	Solution
Olopatadine (Patanol, Pataday)	Solution
Dry eye agents	
Cyclosporine (Restasis)	Emulsion
Vasoconstrictors	
Phenylephrine (Altafrin)	Solution
Tetrahydrozoline (Visine)	Solution
Beta blockers	
Betaxolol (Betoptic-S)	Solution, suspension
Levobunolol (Betagan)	Solution
Timolol (Timoptic, Timoptic-XE)	Solution, gel
Sympathomimetics	
Apraclonidine (Iopidine)	Solution
Brimonidine (Alphagan P)	Solution
Brimonidine/Timolol (Combigan)	Solution
Carbonic anhydrase inhibitors	
Brinzolamide (Azopt)	Solution
Brinzolamide/Brimonidine (Simbrinza)	Solution
Dorzolamide (Trusopt)	Solution
Dorzolamide/Timolol (Cosopt)	Solution
Prostaglandin analogs (suffix–prost)	
Bimatoprost (Lumigan)	Solution
Latanoprost (Xalatan)	Solution
Tafluprost (Zioptan)	Solution
Travoprost (Travatan)	Solution
Miotics	
Pilocarpine (Isopto Carpine)	Solution

TABLE 3-37. Topical Corticosteroids

Corticosteroid Potency Medications	Available Dosage Forms
Low potency	
Desonide (DesOwen)	Cream, ointment, gel, foam, lotion
Hydrocortisone (Cortaid, Cortizone-10)	Cream, ointment, gel, spray, solution, lotion
Medium potency	
Mometasone (Elocon)	Cream, ointment, lotion, solution
High potency	
Desoximetasone (Topicort)	Cream, ointment, gel, solution
Fluocinonide (Vanos)	Cream, ointment, gel, solution
Triamcinolone (Kenalog)	Cream, ointment, lotion, solution
Very high potency	
Clobetasol (Clobex, Clodan, Olux, Temovate)	Cream, ointment, gel, foam, lotion, solution

TABLE 3-38. Biologic Agents to Treat Psoriasis and Psoriatic Arthritis

Classifications and Medications	Available Dosage Forms
Agents to treat psoriasis	
Adalimumab (Humira)	Injection
Brodalumab (Siliq)	Injection
Certolizumab (Cimzia)	Injection
Etanercept (Enbrel)	Injection
Golimumab (Simponi)	Injection
Guselkumab (Tremfya)	Injection
Infliximab (Remicade)	Injection
Ixekizumab (Taltz)	Injection
Secukinumab (Cosentyx)	Injection
Ustekinumab (Stelara)	Injection

WOMEN'S AND MEN'S HEALTH

TABLE 3-39. Contraceptives

Classifications and Medications	Available Dosage Forms
Estrogen and progesterone products	
Azurette, Mircette, Reclipsen, Seasonique, Trivora	Tablets
Xulane	Transdermal patch
NuvaRing	Vaginal ring
Progesterone-only products	
Levonorgestrel (Next Choice, Plan B, React)	Tablets
Medroxyprogesterone acetate (Depo-Provera)	Injection

TABLE 3-40. Fertility Agents

Medications	Available Dosage Forms
Clomiphene	Tablets
Cetrorelix (Cetrotide)	Injection
Chorionic gonadotropin (Pregnyl, Novarel)	Injections
Follitropin alfa (Gonal-F), Follitropin beta (Follistim AQ)	Injections
Ganirelix	Injection
Hydroxyprogesterone caproate (Makena)	Injection
Menotropin (Menopur)	Injection
Micronized progesterone (Prometrium)	Capsules
Progesterone vaginal (Crinone, Endometrin)	Vaginal gel
Urofollitropin (Bravelle)	Injection

Drugs Related to Men's Health

TABLE 3-41. Agents Used to Treat Benign Prostatic Hypertrophy (BPH)

Classifications and Medications	Available Dosage Forms
Alpha$_1$ adrenergic inhibitors	
Alfuzosin (Uroxatral)	Extended-release tablets
Doxazosin (Cardura, Cardura XL)	Tablets, extended-release tablets
Prazosin (Minipress)	Capsules
Silodosin (Rapaflo)	Capsules
Tamsulosin (Flomax)	Capsules
Terazosin	Capsules
Androgen hormone inhibitors	
Dutasteride (Avodart)	Capsules
Dutasteride/tamsulosin (Jalyn)	Capsules
Finasteride (Proscar)	Tablets

XL = extended release.

TABLE 3-42. Drugs for Erectile Dysfunction (suffix–*afil*)

Medications	Available Dosage Forms
Alprostadil (Caverject, Edex, Muse)	Injection, urethral suppository
Sildenafil (Viagra)	Tablets
Tadalafil (Cialis)	Tablets
Vardenafil (Levitra)	Tablets

ANTI-INFECTIVES

TABLE 3-43. Cephalosporins (prefix–*Cef* or *Ceph*)

Classifications and Medications	Available Dosage Forms
First-generation agents	
Cefadroxil	Capsules, suspension, tablets
Cefazolin (Ancef, Kefzol)	Injection
Cephalexin (Keflex)	Capsules, tablets, suspension
Second-generation agents	
Cefaclor	Capsules, suspension, chewable tablets, extended-release tablets

TABLE 3-43. (continued)

Classifications and Medications	Available Dosage Forms
Cefotetan	Injection
Cefoxitin (Mefoxin)	Injection
Cefprozil	Suspension, tablets
Cefuroxime (Ceftin, Zinacef)	Tablets, injection, suspension
Third-generation agents	
Cefdinir (Omnicef)	Capsules, suspension
Cefixime (Suprax)	Suspension, tablets
Cefotaxime (Claforan)	Injection
Cefpodoxime	Suspension, tablets
Ceftazidime (Fortaz)	Injection
Ceftibuten (Cedax)	Capsules, suspension
Ceftriaxone (Rocephin)	Injection
Fourth-generation agent	
Cefepime (Maxipime)	Injection
Fifth-generation agent	
Ceftaroline (Teflaro)	Injection

TABLE 3-44. Fluoroquinolones (suffix–*floxacin*)

Medications	Available Dosage Forms
Ciprofloxacin (Cipro)	Injection, suspension, tablets, extended-release tablets
Gemifloxacin (Factive)	Tablets
Levofloxacin (Levaquin)	Injection, solution, tablets
Ofloxacin (Floxin)	Tablets
Moxifloxacin (Avelox)	Injection, tablets

TABLE 3-45. Macrolides (suffix–*mycin*)

Generic Name	Brand Name	Route of Administration
Azithromycin	Zithromax	Oral, IV
Clarithromycin	Biaxin	Oral
Dirithromycin	Dynabac	Oral
Erythromycin	Various	Oral, IV, topical

IV = intravenous

TABLE 3–46. Penicillins (suffix–*cillin*)

Generic Name	Brand Name	Route of Administration
Penicillin G	Bicillin, Bicillin LA	IM, IV
Penicillin VK	Various	Oral
Penicillinase-resistant		
Cloxacillin	Dynapen, Pathocil	Oral, injection
Nafcillin	Unipen	Oral, IV
Broad-spectrum		
Amoxicillin	Various	Oral
Amoxicillin/clavulanate	Augmentin	Oral
Ampicillin	Principen, Unasyn	Oral, injection

IM = intramuscular, IV = intravenous, LA = long-acting.

Antiviral Agents

TABLE 3-47. HIV Agents

Classifications and Medications	Abbreviation	Dosage Forms
Nucleoside reverse transcriptase inhibitors (NRTIs)		
Abacavir (Ziagen)	ABC	Tablets, oral solution
Didanosine (Videx)	ddI	Capsules, powder for solution
Emtricitabine (Emtriva)	FTC	Capsules, oral solution
Lamivudine (Epivir)	3TC	Tablets, oral solution
Stavudine (Zerit)	d4T	Capsules, powder for solution
Tenofovir (Viread)	TFV	Tablets
Zidovudine (Retrovir)	AZT, ZDV	Tablets, capsules, syrup, IV solution
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)		
Delavirdine (Rescriptor)	DLV	Tablets
Efavirenz (Sustiva)	EFV	Capsules, tablets
Etravirine (Intelence)	ETV	Tablets
Nevirapine (Viramune)	NVP	Tablets, oral suspension, extended-release tablets
Rilpivirine (Edurant)	RPV	Tablets
Protease inhibitors (PIs)		
Atazanavir (Reyataz)	ATV	Capsules
Darunavir (Prezista)	DRV	Tablets

TABLE 3-47. (continued)

Classifications and Medications	Abbreviation	Dosage Forms
Fosamprenavir (Lexiva)	FPV	Tablets, oral suspension
Indinavir (Crixivan)	IDV	Capsules
Nelfinavir (Viracept)	NFV	Tablets
Ritonavir (Norvir)	RTV	Capsules, oral solution, tablets
Saquinavir (Invirase)	SQV	Capsules, tablets
Tipranavir (Aptivus)	TPV	Capsules, oral solution
Integrase inhibitors		
Dolutegravir (Tivicay)	DTG	Tablets
Elvitegravir (Vitekta)	EVG	Tablets
Raltegravir (Isentress)	RAL	Tablets, chewable tablets, powder

Antifungal Agents

TABLE 3-48. Antifungals

Classifications and Medications	Available Dosage Forms
Amphotericin B	
Conventional (Amphotericin B)	Injection
Liposomal (AmBisome)	Injection
Lipid complex (Abelcet)	Injection
Azole antifungals	
Fluconazole (Diflucan)	Tablets, powder for oral suspension, injection
Itraconazole (Sporanox)	Capsules, oral solution
Ketoconazole	Tablets
Posaconazole (Noxafil)	Oral suspension, tablets, injection
Voriconazole (Vfend)	Tablets, powder for oral suspension, injection
Echinocandins	
Anidulafungin (Eraxis)	Injection
Caspofungin (Cancidas)	Injection
Micafungin (Mycamine)	Injection

Vaccines

TABLE 3-49. Vaccines

Vaccines	Available Dosage Form	Disease Prevented
Inactivated vaccines		
Hepatitis A (Havrix, Vaqta)	IM injection	Hepatitis A
Hepatitis B (Recombivax HB, Engerix-B)	IM injection	Hepatitis B
Herpes Zoster (Shingrix)	IM injection	Shingles
Human Papillomavirus (Gardasil-9)	IM injection	Cervical cancer, genital warts
Influenza (Fluzone, Fluvirin, Afluria, FluLaval)	IM injection	Influenza
Meningococcal (Bexsero, Menactra, Menveo)	IM injection	Meningitis
Pneumococcal (Pneumovax-23, Prevnar-13)	IM or sub-Q injection	Pneumonia
Poliomyelitis (IPOL)	IM injection	Polio
Tetanus/diphtheria (Tenivac)	IM injection	Tetanus and diphtheria (Td)
Tetanus/diphtheria/pertussis (Daptacel, Infanrix—children)	IM injection	Tetanus, diphtheria, pertussis (DTAP)
Tetanus/diphtheria/pertussis (Adacel, Boostrix—adult, adolescent)	IM injection	Tetanus, diphtheria, pertussis (Tdap)
Live/attenuated vaccines		
Herpes Zoster (Zostavax)	Sub-Q injection	Shingles
Measles, mumps, rubella (MMR II)	Sub-Q injection	Measles, mumps, rubella
Rotavirus (Rotarix, RotaTeq)	Oral suspension	Rotavirus gastroenteritis
Varicella (Varivax)	Sub-Q injection	Chicken pox

IM = intramuscular, sub-Q = subcutaneous.

HEMATOLOGIC AND ONCOLOGIC AGENTS

TABLE 3-50. Anticoagulants and Thrombolytics

Classifications and Medications	Available Dosage Forms
Heparin	
Unfractionated heparin	Injection
Low-molecular-weight heparins	
Dalteparin (Fragmin)	Injection
Enoxaparin (Lovenox)	Injection
Factor Xa inhibitors	
Apixaban (Eliquis)	Tablets
Betrixaban (Bevyxxa)	Tablets
Edoxaban (Savaysa)	Tablets
Fondaparinux (Arixtra)	Injection
Rivaroxaban (Xarelto)	Tablets
Direct thrombin inhibitors	
Argatroban	Injection
Bivalirudin (Angiomax)	Injection
Dabigatran (Pradaxa)	Capsules
Desirudin (Iprivask)	Injection
Vitamin K_1 inhibitors	
Warfarin sodium (Coumadin, Jantoven)	Tablets
Thrombolytics	
Alteplase (Activase, Cathflo)	Injection
Tenecteplase (TNKase)	Injection

Chemotherapeutic Agents

TABLE 3-51. Chemotherapy Agents

Classifications and Medications	Available Dosage Forms
Alkylating agents	
Busulfan (Busulfex, Myleran)	Tablets, injection
Carmustine (BiCNU)	Injection
Chlorambucil (Leukeran)	Tablets
Cyclophosphamide (Cytoxan)	Capsules, injection
Dacarbazine (DTIC-Dome)	Injection
Estramustine (Emcyt)	Capsules
Lomustine (Gleastine)	Capsules
Mechlorethamine (Mustargen, Valchlor)	Injection, gel
Melphalan (Alkeran)	Tablets, injection
Procarbazine (Matulane)	Capsules
Antibiotics	
Bleomycin	Injection
Dactinomycin (Cosmegen)	Injection
Daunorubicin	Injection
Doxorubicin (Adriamycin)	Injection
Idarubicin (Idamycin)	Injection
Mitomycin (Mutamycin)	Injection
Mitoxantrone (Novantrone)	Injection
Antimetabolites	
Capecitabine (Xeloda)	Tablets
Cytarabine (Cytosar, Depocyt)	Injection, liposomal injection
Floxuridine	Injection
Fluorouracil (Adrucil)	Injection
Gemcitabine (Gemzar)	Injection
Mercaptopurine (Purixan)	Tablets, suspension
Methotrexate (MTX, Trexall)	Tablets, injection
Pemetrexed (Alimta)	Injection
Thioguanine (Tabloid)	Tablets
Aromatase inhibitors	
Anastrozole (Arimidex)	Tablets
Exemestane (Aromasin)	Tablets
Letrozole (Femara)	Tablets

TABLE 3-51. (continued)

Classifications and Medications	Available Dosage Forms
Biologic response modifiers	
Aldesleukin (Proleukin)	Injection
Cytoprotective agents	
Amifostine (Ethyol)	Injection
Leucovorin	Injection, tablets
Mesna (Mesnex)	Injection, tablets
Heavy metal compounds (platinums)	
Carboplatin	Injection
Cisplatin	Injection
Oxaliplatin	Injection
Hormones	
Leuprolide (Lupron, Lupron Depot, Eligard)	Injection, long-acting depot
Medroxyprogesterone (Provera)	Tablets, injection
Megestrol Acetate (Megace)	Tablets, oral suspension, capsules
Mitotic inhibitors	
Cabazitaxel (Jevtana)	Injection
Docetaxel (Taxotere)	Injection
Paclitaxel (Abraxane)	Injection
Vinblastine	Injection
Vincristine (Vincasar)	Injection
Vinorelbine (Navelbine)	Injection
Monoclonal antibodies	
Alemtuzumab (Campath, Lemtrada)	Injection
Bevacizumab (Avastin)	Injection
Cetuximab (Erbitux)	Injection
Ibritumomab (Zevalin)	Injection
Necitumumab (Portrazza)	Injection
Nivolumab (Opdivo)	Injection
Ramucirumab (Cyramza)	Injection
Rituximab (Rituxan)	Injection

continued

TABLE 3-51. (continued)

Classifications and Medications	Available Dosage Forms
Trastuzumab (Herceptin)	Injection
Proteasome inhibitor	
Bortezomib (Velcade)	Injection
Retinoids	
Bexarotene (Targretin)	Capsules
Selective estrogen receptor modulators (SERMs)	
Tamoxifen (Soltamox)	Tablets, oral solution
Toremifene (Fareston)	Tablets
Podophyllotoxin derivatives	
Etoposide (Toposar)	Injection, capsules
Teniposide	Injection
Kinase inhibitors	
Dabrafenib (Tafinlar)	Capsules
Dasatinib (Sprycel)	Tablets
Erlotinib (Tarceva)	Tablets
Gefitinib (Iressa)	Tablets
Idelalisib (Zydelig)	Tablets
Imatinib (Gleevec)	Tablets
Lapatinib (Tykerb)	Tablets
Nilotinib (Tasigna)	Capsules
Ruxolitinib (Jakafi)	Tablets
Sorafenib (Nexavar)	Tablets
Sunitinib (Sutent)	Capsules
Trametinib (Mekinist)	Tablets
Topoisomerase inhibitors	
Topotecan (Hycamtin)	Injection, capsules
Irinotectan (Camptosar)	Injection
Miscellaneous agents	
Asparaginase (Elspar)	Injection
Pegaspargase (Oncaspar)	Injection

NUTRITIONAL AND DIETARY SUPPLEMENTS

TABLE 3–52. Vitamins

Common Name	Chemical Name	Type (Fat-Soluble versus Water-Soluble)
Vitamin A	Retinol	Fat-soluble
Vitamin B_1	Thiamine	Water-soluble
Vitamin B_2	Riboflavin	Water-soluble
Vitamin B_3	Niacin, Nicotinic Acid	Water-soluble
Vitamin B_5	Pantothenic Acid	Water-soluble
Vitamin B_6	Pyridoxine	Water-soluble
Vitamin B_{12}	Cyanocobalamine	Water-soluble
Vitamin C	Ascorbic Acid	Water-soluble
Vitamin D	Ergocalciferol	Fat-soluble
Vitamin E	Tocopherol	Fat-soluble
Vitamin K	Phytonadione	Fat-soluble

Minerals

TABLE 3–53. Minerals and Their Functions in the Body

Mineral	Amount Present	Function in Body
Calcium	Major element	Important in bone and tooth formation and in nerve function
Chloride	Major element	Used in the production of hydrochloric acid; closely connected with sodium in body tissues, fluids, and excretions
Iodine	Trace element	Linked with thyroid function
Iron	Trace element	Important part of the hemoglobin molecule and required in many enzymes
Magnesium	Major element	Second most abundant mineral found in the body; important in body enzymes and in nerve and muscle function
Phosphorous	Major element	Important in metabolism and acid-base regulation
Potassium	Major element	Primary mineral found inside cells; important in cellular metabolism and in nerve and muscle function
Sodium	Major element	Important in growth and in muscle function
Sulfur	Major element	Important for many proteins and heparin

TABLE 3-54. Therapeutic Classes with Common Prefixes and Suffixes

Therapeutic Class	Common Prefix or Suffix
5-HT agonists (Triptans)	-triptan
5α-reductase inhibitors	-steride
ACE Inhibitors	-pril
Alpha$_1$-adrenergic antagonists (α-blockers)	-zosin -osin
Aminosalicylates	-salazine
Anthracyclines	-rubicin
Antifungal agents	-azole
Antivirals that inhibit uncoating	-mantidine
Antivirals used treatment of herpes	-cyclovir -ciclovir
ARB (antgiotensin II receptor antagonists)	-sartan
Aromatase inhibitors	-trozole
Barbiturates	-barbital
Benzodiazepines	-epam -olam
Beta-blockers (β-adrenergic antagonists)	-olol
Calcium channel blockers (dihydropyridines)	-dipine
Carbonic anhydrase inhibitors	-zolamide
Cephalosporins	Ceph- Cef-
Corticosteroids	-sone -one
Dipeptidyl peptidase-4 inhibitors	-gliptin
Echinocandin antifungals	-fungin
Fluroquinolones	-floxacin
H2 receptor antagonists (H$_2$-blockers)	-tidine
HMG CoA inhibitors	-statin
Leukotriene modifiers	-lukast
Local anesthetics	-caine
Loop diuretics	-semide
Macrolides	-thromycin
Macrolides for immunosuppression	-limus
Meglitinides	-glinide
Monoclonal antibody drugs and TNF-α inhibitors immunomodulators	-mab
Nitrates	Nitro; or nitra in brand or generic name
Non-depolarizing neuromuscular blockers	-curonium -curium
PDE5 inhibitors (phosphodiesterase inhibitors)	-afil
Penicillins	-cillin

TABLE 3-54. (continued)

Therapeutic Class	Common Prefix or Suffix
Platinum compounds	-platin
Prostaglandin analogues	-prost
Protease inhibitors	-navir
Proton pump inhibitors	-prazole
Sulfonamides	-sulf
Taxanes	-taxel
Tetracycline	-cycline
Thiazide diuretics	-thiazide
Thiazolidinediones	-glitazone
Thrombolytic drugs	-plase -kinase
Topoisomerase inhibitors	-tecan -poside
Vinca alkaloids	-vin

Herbals and Other Dietary Supplements

Complementary and alternative medicine (CAM) supplements have become popular alternatives to medications. Many patients believe these products must be safe because they are derived from natural sources. The National Centers for Health Statistics have shown that approximately 33.2% of the population is using some type of alternative medicine.[1] The leading herbal remedy categories are immune system modulators (Echinacea), energy/vitality (ginseng, caffeine), weight loss supplements (caffeine, ginseng, bitter orange), women's health (calcium, soy), depression (St. John's wort), and bone/joint (glucosamine/chondroitin).

Reference

1. Clarke TC, Black LI, Stussman BJ, et al. Trends in the use of complementary health approaches among adults: United States, 2002-2012. Available at www.cdc.gov/nchs/data/nhsr/nhsr079.pdf. Accessed March 6, 2018.

SELF-ASSESSMENT QUESTIONS

1. Which medication can be used both as an antiepileptic medication and for the treatment of neuropathic pain?
   a. Phenytoin (Dilantin)
   b. Clobazam (Onfi)
   c. Lacosamide (Vimpat)
   d. Gabapentin (Neurontin)

2. Which of the following drugs is used in the treatment of Parkinson disease?
   a. Amoxicillin
   b. Diazepam
   c. Levodopa/carbidopa
   d. Enalapril

3. The medication fluoxetine (Prozac) can be used to treat:
   a. Anxiety
   b. Depression
   c. Obsessive compulsive disorder
   d. All of the above

4. Which of the following is classified as an HMGCoA reductase inhibitor?
   a. Atorvastatin (Lipitor)
   b. Fenofibrate (Tricor)
   c. Ezetimibe (Zetia)
   d. Gemfibrozil (Lopid)

5. Which of the following medications is considered a preventive medication for migraines?
   a. Frovatriptan (Frova)
   b. Sumatriptan (Imitrex)
   c. Butalbital, acetaminophen, caffeine (Fioricet)
   d. Propranolol (Inderal)

6. Which antihypertensive medication can cause a dry cough?
   a. Lisinopril (Prinivil, Zestril)
   b. Metoprolol succinate (Lopressor)
   c. Irbesartan (Avapro)
   d. Amlodipine (Norvasc)

7. Which long-acting insulin can be given once a day?
   a. Lispro (Humalog)
   b. Glargine (Basaglar)
   c. Regular (Novolin)
   d. NPH (Humulin N)

8. Which of the following medications is used to treat ADHD?
   a. Adderall XR
   b. Ativan
   c. Paxil CR
   d. Valium

9. A patient with osteoarthritis may use celecoxib (Celebrex). To which pharmacological class does celecoxib belong?
   a. COX-2 inhibitors
   b. Opioids
   c. SSRIs
   d. Amphetamines

10. Which of the following agents may be used to treat an asthma attack?
    a. Montelukast (Singulair)
    b. Mometasone (Asmanex)
    c. Fluticasone (Flovent)
    d. Albuterol (Ventolin/Proventil)

11. Which drug belongs to the class of calcium channel blockers?
    a. Lidocaine
    b. Calcium carbonate
    c. Nicardipine
    d. Loperidine
    e. Meperidine

12. Which of the following is *not* an opiate analgesic?
    a. Ibuprofen

b. Hydrocodone
c. Morphine
d. Codeine
e. Hydromorphone

13. Which of the following is *not* a trace element?
a. Iron
b. Potassium
c. Selenium
d. Chromium
e. Copper

14. The brand name for cefoxitin is
a. Ancef
b. Rocephin
c. Fortaz
d. Mefoxin
e. Cefizox

15. Which of the following is a diuretic?
a. Hydroxyzine
b. Hydrochlorothiazide
c. Hydroxyurea
d. Hydrocortisone
e. Hydrochloric acid

16. Which of the following is Vitamin B1?
a. Folic acid
b. Riboflavin
c. Thiamine
d. Ascorbic acid
e. Nicotinic acid

17. Which class of drugs used for hypertension ends in "pril"?
a. ACE inhibitors
b. β-blockers
c. Calcium channel blockers
d. Angiotensin II receptor blockers

18. Which class of drugs used to treat hypertension ends in "sartan"?
a. ACE inhibitors
b. β-blockers
c. Calcium channel blockers
d. Angiotensin II receptor blockers

19. Viagra is to sildenafil as Levitra is to
a. Tadelafil
b. Donepezil
c. Fluoroluricil
d. Vardenafil

20. Lantus and Levemir have
a. A duration of 16–20 hours
b. A duration of 6–10 hours
c. Onset of action in less than 60 minutes
d. Are short-acting insulins

21. Triazolam is used for
a. Treatment of anxiety
b. Sedation before surgical procedures
c. Short term for sleep disorders
d. For sleep maintenance

22. Vicodin is a brand name for
a. Oxycodone
b. Hydrocodone
c. Hydrocodone/acetaminophen
d. Hydrocodone/aspirin

23. Which drug listed below is used to treat ADHD?
a. Tiazac
b. Arixta
c. Celebrex
d. Byetta
e. Concerta

24. Which drug listed below is *not* a penicillin?
a. Amoxicillin
b. Augmentin
c. Biaxin
d. Unasyn

25. The drugs known as "triptans" are used to treat
    a. Migraines
    b. Glaucoma
    c. Parkinson disease
    d. Seizures

26. Amantadine is an antiviral used to treat
    a. Influenza and glaucoma
    b. Influenza and Parkinson disease
    c. Influenza and ADHD
    d. Influenza and Alzheimer

27. Which drug listed below is NOT a benzodiazepine?
    a. Halcion
    b. Valium
    c. Xanax
    d. Lunesta

28. Guiafenesin is
    a. An antihistamine
    b. An antitussive
    c. An expectorant
    d. A decongestant

29. Which drug listed below is a short-acting bronchodilator?
    a. Albuterol
    b. Tiotropium
    c. Salmeterol
    d. Beclamethasone

30. Which drug listed below is NOT an SSRI?
    a. Prozac
    b. Lexapro
    c. Celexa
    d. Effexor

SELF-ASSESSMENT ANSWERS

1. d.
2. c.
3. d.
4. a.
5. d.
6. a.
7. b.
8. a.
9. a.
10. d.
11. c.
12. a.
13. b.
14. d.
15. b.
16. c.
17. a.
18. d.
19. d.
20. a.
21. c.
22. c.
23. e.
24. c.
25. a.
26. b.
27. d.
28. c.
29. a.
30. d.

CHAPTER 4

STERILE AND NONSTERILE COMPOUNDING



Learning Outcomes

After completing this chapter, you will be able to

- Define and explain key elements of USP Chapter <797>, USP Chapter <800>, and USP Chapter <795>.
- Explain how proper aseptic technique improves patient safety.
- Outline the equipment and devices needed for compounding sterile products.
- Describe how sterile compounding is impacted by infection control processes, including use of proper gowning and personal protective equipment.
- Describe the difference between stability and sterility and how they both affect beyond-use dating.
- Differentiate between the handling requirements for nonhazardous and hazardous medications.
- Document the sterile compounding process appropriately.
- Define compounding.
- Describe the steps involved in the nonsterile compounding process.
- Describe the equipment commonly used when compounding nonsterile preparations.
- Identify the types of nonsterile preparations commonly compounded.
- Explain the concept of and reasons for repackaging medications.
- Explain the importance of record keeping for compounding and repackaging.

PARENTERAL MEDICATIONS

There are many different routes of administration for medications. The two main categories of medication administration are enteral and parenteral. Medications absorbed through the gastrointestinal (GI) tract are referred to as **enteral medications**, while those that bypass this route are **parenteral medications**.

TYPES OF IV ADMINISTRATION

Intravenous (IV) medications can vary greatly in their volumes, concentrations, and rates of administration and can be injected directly into the bloodstream using a needle, or more frequently, catheter. Sometimes, small volumes of IV medications can be given quickly with minimal preparation. These are known as *IV push medications*, and are often prepared right before administration. Other times, one or more drugs are added to a base IV solution, or diluent, to prepare a final sterile product. The preparation of a physician-ordered medication under pharmacist supervision, which is not available in a commercial formulation, is called **pharmacy compounding**. The active drug is referred to as the *additive*, and the final product is referred to as the *admixture*.

There are two main categories of medication admixtures: intermittent and continuous. *Intermittent medications*, or *IV piggy backs*, are given over a defined

time period at set intervals. *Continuous medications*, or *drips*, are usually prepared in larger volumes of 250 mL to 1 L, and given at variable rates over long periods of time. Because continuous medications are compounded at a standard concentration, the infusion rate can be titrated to achieve the desired clinical results.

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 inherent risks.

Infection

Infections can result if a product contaminated with microorganisms is infused into a patient.

Pyrogens

Pyrogens are by-products or remnants of bacteria that can cause reactions (e.g., fever, 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 in quantities that would harm the patient.

Incompatibilities

Some drugs are incompatible with other drugs, containers, or solutions. If an incompatibility exists, the drug may precipitate (form a solid), be inactivated, or adhere to the container.

Particulate Matter

Particulate matter refers to unwanted particles present in parenteral products. Similar to precipitates, particulate matter that is injected into the bloodstream can cause adverse effects to the patient.

Air Embolus

The incidence of an air embolus is low because many solutions are administered using infusion pumps equipped with an alarm that sounds when air is in the IV line.

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.

Extravasation

Extravasation occurs when the IV catheter punctures and exits the vein under the skin, causing drugs to infuse or infiltrate into the tissues and not the blood. 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.

Phlebitis

Phlebitis, or irritation of the vein, may be caused by the IV catheter, the drug itself due to its chemical properties or its concentration, the location of the IV site, the rate of administration, or the presence of particulate matter.

ASEPTIC TECHNIQUE

Given all of these risks, special training is required for all personnel who prepare and administer sterile IV solutions. All pharmacy staff who participate in the compounding of parenteral medications must be proficient in the use of aseptic technique. **Aseptic technique** is a means of manipulating sterile products without compromising their sterility. This is a multifactorial process involving the correct use of products, environment, garbing, cleaning equipment, and physical manipulations. When used correctly, aseptic technique can help to stop patients from experiencing any of the preventable adverse effects associated with parenteral therapy.

REGULATIONS

In 2004, the United States Pharmacopeia (USP) officially released Chapter <797>, which outlined detailed standards for the proper preparation, storage, and transport of sterile medications. USP <797> was the first enforceable sterile compounding standard.[3] It was revised and re-released in 2008 to include additional information

on best practices for training, garbing, and the cleaning of compounding areas. A third update of Chapter <797> is anticipated to become official in December 2019. One of the primary purposes of USP Chapter <797> is the formation of microbial contamination risk levels. These risk levels affect what beyond-use dates (BUDs) can be assigned to compounded parenteral products. Enforcing pharmacy compliance with the USP chapters is the responsibility of the state boards of pharmacy as well as hospital regulatory agencies such as the Joint Commission and DNV (Det Norske Veritas). In 2012, the Centers for Medicare & Medicaid Services (CMS) also made <797> compliance a requirement of participation.

ENGINEERING CONTROLS

Compounded sterile preparations (CSPs) are pharmacy compounds free of living microorganisms, pyrogens, and visible particles.

Primary Engineering Control

The most important piece of equipment for the sterile compounding process is the **primary engineering control (PEC)**. Per USP Chapter <797>, sterile products should be prepared in an International Organization for Standardization (ISO) Class 5 environment.[4] This is defined as a space that contains no more than 100 particles per cubic foot that are 0.5 micron or larger in size. Laminar airflow workstations (LAFWs) are common types of PECs that can create an ISO Class 5 environment for nonhazardous, sterile compounding. Sometimes you may hear LAFWs referred to simply as *hoods*. LAFWs maintain ISO Class 5 conditions in two ways:

1. They create twice-filtered aseptic air using **high efficiency particulate air (HEPA) filters**. HEPA filters are composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil. When air is forced through the filters in a uniform fashion, 99.97% of all air particles 0.3 micrometers or larger are removed.[3]
2. They use this sterile air to continuously sweep the work surface of the hood in a unidirectional, or laminar, manner to prevent the entry of contaminated room air. *There are two common types of laminar flow workbenches*: horizontal flow and vertical flow.

Vertical LAFW

Laminar flow workbenches with a vertical flow of filtered air are also available. In vertical LAFWs, HEPA-filtered air emerges from the top of the hood and passes downward through the work area. Because exposure to hazardous drugs (HDs) may be harmful to the compounder, they should only be prepared in vertical LAFWs to minimize the risk of exposure to airborne drug particulates. If a horizontal LAFW were used to prepare HDs, airflow would push HD residue directly at the compounder. The types of vertical LAFW used for the preparation of HDs confine airflow within the hood and are referred to as **biological safety cabinets (BSCs)**. The following are general principles for operating LAFWs properly:

- An LAFW should be positioned away from excess traffic, doors, air vents, or anything that could produce air currents capable of introducing contaminants into the hood.
- LAFWs should not be turned off. If an LAFW power shutdown does occur, nonfiltered, nonsterile air will occupy the LAFW work area. When power is returned to the LAFW, it should be allowed to run for a minimum of 30 minutes before use. Manufacturer recommendations should be consulted for each given hood. A thorough cleaning as discussed later in this chapter is also recommended before sterile compounding activities resume.
- Nothing should be permitted to come in contact with the HEPA filter. This includes cleaning solution, aspirate or drug spray from syringes, or glass from ampules.
- 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 laminar flow workbench provides an aseptic environment, safe for the manipulation of sterile products, it is essential that strict aseptic technique be used in conjunction with proper hood operation. It is important to remember that the use of the LAFW alone, without the observance of aseptic technique, cannot ensure product sterility.

STERILE COMPOUNDING AREA

In addition to using PECs, segregated sterile compounding areas must be separate from normal pharmacy operations, nonessential equipment, and other materials that produce particles. These sterile compounding areas often utilize structural components and additional HEPA filtration known as **secondary engineering controls (SECs)**.

Regardless of the classification of the SEC, particulate-generating activities should be kept to a minimum. For example, the introduction of cardboard into the clean environment of any SEC should be avoided. Traffic should be minimized, and trash should be removed frequently and regularly. Trash cans should be taken outside of the IV room before pulling the trash or otherwise removing it from the container to prevent particulate creation.

Anteroom

Anterooms usually separate a true clean room space from the general pharmacy. USP Chapter <797> defines *anteroom* as a segregated compounding area with positive pressure, a minimum of 20 air changes per hour (ACPH), and an ISO 7 or 8 designation. Anterooms are usually reserved for non-aseptic activities such as order processing, gowning, and handling of stock. Anterooms contain a line of demarcation that designates where dirty activities may and may not occur. Anterooms also must contain a sink for hand hygiene. That sink should be on the clean side of the line of demarcation, but as far from compounding activities as possible.

Buffer Room

The buffer room is where the PEC is located and aseptic compounding takes place. The buffer room is commonly called the *clean room*.

Cleaning of the Compounding Area

Although continuous use of HEPA filters and positive pressure keeps the compounding area clean, diligent cleaning is also required to remove any contamination from compounding staff or stock. Because everything in the anteroom and buffer room is subject to cleanings and moveable, durable equipment is a must.

There are a few general rules for cleanings. *First,* always clean from the cleanest to dirtiest areas. *Second,* all cleaning activities should be recorded. *Third,* cleaning should be done with a germicidal detergent initially, followed by isopropyl alcohol (IPA).

USP Chapter <797> sets minimum standards for the frequency of environmental control cleaning. LAFWs are cleaned most often. LAFW cleaning frequency is at a minimum before each shift, before each mass production compounding session, and every 30 minutes during continuous compounding activities such as cart fill and batches. Other surfaces such as walls, ceilings, and storage shelving should be cleaned monthly at a minimum. In addition to regular cleaning, sites also must conduct environmental testing at least every 6 months for certification. Environmental testing includes doing particle counts, culturing high-use areas for microbial growth, and inspecting HEPA filters and pre-filters.

As the benefits of individualized drug therapy are recognized, **prescription compounding** continues to experience renewed popularity. Prescription compounding allows the prescriber and the pharmacist to meet the unique needs of an individual patient available. Compounding is often associated with specialty practice areas including veterinary medicine, dermatology, hormone replacement therapy, pain management, hospice, and home care.

Gowning for IV Compounding

Although primary and secondary engineering controls are essential parts of sterile compounding, the most common source of contamination to CSPs is the compounder. In addition to daily bathing and good personal hygiene, compounders should refrain from wearing make-up or jewelry, and having long or artificial fingernails. Many facilities provide scrubs for compounders, but regardless if scrubs are utilized, clothes worn underneath gowning must be freshly laundered. Another name for gowning materials is **personal protective equipment** or **PPE**. The order in which they are donned is important. Steps for proper gowning before undertaking sterile compounding:

1. Place shoe covers over footwear.

2. Cover all exposed hair with a hair net.
3. Place fitted face mask over mouth and nose. Men with facial hair should also don a beard cover.
4. Perform hand hygiene. Hands and forearms should be vigorously scrubbed for 30 seconds with an antimicrobial soap.
5. Don a non-shedding, arm-length, outer gown.
6. Don powder-free, sterile gloves in the buffer room. The cuffs of these gloves should be on the outside of the gown and pulled up the arm as far as possible.

COMPOUNDING TECHNIQUE

The critical principle of using LAFWs is that nothing should 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; contaminants from the foreign object may be carried onto the sterile work surface and thereby contaminate the injection port, needle, or syringe. This is referred to as *downstream contamination*. The following are additional best practices to minimize contamination of the direct compounding area:

- Work with objects at least 3 inches from the sides and 6 inches from the front edge of the hood without blocking air vents.
- Only place those objects essential to product preparation in the LAFW.
- Direct actions such as talking and coughing away from the LAFW working area. Any unnecessary motion within the hood should be avoided to minimize the turbulence of airflow.
- Avoid smoking, eating, and drinking in any area related to the aseptic environment, including the anteroom and buffer room/clean room.
- Stay at least 6 inches away from the lip of the hood during compounding to prevent the possibility of contamination.

COMPOUNDING 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 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. 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 incre-

ment 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 that comes in contact with the syringe barrel should be lined up with the calibration mark on the barrel corresponding to the volume desired.

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 laminar airflow hood (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. 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.

If the drug within a vial is in powdered form, it has to be *reconstituted* (an appropriate amount of diluent will be used to turn this powdered drug into liquid form). To reconstitute a vial:

- Inject the desired volume of diluent, such as sterile water for injection, into the vial containing the powdered drug.
- Be sure an equal volume of air is removed to prevent positive pressure from developing inside the vial. This is particularly important when preparing medications that can be harmful if aspirated (sprayed) into the air.
- Allow the air to flow into the syringe before removing the needle from the vial, or use a vented needle, which allows displaced air to escape the vial through a vent in the needle.

Vials with drugs in solution are classified as either multi- or multiple-dose vials (MDVs) or single-dose vials. *Multiple-dose vials* contain a small amount of a preservative agent that is added to retard the growth of bacteria or other organisms that may inadvertently contaminate a product.

When piercing vials with needles, avoid **coring** the rubber stopper with the needle. A *core* is carved out of the rubber stopper when the bevel tip and the bevel heel do not penetrate the stopper at the same point.

Ampules

Ampules are composed entirely of glass and, once broken (i.e., opened), become open-system containers. 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. The use of a filter needle (e.g., a needle with a 5-micron filter in the hub) keeps glass or particles that may have fallen into the solution from being drawn into the syringe. The filter needle must not be used for both withdrawing from the ampule and expelling from the syringe because doing so would nullify the filtering effect.

Beyond-Use Dating

Manufactured pharmaceuticals have expiration dates after which they are no longer supposed to be used. Instead of an expiration date, compounded pharmaceuticals have a **beyond-use date (BUD)**. The *BUD* is the date after which a CSP should no longer be stored or transported to a patient. As soon as a medication is compounded or a base solution is removed from its dust cover, the manufacturer-applied expiration date is no longer valid and a BUD must be applied. A compounded substance's BUD is derived from both its sterility and stability. *Stability* is derived from how the different components of the compound interact with each other.

Sterility information is extrapolated from standards set out in USP Chapter <797>, which separates CSPs into the categories of immediate use, low risk, medium risk, and high risk.[3] Depending on how many manipulations of the sterile compounds are required to make the final CSP, as well as the engineering controls in place, compounds are separated into these categories:

1. *Immediate-use compounds* are usually made outside the pharmacy without any safeguards and are only for life-threatening situations and medical emergencies.
2. *Low-risk compounds* are made in an ISO 5 environment with no more than three products. Low-

risk compounds have a BUD of 48 hours at room temperature, 14 days in a refrigerator, and 45 days in a freezer.

3. *Medium-risk compounds* are made with more than three products and have a BUD of 30 hours at room temperature, 9 days in a refrigerator, and 45 days when frozen.
4. *High-risk compounds* are made from non-sterile ingredients. They have BUDs of 24 hours at room temperature, 3 days in a refrigerator, and 45 days when frozen.

LABELING

Countless medication errors can be attributed to poor labeling of medications. An important benefit of a pharmacy IV admixture program is that it allows for consistent, complete labeling of products prepared. The labeling format must be clear and consistent. Once an IV admixture or other sterile product is compounded, it should be properly labeled with the following information:

- Patient name, identification number, and room number (if applicable)
- Bottle or bag sequence number, when appropriate
- Name and amount of drug(s) added
- Name and volume of admixture solution
- Approximate final total volume of the admixture, when applicable
- Prescribed flow rate (in mL per hour)
- Date and time of scheduled administration
- Date and time of preparation
- BUD
- Initials of person who prepared and person who checked the IV admixture
- Auxiliary labeling—supplemental instructions and precautions

Most labels have a bar code that contains information regarding the medication, the patient, and the anticipated administration. If an IV admixture is prepared and dispensed to a patient as a prescription order, the label must follow all regulations for prescription labeling.

Electronic Infusion Devices and "Smart Pumps"

Usually a specific rate of infusion is maintained for IV medications through the use of an IV pump. The nurse can program the IV pump rates, especially in the case of continuous infusions. However, these "smart" pumps have preset libraries of drugs with limits (alerts) to use for programming. Smart pumps also allow for updates to be sent to the pumps via the hospital network. Most importantly, smart pumps are designed to prevent unintentional overdoses of medication or fluid, referred to as *free-flow protection*.

TOTAL PARENTERAL NUTRITION SOLUTIONS

Total parenteral nutrition (TPN), also known as *hyperalimentation*, refers to the IV administration of nutrients needed to sustain life. TPN contains carbohydrates, protein, fats, water, electrolytes, vitamins, and trace elements, hence the designation "total."

TPN therapy is indicated for patients who cannot meet their nutritional needs from oral or other gastrointestinal (GI) means. TPN may be used for patients who can't eat, patients who will not eat, patients who should not eat, or patients who cannot eat or absorb enough to sustain their nutritional needs because their medical condition has increased their nutritional requirements.

Components of Parenteral Nutrition Solutions

TPN solutions contain base components and additives. Base components are usually mixed first and make up much of the volume of the TPN. They are composed of dextrose (carbohydrates) and amino acids (protein), and they may also include fats and water. Additives are usually mixed with the base component and include life-sustaining nutrients such as electrolytes, vitamins, and trace elements; they may also include drugs such as heparin, insulin, and H_2 antagonists.

Automated TPN Compounding

Automated compounding involves the use of specialized equipment to prepare the TPN solution. There

are two primary versions of TPN compounders available. One version provides a separate compounder for the base solutions and the electrolytes, while the other version uses one compounder to infuse all the compounded ingredients (bases and electrolytes). The computer software controls the system and offers many safeguards:

- It performs many of the calculations that would otherwise be done by hand and be prone to human error.
- It allows the user to enter maximum safe quantities for different components.
- It alerts the user to potential entry errors and inappropriate orders.

Alarms are available to detect free-flowing ingredients and air bubbles in the line. The final products are subsequently checked by comparing the anticipated weight of the product against the actual weight of the product.

The accuracy provided by the automated compounders is not a substitute for checks and balances in ensuring accuracy and quality of the product. Checks and balances must be built into each step of the TPN ordering, preparation, and administration process. Calculations should be verified and double checked, and solutions and their ingredients should be checked and double checked, regardless of the system used.

HAZARDOUS STERILE COMPOUNDING

Some medications can be hazardous, even in small amounts, to those who work with them. Contact with these drugs can cause immediate problems such as dermatitis, dizziness, nausea, and headache. Studies also suggest that repeated long-term exposure to small amounts of the drugs may cause organ or chromosome damage, impaired fertility, and even cancer. HDs are categorized into three categories developed by the National Institute for Occupational Safety and Health:

- *Category 1* includes antineoplastic drugs known to be hazardous with repeated exposure. Most chemotherapies are antineoplastic.
- *Category 2* is for is for non-antineoplastic drugs that are hazardous.
- *Category 3* includes medications with adverse effects on reproduction.

Each HD category requires special handling procedures to minimize the potential for accidental exposure. USP <800> explains these special procedures including safeguards for receiving, preparation, labeling, storage, and transport.

Biological Safety Cabinets

One of the most important pieces of equipment for handling HDs safely is the BSC. As discussed earlier, the *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. Although particle levels often meet ISO 7 limits and HEPA filters are still used, all hazardous compounding areas should be in negative pressure. Negative pressure clean rooms create an environment where hazardous particulate matter in the air is drawn out of the room and vented to the outside, thereby diverting and diluting any HD residue. The area in which the BSC resides must also be physically separated from other compounding areas to prevent contamination.

Another type of BSC used for compounding sterile hazardous medications are compounding aseptic isolators (CAIs). These are commonly called *glove boxes* and are closed environments accessed using flexible, attached, glove sleeves, or gauntlets. CAIs must be operated in a space with negative pressure and at least 12 ACPH. Air inside the CAI is maintained as an ISO 5 environment using HEPA filters and a pass-through chamber. The pass-through chamber is connected to the main chamber, but it is able to be sealed against the main chamber and the outside environment. Compounding materials must all go into the main compounding chamber through the pass-through. Special care must be taken to wipe down all materials with disinfectant before placing them in the pass-through. The pass-through is then sealed and pressurized to the same pressure as the compounding chamber.

Cleaning Requirements of USP Chapter <800>

Each facility will determine and record its own procedures and standards for cleaning the BSC and other areas that may be exposed to HDs. These procedures must comply with the USP Chapter <800> guidelines. There are three main components of such cleanings:

1. Areas must be cleaned with a deactivation agent that can help render any HD residue inert through oxidation.
2. Decontamination must take place whereby HD residue is removed.
3. Because sterile compounding is still taking place, the compounding area must be disinfected with a germicidal detergent followed by sterile IPA.

   Cleaning frequencies at minimum include:

   - Before each shift, during continuous compounding activities.
   - After deactivation and decontamination of spills and suspected contamination.
   - If power is ever lost or turned off to the BSC, once power is restored it is to be left continuously running for 30 minutes before cleaning.

Protective Apparel

There is no substitute for good technique, but PPE is a fundamental element in protecting personnel who handle or prepare HDs. USP Chapter <800> mandates that protective garments must be worn when compounding, cleaning, or administering HDs. USP-compliant PPE includes:

- Two pairs of shoe covers.
- Hair and face covers (goggles if aerosolization is likely).
- An impermeable gown.
- Two pairs of chemotherapy-rated gloves that meet ASTM standard D6978.
- Respirator mask—required when cleaning a spill or cleaning the inside of the hazardous compounding airflow hood.

Labeling, Storage, and Transport of Hazardous Drugs

Safe and effective labeling, storage, and transportation practices are essential to prevent accidental exposure to HDs. Following the appropriate guidelines with respect to these processes, these practices should begin the moment HDs enter the facility. HDs should be identified by distinctive labels indicating that the product requires special handling. Attach the labels to drug packages and their storage shelves, bins, and areas. All areas where HDs are stored should be marked clearly as containing HDs. Access to these areas should be limited to authorized personnel who have been trained in handling HDs.

Waste Disposal and Spill Cleanup

Review your institution's policies and procedures on hazardous waste for identifying, containing, collecting, segregating, and disposal. Hazardous waste should only be disposed of in hazardous containers located within the negative pressure clean room. Regular trash should not be placed in hazardous waste containers. Handle the outside of hazardous waste containers only with uncontaminated gloves.

Spill kits contain:

- Protective gear, eye protection, a respirator, utility and latex gloves, a disposable gown or coveralls, and shoe covers.

They also contain the equipment needed to clean up the spill:

- A disposable scoop, a puncture- and leak-resistant plastic container for disposing of glass fragments, absorbent spill pads, gauze and disposable toweling, absorbent powder, and sealable, thick plastic waste disposal bags. Hazardous waste must be stored in leak-resistant containers until it is disposed of in accordance with government and institution policy.

ADMIXTURE PROGRAMS

Many of the practices described in this chapter are elements of an overall pharmacy-coordinated IV admixture program. Although an admixture program

does not guarantee that problems will not occur, it does minimize risk to the patient by considering all factors that could potentially cause problems.

Policies and Procedures

Detailed and comprehensive written policies and procedures are an important part of the foundation for an IV admixture program. The policy portion of the document serves as a basis for decision making, while the procedure portion serves as a description of how the task or function should be carried out and is used to train personnel who are new to the facility.

Training

Pharmacists and technicians who work with sterile products and prepare them on a daily basis should be knowledgeable about the process. Pharmacy technicians who work with these products should be trained to understand:

- Basic aseptic technique (e.g., handling supplies, hand washing, garb).
- Sources of contamination.
- How to work within a LAFW.
- How to prepare standard types of parenteral products.
- How to prepare nonstandard types of preparations as needed.

Technicians should demonstrate competency after learning from written training materials, videos, and hands-on demonstrations. They should not only demonstrate proper technique but also have a sample product tested for sterility and accuracy.

Quality Assurance Programs

All IV admixture programs should have a quality assurance program to ensure that products and services are of desired quality. Some common methods of ensuring quality include air sample testing in the IV room and sampling of end products by the lab using pyrogen testing, flame testing, or tests for microbial contamination.

Process Validation

Process validation means procedures ensuring that the processes used in sterile product preparation consistently result in sterile products of acceptable quality. For most aseptic processes, validation is actually a method for evaluating the aseptic technique of personnel. Validation may be accomplished through process simulation.

Additionally, personnel can be tested for proper garbing techniques by having them touch their fingertips to growth media before, during, and after compounding activities. This "fingertip testing" and process validation program should be completed before technicians are allowed to prepare sterile products, and then the technique should be re-evaluated regularly.

End-Product Evaluation

End-product evaluation is the pharmacist's final inspection before the product is allowed to leave the pharmacy. It includes an inspection for leaks, cloudiness, particulate matter, color, solution volume, and container integrity. In some instances, the growth medium fill procedure, described above, should be supplemented with a program of end-product sterility testing, and a method of recalling products not meeting specifications should be in place.

POP QUIZ!

What kind of needle is used to withdraw liquid from an ampule?

OVERVIEW OF PRESCRIPTION COMPOUNDING

It is important to differentiate between compounding and manufacturing. **Compounding** involves the preparation, mixing, packaging, and labeling of a small quantity of a drug based on a practitioner's prescription or medication order for a specific patient. This is different than **manufacturing,** which is the production, conversion, and/or processing of a drug, generally in bulk quantities and without a prescription or medication order.

USP-NF CHAPTER <795>

The *United States Pharmacopeia and The National Formulary* (USP-NF) is a book of standards of quality for drug substances, dosage forms, compounded preparations, excipients, medical devices, and dietary supplements.[2] USP-NF Chapter <795> (Pharmaceutical Compounding—Nonsterile Preparations) offers guidelines and an enforceable set of standards describing procedures and requirements for nonsterile compounding.

Compounding Facilities

The **compounding facilities** refer to the separate work area and storage space within a pharmacy that is utilized for nonsterile compounding. This area is to be well lit, neat, orderly, clean, and sanitized to prevent cross-contamination between products. The area should have a sink with hot and cold water for hand washing and equipment cleaning. Controlled temperature and humidity for the safe storage of chemicals and compounded preparations is essential. Adequate space for storage of equipment and support materials is necessary.

Sources of Ingredients

Sources of ingredients for compounded preparations vary. USP, NF, or Food Chemicals Codex (FCC) grade chemicals are the preferred source for compounding. Other sources may be used, but the chemicals should be from a high-quality supplier and meet purity and safety standards. Commercially manufactured prescription and nonprescription medications (e.g., tablets, capsules) are another acceptable source of ingredients for compounded preparations.

Active and Inactive Ingredients

In addition to **active** (or therapeutic) **ingredient(s)**, compounded preparations may contain a number of inactive (or nontherapeutic) ingredients. **Inactive ingredients** are needed to prepare the formulation, but are not intended to cause a pharmacologic response. Inactive ingredients are also referred to as *inert ingredients*, added ingredients (or substances), or excipients.

Examples of categories of inactive ingredients include diluents or fillers, binders, colorants, lubricants, flavorings, sweeteners, suspending agents, emulsifying agents (or surfactants), coating agents, preservatives, perfumes, acidifying agents, alkalizing agents, vehicles, and wetting agents.

Stability and Beyond-Use Date of Nonsterile Compounded Preparations

Stability is defined in USP-NF Chapter <795> 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 it possessed at the time of compounding."[2]

A BUD should be included on all compounded preparations and is the date after which a compounded preparation is not to be used. A BUD is calculated from the date it was compounded and is given in terms of days or months. It is important to understand that a BUD is not the same as an expiration date. Expiration dates apply to commercially manufactured products and are generally expressed in years.

A BUD depends on whether the preparation contains water, the expiration date of each ingredient used, storage temperature of the preparation, and references documenting the stability of the preparation. Many times, when the stability of a nonsterile compounded preparation is unknown, USP-NF Chapter <795> provides the following recommendations for calculating maximum BUDs:

- Water containing oral preparations stored at controlled cold temperature: no longer than 14 days (or the earliest expiration date of any ingredient used).
- Water containing topical/dermal/mucosal liquid and semisolid preparations stored at controlled room temperature: no longer than 30 days (or the earliest expiration date of any ingredient used).
- Nonaqueous (no water present/added) preparations stored at controlled room temperature: no longer than 6 months (or the earliest expiration date of any ingredient used).

Compounding Attire and Safety Data Sheets

Clean clothing with a clean laboratory jacket is considered proper attire for most nonsterile compounding. It may, however, be necessary to wear head covering, safety glasses, gloves, a facemask, gown, and foot covers if the ingredient(s) in the preparation are considered potentially hazardous. Such precautions are for the safety and protection of the individual preparing the compound and for the prevention of drug contamination.

Corresponding to this, proper procedures for working with a particular ingredient can be found in the Safety Data Sheet (SDS), formerly called Material Safety Data Sheet (MSDS). SDSs are designed to prevent hazardous exposure and accidents and therefore, should be reviewed prior to working with the ingredients. SDSs (electronic or hardcopy) are readily available to all employees in the pharmacy for each drug substance in the compound.

POP QUIZ!

Work inside an LAFW must be done at least how many inches from the sides?

Master Formulation Record and Compounding Record

Each step of the compounding process is to be documented. USP-NF Chapter <795> requires pharmacies to maintain a **master formulation record** and a **compounding record** for each compounded preparation. The master formulation record is an individual record (like a recipe) that is followed each time a preparation is compounded and includes information on ingredients, calculations, compounding equipment, compounding instructions, stability information, and labeling information. A compounding record is completed each time a preparation is made and includes:

- The name of the technician preparing the compound; the name, strength, and amount of preparation; master formulation record reference; lot numbers of ingredients; name of the pharmacist checking the compound; date of preparation; prescription number; BUD; duplicate label; and quality control results.

Quality Control, Labeling, and Patient Counseling

Quality control is the final check of the preparation to ensure its safety and quality. The pharmacist must evaluate the finished preparation both physically and by reviewing the compounding procedure to be sure the preparation is accurate. Discrepancies should be noted and evaluated to determine if the preparation is acceptable. The label should include:

- The name of the preparation, strength, dosage form, quantity, BUD, initials of the pharmacist checking the preparation, storage information, and any other statements or items that may be required by law.

Patient counseling is important with all medications, including compounded preparations. The patient (or the patient's agent) should be counseled by the pharmacist on the correct use, storage, beyond-use date, and evidence of instability of the compounded preparation.

COMPOUNDING EQUIPMENT AND PROCEDURES

The compounding equipment found in a pharmacy depends on the type and scope of compounding performed. The most common types of equipment are those used to weigh and measure ingredients in the preparation. An electronic or class A torsion balance is used to weigh solids needed for the compound.

Graduates are used to measure the volume of liquid ingredients. The **meniscus** is the natural curvature of the surface of the liquid, and it is lower in the middle than at the edges. The bottom of the meniscus should be read at eye level. In terms of graduates, the cylinder-shaped graduates are usually the most accurate.

Mortars and pestles are used to crush, grind, and blend various medicinal ingredients. Mixing powders or crushing tablets is achieved by moving the pestle in a circular motion in the mortar until a state of fine, evenly-sized particles is achieved. This is termed **trituration**. It is necessary to reduce particle size and blend the ingredients into a homogenous mixture to ensure accurate dosing.

An **ointment slab** or tile is a square glass tile that is used for preparing and mixing creams and ointments. Similarly, many facilities use ointment paper instead of an ointment slab because of convenience in reducing clean-up. Before incorporating a powder into the ointment, a paste is first formed by adding a small amount of an appropriate levigating agent. Particle size is then reduced by rubbing the paste on the ointment slab/paper using a spatula. This method of incorporating a solid into the ointment is termed **levigation**.

Electronic mortars and pestles are often used for the preparation of ointments and creams. The chemicals in the preparation can be conveniently weighed, mixed, and dispensed in the same ointment jar.

Geometric dilution is a technique that is used to ensure the uniform mixing of various amounts of different ingredients. This process is used when there is a wide discrepancy in amounts of individual ingredients. To mix ingredients using geometric dilution, the technician starts with the smallest ingredient amount and mixes it with an equal amount of the next smallest ingredient amount. This process then continues until all ingredients are integrated.

CATEGORIES OF NONSTERILE COMPOUNDED PREPARATIONS

Nonsterile compounded preparations vary based on the difficulty of the compounding process, calculations, dosage form, availability of stability information, and the potential for risk/harm to the compounder and/or patient. Because of this, USP-NF <795> has three categories of nonsterile compounded preparations. Simple preparations include those that have a USP compounding monograph or involve reconstituting commercial products. Moderate preparations require special calculations or procedures, and stability information is often unknown. Complex preparations require special training, facilities, equipment, and include—for example—transdermal dosage forms and modified-release preparations.

COMMONLY COMPOUNDED PREPARATIONS

Types of commonly compounded preparations include:

- Ointments, creams, solutions, suspensions, suppositories, lozenges/troches, capsules, and other preparations.

It is important that the pharmacist counsels the patient on the correct way to use or apply the preparation.

POP QUIZ!

What does BUD mean?

Solutions and Suspensions

Solutions and suspensions are both liquid preparations and are generally administered orally. These preparations may be prepared for other routes of administration such as topical, rectal, or vaginal application.

Solutions contain one or more drug ingredients that once mixed result in a homogenous or single phase and, therefore, contain no visible undissolved particles. **Suspensions** have two phases: the insoluble solid particles (active ingredient) and a liquid. The insoluble particles will eventually settle in the bottom of a bottle of a compounded suspension. It is important for patients to gently shake a suspension until no powder remains on the bottom of the container before using.

Suspensions are generally prepared by levigating the insoluble powder to a smooth paste in the mortar with an appropriate wetting agent. A small amount of vehicle is then added to the mortar to make the preparation pourable into a graduate or calibrated dispensing bottle. This process is repeated to transfer all of the medication from the mortar.

Flavoring and sweetening the preparations for oral administration is almost always necessary. A wide variety of sweeteners including sucrose, aspartame, and saccharin are available.[5]

Whenever possible, use a pure chemical to compound the solution or suspension. When the pure chemical is unavailable, tablets or capsules may be used to compound the medication.

Suppositories

Suppositories are a solid dosage form used to administer medication rectally or vaginally. Suppositories are most commonly used to deliver medications such as analgesics, hormones, anti-nausea agents, laxatives, and vaginal anti-infectives. Suppositories must remain a solid at room temperature, but melt at body temperature.

Lozenges/Troches

Lozenges and troches are small, medicated squares that can be soft or hard. Lozenges and troches are intended to dissolve slowly between the cheek and gum and allow for the medication(s) to be absorbed through the lining of the mouth. This medication form is useful for pediatric and geriatric patients who may be unable to swallow solid oral dosage forms.

Capsules

Pharmacists who specialize in compounding may prepare a wide variety of capsules. In the past, capsules were packed by hand, but most pharmacists specializing in compounding now use a capsule-filling machine.

Numerous capsule sizes and colors are available, depending on the amount of powder to be placed in each capsule. For human use, eight sizes of gelatin capsules are used, ranging from the smallest (No. 5) to the largest (No. 000).

REPACKAGING

As pharmaceutical manufacturers prepare, package, and distribute most prescribed medications, the role of the pharmacy has expanded from formulator, compounder, and packager to include repackager of commercially available products. Pharmacies can repackage medications from bulk containers into patient-specific containers including unit-of-use, single-unit, and unit-dose packaging (**Table 4-1**).

The availability of single-unit and unit-dose packages from manufacturers has somewhat reduced the need for pharmacy personnel to repackage. Repackaging, however, is still performed because not all medications are available in unit-dose packages. Drug distribution processes using unit-dose medication packaging are considered to be a best practice and is almost universally used in the hospital setting. Most oral liquid medications for pediatric patients and a number of less commonly prescribed oral solids are not available in unit-dose forms.

Unit-of-Use Packaging

Unit-of-use packaging is characterized by a vial, an envelope, or a plastic bag containing several doses of the same medication. Most unit-of-use packages contain enough medication for the entire treatment period (e.g., 10 days of an antibiotic).

As the benefits of unit-of-use packaging became known, further modifications gave rise to the unit-dose concept. A **unit-dose package** is a non-reusable container designed to hold a quantity of drug to be

TABLE 4-1. Advantages and Disadvantages of Using Repackaged Medications

Advantages	Disadvantages
■ Safety—one unit of measure or one dose typically per package, which can decrease medication error potential due to labeling and, often, barcoded labeling. ■ Efficiency and ease of use for nursing staff and clinicians during medication administration. ■ Medication inventory control by eliminating or minimizing floor stock bulk medication products.	■ Costs associated with time, labor, repackaging equipment, and repackaging supplies in the repackaging process if conducted in-house. ■ Costs associated with the purchase of repackaged medications from a repackaging company. ■ Lack of close regulatory control of repackaging companies by the U.S. Food and Drug Administration (FDA) compared to pharmaceutical manufacturers.

administered as a single dose. The package may contain one unit or multiple units, depending on the dose ordered. The benefits of unit-dose packaging include improved patient safety, reduced waste, more accurate patient charges, ability to use automated dispensing machines, and improved control of medications.

Unit-Dose Packaging

The unit-dose or single-dose package is often confused with the single-unit package. The important difference is that the *unit-dose package contains one dose of the drug for a given patient.*

Extemporaneous versus Batch Repackaging

Extemporaneous repackaging is repackaging quantities of medications that will be used within a short period of time. Extemporaneous repackaging is done on an as-needed basis. The quantities repackaged are based on the anticipated immediate need. Extemporaneous repackaging is also known as *just-in-time* packaging.

Batch repackaging is the periodic repackaging of large quantities of medications in unit-dose or single-unit packages. Batch repackaging is done for medications that have extended stability and are prescribed more frequently. Because the packages are prepared in advance of when they are needed, batch repackaging is sometimes called *prepackaging*

Containers and Repackaging Materials

Repackaging materials and the package itself must protect the drug from harmful external elements such as light, heat, moisture, air, and (in the case of sterile products) microbial contaminants. The material must not deteriorate during the shelf life of the drug. Packages should be lightweight and made of materials that do not interact with the dosage form. Repackaging materials should not absorb, be absorbed by, or chemically interact with the drug. Materials that are recyclable or biodegradable are preferred over those that are not.

REPACKAGING EQUIPMENT

Repackaging equipment can be manual, semi-automated, or fully automated. These systems are reviewed as they pertain to repackaging of oral solids and oral liquids. Manual systems introduce more variability into the final package quality. More repackaging systems are available for oral solids than for any other dosage form, because most doses dispensed in institutions are oral solids.

Oral Solid Systems

Oral solids can be packaged in blister packages or in pouch packages, and they can be manual or automated systems.

Blister Packaging Systems

Blister packages (often called *bubble packs* or *punch cards*) are composed of an opaque and nonreflective backing that is typically used for printing or labeling.

Pouch Packaging Systems

Pouch packages have one or both sides composed of an opaque, non-reflective surface intended for printing.

Manual Systems

Manually operated oral solid repackaging systems use either pouch packages or blister packages. Both pouch packages and blister packages use either heat sealing or adhesive sealing. *Manual pouch repackaging systems* use clear or light-resistant plastic bags (usually PVC).

Manual blister repackaging systems use a plastic blister package made of clear PVC or a laminate of PVC and low-density polyethylene plastic. The blisters or bubbles come in various sizes, depending on the type and size of the product being repackaged.

Automated Systems

Automated oral solid repackaging systems, or unit-dose strip packaging machines, can be semi-automated or fully automated. They all produce a pouch package made of two polyethylene-paper-foil laminates or a polyethylene-paper-foil laminate and a polyethylene-cellulose laminate.

Semi-Automated Systems

In *semi-automated systems*, tablets or capsules are manually fed into a wheel that drops the dose into a pouch formed by two heated wheels or a heated press, and then the package is sealed.

Newer, fully automated repackaging systems have canisters that are calibrated for a drug or product each with one specific *National Drug Code* (NDC), which is a unique three-segment number used to identify a specific drug product. These canisters can hold up to 500 different oral solid products.

The advantages and disadvantages of placing multiple medications in the same pouch vary depending on the setting in which they are used. In the hospital setting where doses are typically dispensed for a 24-hour period or removed from an automated dispensing machine, it is more cost effective to package oral medications individually. This allows for crediting and reuse of doses that are not used by the patient. In an outpatient or long-term care environment, having all of the medications that are due at a particular time in the same pouch has multiple benefits. This system would make it easier for patients to know if they had taken all of the medications that were due at a particular time. This could also lead to improved adherence to drug regimens and lessen the possibility of taking a second dose if they were unsure as to whether they had already taken the dose. Disadvantages to placing multiple medications in the same pouch include not being able to reuse doses and having to re-dispense pouches when there is a change in the medication regimen.

Oral Liquid Systems

Oral liquids can be packaged with manual, semi-automated, and automated systems.

Manual Systems

Manual repackaging systems for oral liquids can be divided into those that use a glass or plastic vial as the reservoir for the liquid medication and those that use a glass or plastic syringe.

Manual repackaging systems that require vials have several different closure systems: Screw cap vials, vials with permanently affixed tops and small fill holes for medication that a plastic ball fits into to prevent liquid from escaping from the container, and vials that require the addition of a cap that must be crimped. Manual systems for repackaging oral liquids into syringes use one of two methods of repackaging:

1. The first method relies on the operator transferring the liquid to a suitable vessel (e.g., beaker) and withdrawing the liquid into the syringe.
2. Another method is where the operator attaches a specially designed cap or cork to the bulk bottle that allows a syringe to be introduced into the cap; the contents are then withdrawn via the syringe by inverting the bottle. Oral syringes are similar to injectable syringes (except they are not sterile) and a hypodermic needle cannot be connected to the syringe, which prevents the injection of oral products parenterally.

Semi-Automated Systems

Semi-automated systems are manual systems that use some piece of automated equipment as part of the filling or sealing process. Semi-automated filling pumps are either volumetric or peristaltic in design and can be used with oral syringes or vials.

Volumetric Pumps

These pumps operate on the same principle as the Cornwall syringes. The volume to be dispensed into the container is preset on the basis of the draw back setting and the type of reservoir selected for the pump.

Peristaltic Pumps

These pumps get their name from the form of pumping action they employ in delivering fluid.

Automated Systems

Plastic cups are used as the fluid reservoir, and the sealing system is a PVC-paper-foil overseal. The overseal acts as the label stock, and the labeling is printed directly on the seal as the machine fills and seals the product in much the same way as automated oral solid packaging machines.

BEYOND-USE DATING AND LABELING

Labeling is the responsibility of the dispenser, who should take into account the nature of the drug repackaged, the characteristics of the containers, and the storage conditions to which the medication may be subjected in order to determine a BUD for the label. USP offers standards for determining an appropriate expiration date in the absence of published stability data: "For nonsterile solid and liquid dosage forms that are packaged in single-unit and unit-dose containers, the beyond use date shall be one year from the date packaged or the expiration date on the manufacturer's container, whichever is earlier."[1]

Current federal labeling requirements are described in the *ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs*. The technical bulletin states that the nonproprietary name (generic name), proprietary name (brand name) if appropriate, dosage form, strength, amount delivered in package, notes (such as storage conditions, preparation or administration instructions), expiration date, and control number or lot number should appear on the package. A bar code should also be included on repackaged items to facilitate bedside barcode scanning in healthcare facilities.

RECORD KEEPING

Standards of practice and government regulations require maintaining accurate and complete records of the repackaging process. Accurate records help in managing inventory and monitoring the efficiency of the repackaging process. Such records can provide a focal point for a quality assurance program and maximize the technician's role in repackaging.

Most repackaging record-keeping systems are now computerized and individual state laws and regulations will dictate what needs to be kept, whether records may be maintained as paper or electronic records, and how long records must be maintained.

QUALITY CONTROL

A well-defined quality control program is essential to ensure the continuous production of high-quality repackaged medications. Quality control of repackaging involves written procedures, formal training of the operators of the equipment, maintenance of equipment, checkpoints during the process, and end-product testing.[9] GMP or Good Manufacturing Practice refers to guidelines for various aspects of production that would affect the quality of the final product and include the following:

- Manufacturing/repackaging processes are clearly defined and controlled.
- Instructions and procedures are written in clear and unambiguous language.
- Personnel training is documented.
- Records are kept that show the procedures were followed.
- Storage and distribution of the final product minimizes negative effects to the quality.
- There is an established system for recalling any batch of product.

Personnel Training and Competency

Formal training programs are important because they promote consistency and standardization. Over time, training programs can pay for themselves by preventing medication errors, the loss of medication, supplies, and personnel time associated with improper repackaging. Training such as teaching proper operating procedures, cleaning and maintenance, and adjustment and repair of malfunctioning machinery can extend the life of equipment. Teaching aids, including programmed texts and video presentations, are available through professional organizations.

Maintenance of Equipment

Most equipment that is used in the repackaging process requires maintenance. Some maintenance will be part of the daily operation of the equipment, and some can

be done on a set schedule. Refer to the instructions that come with the equipment to see what needs to be done every time the equipment is used and what can be done less often. Regularly scheduled preventive maintenance can extend the life of equipment, which decreases overhead in the repackaging operation.

Checkpoints

Checkpoints are the steps in the repackaging process that are crucial to ensuring a high-quality package. It is important to double-check each step. Checkpoints may include the following:

- Double-checking to ensure that the drug and dosage form being repackaged are the ones that are supposed to be repackaged. It is also important to ensure that the bulk product has not expired and has a long enough remaining shelf life to warrant repackaging.
- Double-checking the fill volumes to ensure that the amount of liquid delivered is proper for the dose and the container selected.
- Double-checking any calculations.
- Double-checking the information (e.g., spelling) on a label or computer screen to ensure that the label is complete and accurate.

End-Product Testing

End-product testing is the type of quality control most industries practice. End-product testing requires sampling the final product and determining whether it meets all of the standards it met before repackaging. Examples of end-product testing include testing a sterile product for sterility and testing a package of a solid or liquid oral dosage for moisture impermeability. The uniformity and potency of a product can be tested by a number of chemical analyses. End-product testing is not generally performed for basic repackaging processes, but it may be used more commonly in institutional practice to validate certain types of sterile compounding. End-product testing of repackaged oral liquids may include validating that the package delivers the specified volume of medication.

CONCLUSION

Compounding offers a unique clinical experience in meeting patient needs. Patients benefit from the customized medication and the care of the pharmacist in meeting their needs with dosage forms, routes of administration, or strengths of medication not commercially available. The demand for compounded medications is increasing as more pharmacies offer this service. With the superb technical support of compounding support services, compounding pharmacists and technicians offer a new level of patient care. When commercial medications are available but not in the packaging best suited to the needs of the patient or staff, repackaging offers a convenient, cost-effective method of providing medications to the patient. To summarize,

- USP Chapter <797> seeks to protect patients receiving medications from the compounders.
- USP Chapter <800> protects the compounders from the medications.
- New versions of USP Chapter <797> and USP Chapter <795>, as well as USP Chapter <800>, are expected to officially go into effect on December 1, 2019.

Reference

1. USPC. *United States Pharmacopeia,* 39th rev., and the *National Formulary*, 34th ed. Rockville, MD: The United States Pharmacopeial Convention; 2016.

SELF-ASSESSMENT QUESTIONS

1. IV drug therapy is used:
   a. When the patient is unable to take needed medications by mouth.
   b. When a drug is not needed emergently.
   c. When a drug is well absorbed in the stomach.
   d. When the patient is afraid of needles.

2. Parenteral drug products should:
   a. Contain pyrogens.
   b. Be nonsterile.
   c. Be free of particulate matter.
   d. Be cloudy.

3. Which chapter of the USP Pharmacists' Pharmacopeia defines practice standards regarding the preparation of sterile compounds?
   a. Chapter <795>
   b. Chapter <797>
   c. Chapter <799>
   d. Chapter <800>

4. A clean room that contains a BSC should be a pressure environment.
   a. Positive
   b. Negative

5. The space between the HEPA filter and the sterile product being prepared is referred to as the
   a. Hot spot
   b. Backwash zone
   c. Zone of turbulence
   d. Critical area

6. All manipulations inside a LAFW should be performed at least _____ inside the hood to prevent _____ .
   a. 12 inches; smoke
   b. 6 inches; backwash
   c. 10 inches; contamination
   d. 2 inches; breakage from falling on the floor

7. Before working in the LAFW that has been inoperable,
   a. Interior surfaces should be wiped with sterile 70% IPA.
   b. The hood should be operated for at least 30 minutes.
   c. Hands don't need to be washed since gloves are worn.
   d. Both a. and b.

8. Items inside a LAFW should be placed away from other objects and the walls of the hood to prevent:
   a. Zones of turbulence
   b. Dead spaces
   c. Windows of contamination
   d. Laminar air

9. It is permissible to touch any part of the syringe while making sterile products as long as you are wearing sterile gloves.
   a. True
   b. False

10. A 30-mL syringe with 1-mL calibrations on its barrel can be used to accurately measure 15.5 mL of a solution for injection.
    a. True
    b. False

11. To ensure sterility of a new needle,
    a. The user should make sure the package was intact and not damaged.
    b. Wipe the needle with 70% IPA to disinfect it.
    c. Apply additional silicone so the needle self-sterilizes upon insertion into a vial.
    d. Only touch the needle while wearing gloves.

12. To prevent core formation when entering a vial diaphragm:

a. Only small needles should be used.
b. Needles should be inserted quickly before a core is formed.
c. The needle should be inserted with the bevel tip first, then pressing downward and toward the bevel so the bevel tip and heel enter at the same point.
d. The needle should be inserted straight into the vial diaphragm.

13. Ampules differ from vials in that they:
a. Are closed systems.
b. Require the use of a filter needle.
c. Can be opened without risk of breakage.
d. Ampules do not differ from vials.

14. Prior to compounding a product for parenteral administration, one should do all of the following *except:*
a. Gather all needed supplies.
b. Gather supplies anticipated for the entire shift and place them into the LAFW.
c. Inspect all materials for signs they might be defective.
d. Disinfect injection sites before entry.

15. Labels for IV products:
a. Should be handwritten to show personal touch.
b. Should not include anything but the drug name and the patient's name, so the patient doesn't become alarmed when reading the label.
c. Should be in a format that is consistent and easily understood.
d. Are not necessary if the nurse knows what's in the IV.

16. Preservatives in parenteral products:
a. Kill organisms and therefore eliminate the need for aseptic technique and LAFWs.
b. Are harmless and nontoxic in any amount.
c. Are present in multi-dose vials.
d. Should be used in epidural dosage forms to ensure sterility.

17. An IV system that uses a threaded drug vial screwed into a corresponding receptacle on an IV bag is called:
a. Drug-o-matic
b. Piggyback vial
c. Add-Vantage®
d. LVP

18. A clean room that contains only LAHs should be a pressure environment.
a. Positive
b. Negative

19. Chronic contact with cytotoxic drugs has the potential to cause:
a. A latex allergy.
b. A positive test for tuberculosis.
c. Nightmares.
d. Possible chromosome damage, impaired fertility, or cancer.

20. Protective apparel for those preparing cytotoxic or hazardous injections in a BSC includes:
a. A low permeability, solid front gown with two pairs of chemo-certified gloves.
b. A helmet.
c. A self-contained respirator.
d. Scrubs.

21. After a cytotoxic agent is prepared in the pharmacy, delivery:
a. Should be done immediately.
b. Can be done by anyone in the pharmacy.
c. Can be expedited with systems like pneumatic tubes.
d. Includes making the transporter aware of what they are carrying and what the procedure would be in the event of a spill.

22. Contents of a chemo spill kit include each of the following *except:*
    a. Gloves
    b. Goggles
    c. A loudspeaker
    d. Disposable gown

23. 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

24. 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

25. What is the ingredient that warrants the need for preservative-free ingredients in the compounding of neonatal sterile compounds?
    a. Heparin
    b. SW
    c. Benzyl alcohol
    d. 70% IPA

26. After leaving the non-hazardous compounding area, all PPE must be discarded except for:
    a. Gloves
    b. Gowns
    c. Hair nets
    d. Shoe covers

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

28. A 27 gauge needle is much larger than a 13 gauge needle.
    a. True
    b. False

29. How should chemotherapy products and any item that has entered the BSC hood be disposed of?
    a. Sharps container
    b. Waste log
    c. Yellow biohazard waste container
    d. Trash can

30. Space and facilities used for sterile product preparation:
    a. Should be set up to meet recommendations of ASHP and USP.
    b. Can be anywhere as long as it is within the pharmacy.
    c. Should be carpeted to minimize noise disturbances.
    d. Should have a good breeze to keep workers cool.

31. Which PPE item would be specifically worn in a negative pressure environment?
    a. Gown
    b. Sterile gloves
    c. Chemo gloves
    d. Shoe covers

32. Extravasation:
    a. Is another term used to describe an infiltration of an IV.
    b. Is a term used to describe the irritation caused by the IV catheter.
    c. Is the term used to describe the presence of particles in an IV solution that have been solidified.
    d. Is the term describing the occurrence of the IV catheter puncturing and exiting the vein under the skin, causing the fluid to infuse into the tissues.

33. Process validation means:
    a. Procedures that ensure the processes used in sterile product preparation consistently result in sterile products of acceptable quality.
    b. The master formulation record is followed each time that preparation is compounded.
    c. The label includes the name of the preparation, strength, dosage form, quantity, BUD, initials of the pharmacist checking the preparation, and storage information.
    d. Additional HEPA filtration known as secondary engineering controls were utilized in the preparation of sterile products containing hazardous materials.

34. List the following PPE items in order of proper donning:
    a. Shoe covers
    b. Gown
    c. Hair cover
    d. Gloves
    e. Facemask

35. When donning sterile chemo gloves, the cuff is to be placed:
    a. Under the cuff of the chemo gown.
    b. Over the cuff of the chemo gown.

36. Which statement is false regarding BUDs for a compounded preparation?
    a. A BUD is calculated from the date the preparation is compounded.
    b. A BUD is generally expressed in years.
    c. A BUD is to be included on all compounded preparations.
    d. A BUD is the date after which a compounded preparation is not to be used.

37. Examples of nonsterile compounded preparations include all of the following except:
    a. Analgesic suppository
    b. Antibiotic ophthalmic suspension
    c. Antifungal oral suspension
    d. Hormone vaginal cream

38. USP-NF Chapter <797> offers guidelines and an enforceable set of standards describing procedures and requirements for nonsterile compounding.
    a. True
    b. False

39. Common sources of ingredients for compounded preparations include all of the following except:
    a. Chemicals that the pharmacist determines are from a high-quality supplier and meet purity and safety standards.
    b. Commercially manufactured prescription medications.
    c. Medications withdrawn from the market by the FDA for safety or effectiveness reasons.
    d. USP or NF grade chemicals.

40. Which statement is true regarding inactive ingredients?
    a. Excipients are also known as therapeutic ingredients.
    b. Inactive ingredients are an unnecessary part of the preparation.
    c. Inactive ingredients cause a pharmacological response.
    d. Preservatives and emulsifying agents are examples of inactive ingredients.

41. Which standards are utilized when choosing repackaging materials?
    a. FDA standards
    b. Local health department standards
    c. State pharmacy board standards
    d. USP standards

42. Dispensing units of repackaged medications commonly include all of the following *except*:
    a. Reusable containers
    b. Single-dose packaging
    c. Single-unit packaging
    d. Unit-of-use packaging

43. Which statement is *true* regarding repackaging records?
    a. Repackaging records are not used for monitoring inventory and the efficiency of the repackaging process.
    b. Repackaging records are not used to determine if the medication was correctly packaged.
    c. Repacking records are useful for quality control purposes.
    d. Repacking records may be destroyed once the medication supply has been dispensed.

44. Considerations for repackaging materials include which of the following:
    a. The day of the week to repackage.
    b. The sensitivity of the repackaging person to light.
    c. The time of day when repackaging.
    d. The type of packaging material and medication to be repackaged.

45. SDS (formerly called Material Safety Data Sheets or MSDS) are designed to:
    a. Prevent compounding misadventures that introduce pyrogens into sterile products.
    b. Are utilized only when compounding personnel are exposed to hazardous materials.
    c. Are designed to prevent hazardous exposure and accidents.
    d. All the above.

46. USP <797> requires pharmacies to maintain a master formulation record and a compounding record for each compounded preparation.
    a. True
    b. False

47. Geometric dilution:
    a. Is a compounding method of incorporating a solid into an ointment.
    b. Is a technique that is used to ensure the uniform mixing of various amounts of different ingredients.
    c. Refers to the process of adding liquid to a vial containing powder for the purpose of reconstitution.
    d. Refers to the addition of a solvent to a solute.

48. How does a master formulation record differ from a compounding record?

49. If a patient were ordered to receive 750 mg of a drug that is only available in 500 mg scored tablets, what would the pharmacy prepare for the patient?
    a. Two unit-dose packages, one containing the 500 mg tablet and the other ½ of a tablet.
    b. One unit-dose package with two 500 mg tablets and instructions for the patient to take 1½ tablets per dose.
    c. One unit-dose package containing 1½ tablets.

50. USP Chapter <800>:
    a. Seeks to protect patients receiving medications from the compounders.
    b. Protects the compounders from the medications.
    c. Is expected to officially go into effect on December 1, 2019.
    d. Provides guidelines for BUD for all compounded materials.

SELF-ASSESSMENT ANSWERS

1. a.
2. c.
3. b.
4. b.
5. d.
6. b.
7. d.
8. a.
9. b.
10. a.
11. a.
12. c.
13. b.
14. b.
15. c.
16. c.
17. c.
18. a.
19. d.
20. a.
21. d.
22. c.
23. e.
24. b.
25. c.
26. b.
27. a.
28. b.
29. c.
30. a.
31. c.
32. d.
33. a.
34. a., c., e., b., d.
35. b.
36. b.
37. b.
38. b.
39. c.
40. d.
41. d.
42. a.
43. c.
44. d.
45. c.
46. b.
47. b.
48. The master formulation record is an individual record (like a recipe) that is followed each time that preparation is compounded and includes information on ingredients, calculations, compounding equipment, compounding instructions, stability information, and labeling information. The compounding record is completed each time the preparation is made and includes the name of the technician preparing the compound; the name, strength, and amount of preparation; master formulation record reference; lot numbers of ingredients; name of the pharmacist checking the compound; date of preparation; prescription number; BUD; duplicate label; and quality control results.
49. c.
50. b. and c.

CHAPTER 5

MEDICATION SAFETY



Learning Outcomes

After completing this chapter, you will be able to

- List 10 different types or categories of medication errors.
- Identify causes or factors that contribute to medication errors.
- List five "high-alert" medications.
- Describe 10 medication error prevention strategies.
- Define *culture of safety*.
- Describe the possible consequences of actual medication errors.
- Explain the steps taken when an error has been identified.
- Identify the four steps in the PDSA cycle.

Responsibility for **patient safety** is shared by all members of the healthcare team. The Agency for Healthcare Research and Quality defines ***patient safety*** as the "freedom from accidental or preventable injuries produced by medical care." This definition further states that "practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events." From this definition, it is reasonable to describe **medication safety** as freedom from accidental or preventable injury related to the medication-use process.

Medication error is defined by the National Coordinating Council for Medication Error reporting and Prevention (NCC MERP) (https://www.nccmerp.org/about-medication-errors) as

> any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.[1]

TYPES OF MEDICATION ERRORS

Medication errors can happen at any point during the medication-use process and do not occur only in the pharmacy. According to the ASHP Guidelines on Preventing Medication Errors in Hospitals*, medication errors can be categorized into 11 types, including:

1. **Prescribing errors** occur at the time a prescriber orders a drug for a specific patient. Errors can include the selection of an incorrect drug, dose, dosage form, route of administration, length of therapy, or number of doses. Other prescribing errors include inappropriate rate of administration, incorrect drug concentration, and inadequate or incorrect instructions for use.
2. **Omission errors** include failure to administer a medication to a patient in a hospital or long-term care facility or a patient forgetting to take a dose before the next scheduled dose.
3. **Wrong time error** is administering the medication at the wrong time.
4. **Unauthorized drug errors** is the administration of a medication to a patient *without* the prescriber's proper authorization. An unauthorized drug error might occur if a medication for one patient was given mistakenly to another patient (wrong patient) or if a nurse gave a medication without a prescriber order.
5. **Improper dose error** occurs when a patient is given a dose that is greater than or less than the prescribed dose. Many Boards of Pharmacy now indicate *Best Practice* for labeling liquid dosage forms in milliliters rather than teaspoons to avoid errors. This type of error can occur when there is a delay in documenting a dose, or absence of documentation, that results in administration of an additional dose.
6. **Wrong dosage form errors** are defined as doses administered or dispensed in a different form than the prescriber ordered. Depending on state laws and healthcare facility guidelines, dosage form changes may be acceptable to accommodate particular patient needs.
7. **Wrong drug preparation errors** include those in which the drug is not properly prepared prior to dispensing or administration such as improper reconstitution.
8. **Wrong administration technique errors** include doses that are administered using an inappropriate procedure or incorrect technique.
9. **Deteriorated drug errors** would be medications that are dispensed or administered beyond their expiration date or that have deteriorated because of improper storage.
10. **Monitoring errors** result from inadequate drug therapy review.
11. **Compliance errors** occur when patients fail to follow or adhere to a prescribed drug regimen.

*See American Society of Hospital Pharmacists. ASHP guidelines on preventing medication errors in hospitals. *Am J Hosp Pharm.* 1993;50:305-14.

Technology

Barcode technology has been shown to decrease medication errors, but is not without limitations. For example, a barcode that is wrapped around a cylindrical product such as a small vial or syringe may be difficult to scan because the barcode reader is unable to capture the image properly. Some drug products contain more than one barcode, making it important to know which bar code to scan.

Errors Related to Drug Shortages

Errors directly associated with drug product shortages may be categorized together so that a comprehensive review can be completed to specifically address issues related to managing drug shortages.

Computer Order Entry or Computer Prescriber Order Entry Errors

Computer order entry errors occur when a medication order is entered into the pharmacy computer system incorrectly.

Automated Dispensing Cabinet Errors

Automated dispensing cabinets (ADCs) are readily available in many healthcare facilities. This form of automation coupled with barcode technology can improve dispensing accuracy. Errors associated with ADCs include refilling the medication bins with the wrong product, selection of the wrong drug when the product is stored in a multidrug bin, or when safety steps are bypassed.

Transitions of Care Errors

Transitions of care errors occur when incomplete or inaccurate medication information shared between healthcare settings results in errors.

Medication Error Reporting

The rate of medication errors is often based on incident reports or reported patient safety events. Ideally, healthcare providers report patient safety events per established procedures when a medication error is discovered. Often errors are discovered when a pharmacist checks a prescription or medication order prior to dispensing, and the error is corrected promptly before the medication reaches the patient.

IMPACT OF MEDICATION ERRORS

- **Impact on the Patient** resulting in negative patient outcomes.
- **Financial Implications** by prolonging hospital stays or increasing healthcare costs.
- **Loss of Trust** in pharmacy practice and physicians is possibly causing patients to seek unconventional treatments.

POP QUIZ!

To ensure the caregiver administers the correct dose of amoxicillin 250 mg/5 mL suspension when 187.5 mg is ordered per dose, how should the label read?

CAUSES OF MEDICATION ERRORS

Medication errors are often attributed to one or more contributing factors including calculation errors, improper use of zeros and decimal points, inappropriate use of abbreviations, inappropriate prescribing, illegible handwriting, incomplete information, drug product characteristics, compounding/drug preparation errors, labeling, work environment and human factors, and deficiencies in medication-use systems. **Table 5-1** lists some of the factors that contribute to medication errors that are discussed in this chapter.

TABLE 5-1. Examples of Factors Contributing to Medication Errors

Factors Contributing to Medication Errors
Calculation errors
Improper use of leading or trailing zeros
Use of abbreviations
Inconsistent labeling of drug products
Look-alike or sound-alike drug names
Human factors
Busy or cluttered work environment
Unclear communications
Improper use of technology

Calculation Errors

Calculation errors are often made by using the wrong concentration of stock solutions, misplacing a decimal point, or using wrong conversions. *"Does the answer seem reasonable?"*

Decimal point errors can occur as a result of a miscalculation, as described above, and also when writing orders or instructions. Failure to write a leading zero in front of a number less than 1 (e.g., **.1** mg instead of **0.1** mg) can result in the number being read as a whole number (**1** mg). Writing unnecessary trailing zeros can also be confusing (e.g., **10.0** mg instead of **10** mg, which could be misinterpreted as **100** mg).

Abbreviations

The abbreviation of medical terms and drug names can lead to medication errors. Drug names should be written without abbreviations. Another example would be using the abbreviation "**U**" as an abbreviation for units. There is ***NO*** acceptable abbreviation for unit. **Table 5-2** lists dangerous abbreviations that the NCC MERP recommends should not be used.[2]

POP QUIZ!

What is the proper way to write an order for ½ mg of a drug substance to best avoid a medication error?

High-Alert Medications

Several medications or drug classes have been categorized as **high-alert medications** because of their high risk of causing serious harm to patients when given in error. High-alert drug errors do not necessarily occur more frequently than others. According to the Institute for Safe Medication Practices (ISMP), the following classes/categories of medications are examples of high-alert medications:[3-5]

- Antithrombotics (e.g., heparin)
- Opioids (e.g., morphine, hydromorphone, fentanyl)
- Potassium chloride concentrated injection
- Hypoglycemic agents (e.g., insulin, insulin U-500)
- Chemotherapeutic agents—parenteral and oral (e.g., methotrexate, vincristine)

TABLE 5-2. Dangerous Abbreviations that NCC MERP Recommends to Never Use

Abbreviation	Intended Meaning	Common Error
U	Units	Mistaken as a zero or a four (4) resulting in overdose. Also mistaken for "cc" (cubic centimeters) when poorly written.
µg	Micrograms	Mistaken for "mg" (milligrams) resulting in an overdose.
Q.D.	Latin abbreviation for every day	The period after the "Q" has sometimes been mistaken for an "I," and the drug has been given "QID" (four times daily) rather than daily.
Q.O.D.	Latin abbreviation for every other day	Misinterpreted as "QD" (daily) or "QID" (four times daily). If the "O" is poorly written, it looks like a period or "I."
SC or SQ	Subcutaneous	Mistaken as "SL" (sublingual) when poorly written.
T I W	Three times a week	Misinterpreted as "three times a day" or "twice a week."
D/C	Discharge; also discontinue	Patient's medications have been prematurely discontinued when D/C (intended to mean "discharge") was misinterpreted as "discontinue," because it was followed by a list of drugs.
HS	Half strength	Misinterpreted as the Latin abbreviation "HS" (hour of sleep).
cc	Cubic centimeters	Mistaken as "U" (units) when poorly written.
AU, AS, AD	Latin abbreviation for both ears; left ear; right ear	Misinterpreted as the Latin abbreviation "OU" (both eyes); "OS" (left eye); "OD" (right eye)
IU	International Unit	Mistaken as IV (intravenous) or 10 (ten)
MS, MSO_4, $MgSO_4$	Confused for one another	Can mean morphine sulfate or magnesium sulfate

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- Neuromuscular blocking agents (e.g., vecuronium, cisatracurium, succinylcholine)

Prescribing Concerns

Verbal and Telephone Orders

Oral orders — orders given orally by a prescriber — can lead to medication errors when they are heard incorrectly or when they are transcribed to writing or entered into a computer incorrectly.

When verbal or telephone orders are necessary, the **3-way repeat back patient safety tool** should be used.

3-Way Repeat Back Patient Safety Tool

The recipient of a verbal or telephone order should immediately:

1. Write down the order.
2. Read it back to the prescriber to ensure clarity of the order.
3. The prescriber should acknowledge that the order is correct as it is read back.

Drug Concentration

Failure to include the concentration of a liquid formulation in a prescription can result in dispensing a wrong dose.

Illegible Handwriting

Many medications are prescribed electronically; however, handwritten prescriptions have not been eliminated completely. Poor prescriber handwriting may contribute to medication errors.

Missing Information

Lack of complete medical information about the patient such as age, weight, height, allergies, and diagnosis can contribute to medication errors. Medical information is important because dose often depends on the indication and severity of the condition.

Course Dose versus Daily Dose

Chemotherapy medication regimens are commonly prescribed on a per-course or cycle-of-treatment basis as opposed to a per-dose basis. This practice increases the risk of medication errors because the orders may be difficult to interpret.

Chemotherapy drugs are considered high-alert medications. Ask clarifying questions when reviewing incomplete or unclear orders to ensure understanding prior to acting on them.

Drug Product Characteristics

Look-Alike and Sound-Alike Drug Names

Many case reports deal with medication errors caused by confusion surrounding drug names. Hundreds of drug names either sound or look like other trade or generic drug names. **TALL man lettering** is a practice of using *bolded upper-case letters* as part of a drug name to distinguish it from another drug name that is similar.

Numbers and Letters as Part of Medication Names

Manufacturers sometimes include numbers and letters as prefixes and suffixes to brand names (e.g., Tylenol with Codeine No.3, Cartia XT, Effexor XR). Although the intent may be to indicate strength or that a product is an extended-release formulation, it can lead to errors. Numbers in the medication name can be misinterpreted as the dose.

Product Labeling

As a marketing strategy, product labels often emphasize a manufacturer's name or logo, potentially making it difficult to readily identify the drug name and dose. Manufacturers often use the same labeling scheme including letter size, print, and background color, to associate the product with the manufacturer. Sometimes this strategy, which makes all labels look alike, can be detrimental.

Color Coding

Relying on the color of product packaging is not a safe practice. Manufacturers may change their packaging color scheme at any time, and color-coding schemes for similar products may differ among manufacturers. Sometimes there is too little difference between colors in a color scheme, which leads to mix-ups.

Compounding/Drug Preparation Errors

Errors can occur during the compounding and drug preparation phase. These errors can be difficult for others to catch, so it is essential that technicians take steps to decrease the risk of error when compounding and preparing drug products. Steps to decrease the risk of error include:

- Reading the product labels carefully.
- Not processing more than one prescription at a time.
- Labeling prescriptions properly.
- Storing drugs properly.
- Maintaining a safe work environment.
- Keeping up with changes related to new drugs, formulations, or labeling changes.

Processing Multiple Products

Processing more than one prescription or order at the same time can result in errors. Technicians should process only one prescription or common batch (e.g., batch of cefazolin 1-g intravenous [IV] bags) at a time.

Labeling

Technicians should be familiar with the labeling requirements for prescriptions in their pharmacy as dictated by state law and pharmacy policies and procedures. If a label is handwritten, it should be neat and legible. Ink and toner cartridges and printer ribbons should be changed before the print is too faded to read; the label should be free of smudges; and the print should be aligned on the label appropriately. Labels that are difficult to read can result in miscommunication and medication errors.

Auxiliary labels should be placed carefully on the drug container so they do not cover up other pertinent information.

Deteriorated Medications

Because expired medications and improperly stored medications may have lost their potency and thus, their effectiveness, technicians should take steps to keep these medications out of the dispensing stock. When replenishing stock, always remove expired medications and place the stock with the earliest expiration date near the front to be used first.

Medications that require special storage conditions, such as refrigeration or freezing, should be stored in those conditions as long as possible prior to use.

Work Environment and Human Factors

Factors within the workplace can contribute to medication errors. Inadequate lighting, poorly designed work spaces, and inefficient workflow can make it difficult to perform assigned duties accurately. Cluttered work spaces or stock areas can increase the risk of picking up the wrong drug. The many distractions and interruptions, including phone calls, in a busy pharmacy can cause loss of concentration. Use the **STAR safety tool** when performing critical tasks to prevent errors:

- **S**top (for a second or two)
- **T**hink (before you act)
- **A**ct (complete the task)
- **R**eview (check your work)

Deficiencies in Medication-Use Systems

Medication errors cannot be attributed to human error alone. Errors are frequently due in part to defective or inadequate systems.[6] For example, stocking dangerous drugs in patient care areas (i.e., open floor stock) increases the risk of an error because the drugs are available to nurses without a pharmacy check. Floor stock mix-ups, such as between heparin injection and normal saline injection for flushing IV tubing, potassium chloride and furosemide injections, and premixed lidocaine in D5W 500-mL and plain D5W 500-mL bags, can lead to serious consequences.

MEDICATION SAFETY STRATEGIES

It is impossible to eliminate all potential for error. People are not perfect, and even the most conscientious and knowledgeable staff members can make mistakes.

TABLE 5-3. Medication Error Prevention Strategies

Medication Error Prevention Strategies
Tall man lettering
Avoid dangerous abbreviations
Consistent nomenclature
Avoid decimal points and trailing zeros for whole numbers
Effective handoffs
Independent double check
3-way repeat back for telephone orders
Ask clarifying questions
Segregate look-alike drug products

STAR = stop, think, act, review.

Failure Mode and Effects Analysis

Sometimes the systems that people work within present numerous opportunities for errors. **Failure mode and effects analysis (FMEA)**, also called *failure mode effect and criticality analysis* (FMECA), is a systematic evaluation of a process or system used to predict the opportunity for and severity of errors at various steps in the process. FMEA focuses on finding flaws within a system that creates opportunities for individuals to make errors. It evaluates the *how* and *why* of an error instead of the *who*. The steps to evaluate a process using FEMA are:

- Describe in detail the individual steps involved in the overall process from start to finish. Use of a flow diagram is helpful to create a visual representation of the process.
- List the potential opportunities for failure at each stage.
- Describe the effects of these failures on the process and their root causes.
- Estimate the severity, likelihood of occurrence, and probability of identifying the failure.

Patient counseling is designed to help prevent medication errors in the outpatient setting.

Multiple Check Systems

Another system designed to prevent medication errors is a **multiple check system**. This can include the pharmacist reviewing a physician order, a pharmacy technician preparing a medication for the pharmacist to check, a nurse inspecting the dose from the pharmacy, and a patient asking questions and examining the medication before taking it. Technicians should always recheck their work — prior to having it checked either by the pharmacist or another technician — in a *Tech-Check-Tech* system.

Standardization

Preprinted Order Forms

Standardized, preprinted order forms are used to prevent medication errors by making medication orders easier for the prescriber to read and easier for the pharmacist and nurse to interpret.

ISMP has also designated chemotherapeutic agents as high-alert medications, making them ideal drugs to be included on a standardized order form.[3-5] ASHP recommends the use of standardized forms for ordering chemotherapy treatment as a medication safety strategy.[7]

Education and Training

Education and training are important in reducing medication errors. Training can include pharmacy calculations, compounding techniques, pharmacy abbreviations, preparation of IV medications, and computer operation skills. Healthcare personnel should be familiar with the classes of medications, their generic and trade names, and their forms and doses. The Joint Commission requires organizations to prove that their personnel are competent.

Computerization and Automation

The proper use of computerization and automation are effective ways to prevent medication errors. Many healthcare facilities use barcoding, ADCs, and robots to reduce medication errors.

PROCESS IMPROVEMENT

Despite efforts to prevent medication errors, they do occur, in which case it is important to *document* and *evaluate* the circumstances involved in the error so that healthcare personnel can be educated on how to prevent such errors from occurring in the future.

What to Do When an Error Occurs

When a potential medication error occurs, it is important to review the error as a learning experience for the technician as well as to provide an opportunity to ask questions.

Pharmacies should have procedures in place that describe when and how to inform patients of errors. The procedures should also include who is responsible for informing the patients, what follow-up procedures should be taken, and what documentation is required.

Documentation

When a medication error occurs, the organization's medication error reporting form should be completed according to the organization's established reporting procedures. Often this form can be submitted electronically.

Root Cause Analysis

If an error occurred that reached the patient and caused harm, it is important to thoroughly examine the error to learn why it occurred and how such an error can be avoided in the future. A **root cause analysis (RCA)** is a process that examines the contributing factors regarding why and how an error occurred.

Implementing Change

Once a trend has been identified, action must be taken to reduce the possibility of future errors. Changes may involve educating staff, purchasing a more appropriately labeled medication from another company, revising department policies and procedures, or purchasing a piece of equipment. Three ways the pharmacy department can educate its staff on a continual basis about actual medication errors are:

1. Publishing summaries of errors that have occurred in staff newsletters.
2. Conducting educational programs.
3. Discussing medication errors as a regular agenda item at staff meetings.

Plan-Do-Study-Act Cycle

The **P**lan-**D**o-**S**tudy-**A**ct (PDSA) cycle is another quality tool used to improve medication safety. When a problem is identified and ideas are generated to address the problem, the team develops a plan to test the ideas to see if they will make an improvement. The test plan describes the procedure changes and the data to be collected. The new procedures are carried out on a small sample or for a short period of time. Data are collected during this test period to determine if the changes are effective. Then the data are studied to see if there were any improvements. Based on the findings, the team acts on what was learned from the test and modifies procedures if needed. The process can be repeated after modifications are implemented to see if further improvement is achieved. This tool is helpful in testing changes on a small scale prior to full implementation.

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SELF-ASSESSMENT QUESTIONS

1. A medication error is defined as "an error made by a pharmacist or pharmacy technician at any time during the dispensing process."
   a. True
   b. False

2. Which of the following actions might increase the likelihood of a medication error?
   a. Reading the drug label carefully when selecting the drug from the shelf.
   b. Reviewing recent medication errors at a pharmacy staff meeting.
   c. Asking another pharmacy technician to double-check a calculation.
   d. Having a nurse phone in a prescription order that was communicated verbally by the doctor.

3. Manufacturers are required to print the warning, "MUST BE DILUTED," on the container cap and label for which of the following products?
   a. Potassium chloride injection vial
   b. Vincristine injection
   c. Digoxin oral liquid
   d. Amoxicillin suspension

4. The term *high-alert medication* is defined as a medication that:
   a. Is involved in more mistakes than others.
   b. Requires drug level monitoring.
   c. Has a high risk of causing patient harm if used in error.
   d. Is highly effective when used for its FDA approved indication.

5. Which of the following error prevention strategies might be useful in distinguishing between two drug products available in similar packaging (similar size, color, and labeling)?
   a. Store the drugs in separate locations in the pharmacy.
   b. Use barcode scanning technology to verify selection of the correct product.
   c. Ask a co-worker to double check the selection via independent verification.
   d. All the above.

6. Failure mode and effects analysis (FMEA) is a systematic approach evaluating
   a. Who is causing errors in the drug-use process.
   b. What process should be fixed to eliminate errors in the drug-use process.
   c. How and why an error was made in the drug-use process.
   d. Standardized training of pharmacy technicians to minimize errors in the drug-use process.

7. Because pharmacists have the responsibility for the final check of all products, the pharmacy technician is free of all liability.
   a. True
   b. False

8. When compounding an order for gentamicin 10 mg IVPB (piggyback) every 8 hours, the technician inadvertently used 1 mL of the 40 mg/mL concentration solution instead of the pediatric concentration (10 mg/mL). Identify the category in which this error could be classified.
   a. Wrong dosage form error
   b. Calculation error
   c. Improper dose error
   d. Wrong administration technique error

9. As a technician undergoing on-the-job training, you are falling behind in putting away the drug shipment that arrived earlier this morning. To save time, you fail to rotate the stock and put all the new stock in front of the containers already in the stock area. Failure to rotate stock could lead to which of the following medication errors?

a. Deteriorated drug error
b. Improper dose error
c. Compliance error
d. Monitoring error

10. Experienced pharmacy technicians are less likely than technicians-in-training to make calculation errors.
    a. True
    b. False

11. Which of the following can lead to a calculation error?
    a. Not verifying that the final answer is reasonable.
    b. Using an inaccurate conversion.
    c. Misplacing the decimal point.
    d. All the above.

12. Which of the following is LEAST likely to lead to a wrong dose error?
    a. 10 mg
    b. .10 g
    c. 10 U
    d. 10.0 units

13. Using abbreviations that have been published in reputable medical journals is acceptable because only widely accepted abbreviations are used in publications.
    a. True
    b. False

14. An antibiotic suspension is ordered that is available only in a 500-mg/5-mL concentration. The order reads "250 mg TID X 10 days." What is the best way to write the label to help minimize the possibility of a medication error?
    a. Take 250 mg three times a day for 10 days.
    b. Take ½ teaspoonful three times a day for 10 days.
    c. Take 2.5 mL three times a day for 10 days.
    d. Take as directed.

15. One morning you are busy preparing IVPB antibiotic orders for the 10 AM delivery. The orders are:

    Pat Carlson Cefazolin 1 g IVPB every 8 hr

    Paul Cariton Ceftazidime 1 g IVPB every 8 hr

    You decide to prepare both orders simultaneously to save time and avoid missing the delivery.

    List four reasons why the risk of making an error this morning is increased.

16. A prescriber calls the pharmacy with a new prescription. The pharmacist writes down the prescription and then reads it back to the prescriber. The prescriber confirms that the prescription was communicated correctly by saying, "That's correct." The safety strategy being used in this scenario is called:
    a. S-T-A-R
    b. Clarifying questions
    c. 3-way repeat back
    d. Telephone confirmation

17. When taking a verbal order from a prescriber via telephone, to best avoid an error the person taking the order should repeat the order back to the prescriber and then translate the order into writing.
    a. True
    b. False

18. Which could be considered a contributing factor(s) to medication errors?
    a. Performing routine maintenance procedures on the tablet counting machine.
    b. Failing to read current pharmacy literature about new drug products.
    c. Scheduling additional staff to work during periods of heavy workload.
    d. Always using leading zeros.

19. Why are published medication error rates usually underestimated?

a. Only errors that result in patient injury are reported.
b. Some errors go undetected.
c. Few errors are identified and corrected during the prescribing phase.
d. Efficient anonymous reporting systems are common.

20. The purpose of TALL man lettering in drug names is to:
a. Identify the drug class of the product.
b. Highlight the generic name of a drug.
c. Distinguish between two drugs with similar looking or sounding names.
d. Identify medications associated with serious side effects.

21. Omission errors are less likely to result in negative outcomes than improper dose errors because the patient is not receiving a harmful dose.
a. True
b. False

22. Lisa Kim, a technician working in the unit dose cart fill area, notices the 25-mg and 50-mg strengths of diphenhydramine (Benadryl) are mixed together in the same storage bin. What can Lisa do to correct this problem?
a. Make no changes, because technicians are responsible for reading labels carefully and will notice the different strengths.
b. Modify the stock shelf so each strength has its own section or bin.
c. Change the label to indicate that both strengths are in the bin.
d. Store the 25-mg capsule under "Benadryl" and the 50-mg capsule under "Diphenhydramine."

23. A technician compounds a continuous infusion of heparin 25,000 units in 500 mL of 5% Dextrose in Water (D5W) and places the bag on the counter for the pharmacist to check. The technician then begins to fill other medication orders. One of the orders the technician fills is for two heparin 5,000 unit syringes for subcutaneous injection. The technician notices the same patient name on the continuous infusion label and the subcutaneous injection labels. What should the technician do?
a. Fill the medication orders and assume the pharmacist will notice the duplication.
b. Inform the pharmacist that both heparin prescriptions have the same patient name and ask if both orders are correct.
c. Ask another technician what the standard dose of heparin is and fill both orders.
d. Check the patient's medication profile and fill both orders for heparin.

24. A patient comes into the pharmacy stating that he was recently started on a new medication and has been experiencing severe diarrhea for several days. He asks the pharmacy technician to assist in selecting an anti-diarrheal medication. What should the technician do?
a. Tell the patient to contact his doctor for a recommendation.
b. Recommend the product that is the best seller at the pharmacy.
c. Refer the patient to the pharmacist for assistance in assessing the patient needs and making an appropriate recommendation.
d. Show the patient the OTC antidiarrheal section and tell him to pick one out.

25. Barbara Steinbaum calls the pharmacy asking why her Effexor XR (venlafaxine extended release) prescription was filled with tablets instead of the capsules she usually receives. Her prescribed dosage regimen is "37.5 mg PO once daily." It is discovered that the prescription for Effexor XR (Venlafaxine) 37.5 mg—an extended-release capsule—was mistakenly filled with immediate-release venlafaxine 37.5-mg tablets. This medication error would be considered which of the following types of error?

a. Wrong dosage form error
b. Monitoring error
c. Incorrect dose error
d. Patient compliance error

26. A technician compounding an IV preparation of calcium gluconate and 5% D5W notices the calcium gluconate injection looks slightly cloudy before preparing the IV bag. What should the technician do to prevent a medication error?
    a. Place the calcium gluconate vials in the refrigerator to see if the cloudiness disappears in a few minutes.
    b. Return the vial of calcium gluconate back to the shelf and use another vial that looks clear.
    c. Place the calcium gluconate vial in a tub of warm water for 15 minutes.
    d. Inform the pharmacist that the calcium gluconate vials look cloudy and inspect all the calcium gluconate vials in stock.

27. Root cause analysis is:
    a. A process that determines who is to blame for the medication dispensing error.
    b. A process that examines the contributing factors regarding why and how an error occurred.
    c. A system designed to prevent medication errors utilizing multiple checks.
    d. Also called *failure mode effect and criticality analysis*.

28. Match the common error in the right column with its associated dangerous abbreviation in the left column:

T I W	might be misinterpreted as "QID"
µg	unclear if referring to morphine sulfate or magnesium sulfate
HS	misinterpreted as "three times a day"
Q.D.	unsure if it means "half-strength" or "at bedtime"
MS, MSO_4, $MgSO_4$	mistaken for "mg"

29. The pharmacy receives a prescription for betamethasone dipropionate AF cream 0.05%, but there is none in stock. Instead, the prescription is filled with betamethasone dipropionate AF ointment 0.05%. Which of the following statements is TRUE regarding this scenario based on the information provided?
    a. A wrong dose error occurred.
    b. No error occurred because both products contain the same drug—betamethasone dipropionate AF 0.05%.
    c. The products are not interchangeable, and the prescriber should have been contacted to obtain an order for an alternative product.
    d. According to the NCC MERP index for categorizing medication errors, this event would be considered Category D (reached the patient and required monitoring).

30. S-T-A-R is an acronym for a safety strategy that is useful to prevent medication errors. What do the letters S-T-A-R stand for?
    a. Steady – Test – Attention – Repeat
    b. Stop – Think – Act – Review
    c. Slow down – Think – Apply – Re-do
    d. Stop – Test – Act – Review

31. A pharmacy technician supervisor notices several technicians making the same calculation error. At the next staff meeting, the supervisor discusses the errors with the group without mentioning who made the mistakes. The supervisor also demonstrates how to perform the calculations correctly. This practice can help prevent medication errors.
    a. True
    b. False

32. The purpose of a national medication error reporting program is to share experiences among healthcare personnel so patient safety can be improved. It also can contribute to educational efforts to prevent future medication errors.

a. True
b. False

33. Which of the following medications have been identified as high-alert in all three healthcare settings—long-term care, community/ambulatory care, and acute care?
    a. Insulin, methotrexate (oral, non-oncology use), opioids, oral hypoglycemics
    b. Enoxaparin, warfarin, opioids, EPINEPHrine injection
    c. MetFORMIN, chemotherapeutic agents, promethazine IV, loratadine
    d. Heparin, enalapril, ISOtretinoin, potassium chloride injection

34. Which of the following is an error prevention strategy that can be used to avoid entering an order/prescription on the wrong patient?
    a. Verify the correct spelling of the patient name on a handwritten prescription.
    b. Use a minimum of two distinct identifiers such as patient full name and date of birth to confirm correct patient selection in the computer.
    c. Confirm patient address associated with name selection prior to entering order.
    d. All the above.

35. Which of the following describes the four steps of the PDSA cycle?
    a. Plan - Direct – Study – Act
    b. Predict – Do - Secure – Apply
    c. Plan – Do – Study – Act
    d. Process – Demonstrate – Statistics – Apply

SELF-ASSESSMENT ANSWERS

1. b.
2. d.
3. a.
4. c.
5. d.
6. c.
7. b.
8. c.
9. a.
10. b.
11. d.
12. a.
13. b.
14. c.
15. 1. The drug names are similar.
    2. More than one order is being prepared at the same time.
    3. The patient names are similar.
    4. It is a rushed work environment.
16. c.
17. b: write then repeat
18. b.
19. b.
20. c.
21. b.
22. b.
23. b.
24. c.
25. a.
26. d.

27. b.

28. T I W—misinterpreted as “three times a day”

    µg—mistaken for “mg”

    HS—unsure if it means “half-strength” or “at bedtime”

    Q.D.—might be misinterpreted as “QID”

    MS, MSO_4, $MgSO_4$— unclear if referring to morphine sulfate or magnesium sulfate

29. c.

30. b.

31. a.

32. a.

33. a.

34. d.

35. c.

CHAPTER 6

PHARMACY LAW AND QUALITY ASSURANCE



Learning Outcomes

After completing this chapter, you will be able to

- Understand how the practice of pharmacy is regulated by federal and state laws and regulations and the role of state boards of pharmacy.
- Discuss state pharmacy laws and regulations that govern pharmacy technicians, including permitted functions and the requirements for pharmacy technician registration or licensure.
- Discuss the laws that regulate controlled substances, special requirements for pharmacy ordering and dispensing controlled substances, and the role of state prescription monitoring programs.
- Describe the restrictions on the sales of products containing pseudoephedrine and ephedrine.
- Describe the U.S. Food and Drug Administration's approval process for drugs and the differences between brand name and generic drugs.
- Discuss generic drug substitution and the means for prescribers to indicate if substitution is not authorized.
- Discuss the difference between prescription drug inserts for prescribers and for patients.
- Discuss patient privacy in the pharmacy and the federal law that governs privacy of protected health information.
- Demonstrate an understanding of pharmaceutical products that require special handling.
- Identify products that require special handling.
- Complete the appropriate processes in the management of pharmaceutical recalls.
- Define quality assurance and describe the process.

The practice of pharmacy is extensively regulated by a number of laws and regulations. These laws and regulations cover essentially all aspects of pharmacy practice and establish permitted and prohibited conduct for pharmacies, pharmacists, and pharmacy technicians. States require pharmacies and pharmacists to be licensed. Many states have laws or regulations that

require pharmacy technicians to be licensed or registered and meet other requirements such as specific training and education, certification, and criminal history background checks. Pharmacy practice is also covered by ethical principles to provide a fundamental framework for interacting with patients. Examples of ethical principles are acting with honesty, integrity, compassion, and respect for patients.

Although states have the primary authority to regulate pharmacy practice, pharmacy is also subject to a number of federal laws. Examples of federal laws include the Food, Drug, and Cosmetics Act (FDCA), which regulates the safety of food, drugs, and cosmetics, and the Controlled Substances Act, which establishes requirements for the handling and dispensing of narcotics and other controlled substances. The Omnibus Budget Reconciliation Act of 1990 (commonly called OBRA 90) requires pharmacists to provide patient counseling as a condition of reimbursement when dispensing prescriptions to Medicaid patients. **Table 6-1** provides a timeline of some of these and other important federal drug laws.

✓ **If the state and federal laws or regulations differ, both laws and regulations must be followed, including the more stringent requirements, whether federal or state.**

STATE PHARMACY LAWS AND REGULATIONS

State pharmacy laws and regulations set the requirements for pharmacies, pharmacists, pharmacy technicians, and the practice of pharmacy. Both laws and regulations are necessary to regulate the practice of pharmacy, including pharmacy technicians. State pharmacy laws establish the legal requirements, restrictions, and prohibitions for the practice of pharmacy.

Because each state enacts legislation and adopts regulations for pharmacy, the particular requirements may vary from state to state. Nonetheless, an important and universal distinction for pharmacy technicians to understand is that they work under the supervision and direction of pharmacists and may perform only the tasks permitted under state law.

✓ **State pharmacy laws do not permit pharmacy technicians to perform pharmacy tasks and responsibilities that are limited to pharmacists and require the professional judgment, education, and training of a pharmacist.**

STATE BOARDS OF PHARMACY

State boards of pharmacy are responsible for regulating the practice of pharmacy including pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The state boards of pharmacy have regulatory authority over a number of areas such as licensing pharmacies and pharmacists; registering or licensing pharmacy technicians; inspecting pharmacies; issuing rules and regulations; investigating complaints; and disciplinary actions against pharmacies, pharmacists, and pharmacy technicians for violations of pharmacy laws and regulations.

PHARMACY TECHNICIANS

Many states have enacted laws and adopted regulations that pharmacy technicians must follow to assist pharmacists. However, the regulations for pharmacy technicians vary from state to state. The state board of pharmacy in each state is the best resource for obtaining the current standards.

✓ **The qualifications for pharmacy technician registration or licensure generally include a minimum age; high school graduation or the equivalent; completion of a training program, including pharmacy employer training programs; and an examination.**

Many states have established laws and regulations that set a limit on the number of pharmacy technicians that may assist a pharmacist at one time. Other states have no limits. These limits are known as *pharmacy technician ratios*.

PATIENT COUNSELING

OBRA 90 requires patient counseling for Medicaid patients, but states have laws and regulations addressing

TABLE 6-1. A History of the FDA and Drug Regulation in the United States

Year	Act	Purpose
1906	Food and Drugs Act	Outlaws states from buying and selling food, drinks, and drugs that have been mislabeled and tainted
1912	Sherley Amendment	Outlaws labeling drugs with fake medical claims meant to trick the buyer
1930	FDA	Food and Drug Administration is named
1938	Food, Drug, and Cosmetic (FDC) Act	Requires new drugs to be proven safe prior to marketing; starts a new system of drug regulation; requires safe limits for unavoidable poisonous substances; and allows for factory inspections
1951	Durham-Humphrey Amendment	Defines the type of drugs that cannot be used safely without medical supervision and limits the sale to prescription only by medical professionals
1962	Kefauver-Harris Drug Amendments	Requires manufacturers to prove that their drugs are effective prior to marketing
1972	Over-the-Counter Drug Review	Nonprescription medications must be safe, effective, and appropriately labeled
1982	Tamper-resistant Packaging Regulations	Makes it a crime to tamper with packaged products and requires tamper-proof packaging
1984	Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act)	Allowed FDA to approve generic versions of brand-name drugs without repeating research to prove safety and efficacy; allowed brand-name drugs to apply for up to 5 years of additional patent protection for new drugs to make up for time lost while their products were going through the FDA approval process
1988	Prescription Drug Marketing Act	Designed to eliminate diversion of products from legitimate channels of distribution and requires wholesalers to be licensed
1997	Food and Drug Administration Modernization Act	Expands scope of agency activities and moves agency to the Department of Health and Human Services (DHHS)
2003	Medicare Prescription Drug Improvement and Modernization Act	Includes Medicare Part D which increases access to medications through private insurers
2004	Project BioShield Act	Promotes timely distribution of medications in the event of a bioterrorist attack
2004	Anabolic Steroid Control Act	Prohibits over-the-counter sales of steroid precursors, such as dehydroepiandrosterone (DHEA)
2005	Drug Safety Board	Formed to advise the FDA's Center for Drug Evaluation and Research on drug safety issues and communication of safety information to healthcare professionals and patients
2005	Combat Methamphetamine Epidemic Act	Limits retail sale of over-the-counter products that contain ephedrine, pseudoephedrine, and phenylpropanolamine (PPA), which can be used to manufacture methamphetamine
2006	Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products	Approval of new labeling requirements designed to improve access, readability, and use of FDA-approved prescription labels

Source: Adapted from U.S. Food and Drug Administration, Center for Drug Evaluation and Research.

pharmacist patient counseling regarding prescription medications. *Pharmacist counseling* involves the pharmacist discussing the patient's medication treatment with the patient or the patient's caregiver. Counseling includes providing the patient with information about their medications such as what they are for, when and how much to take, whether to take with meals, how to store the medication, and possible side effects. Patient counseling is very important to ensure that patients take their medications correctly.

Nearly every state requires pharmacists to *offer to counsel* patients on new prescriptions. *An important point for pharmacy technicians is that a pharmacist must provide the patient counseling.*

CONTROLLED SUBSTANCES

Controlled substances are subject to stricter controls through federal and state laws and regulations than other drugs because of their potential for misuse, abuse, diversion, and addiction. Pharmacies, pharmacists, pharmacy technicians, as well as drug manufacturers, drug distributors, physicians, and other healthcare providers must comply with these additional requirements to avoid penalties and maintain their authorization to handle controlled substances.

The federal law regulating controlled substances is the *Controlled Substances Act*. The law and its regulations establish comprehensive requirements and controls over the manufacture, import, export, distribution, ordering, dispensing, and prescribing of controlled substances. The definition of **controlled substances** in the federal law includes drugs and other substances and their immediate precursor chemicals. A *precursor* is a substance that may be turned into a controlled substance through a chemical reaction (e.g., pseudoephedrine is a precursor for methamphetamine).

The federal law includes a number of requirements. Pharmacies, prescribers, wholesale distributors, drug manufacturers, and others must be registered with the Drug Enforcement Administration (DEA). Once registered, a DEA number is assigned. For a physician, the number starts with the letter A, B, F, or G followed by the first letter of the physician's last name and seven numbers. An example of the format of a DEA number is AS1234567. On occasion, the pharmacist may instruct the pharmacy technician on how to verify whether the prescriber's DEA number is valid.

One of the requirements for pharmacies includes using DEA Form 222, a special form to order Schedule II controlled substances. A pharmacist must complete DEA Form 222 and then the pharmacy's authorized pharmacist must sign it. Pharmacies are required to keep complete, accurate, and up-to-date records for controlled substances that they purchase, receive, distribute, dispense, or discard. Schedule II records must be kept separately from Schedule III, IV, and V records. Pharmacies are required to immediately report any theft or significant loss of controlled substances to the DEA using DEA Form 106, Report of Theft or Loss of Controlled Substances.

Schedules of Controlled Substances

The federal controlled substances law created five schedules (i.e., classifications) for controlled substances numbered I, II, III, IV, and V. A drug is placed into a controlled substance schedule based on certain criteria such as its potential for abuse or addiction and its medical use. The schedule a drug or substance is placed in determines its level of control. Schedule I *is the most restrictive schedule, and* Schedule V *is the least restrictive schedule of controlled substances* (**Table 6–2**). Because they have no legally approved medical uses, Schedule I drugs are not available in the pharmacy.

Federal regulations allow certain controlled substances to be dispensed only by a pharmacist without a prescription if specific criteria are met. These medications are called *exempt narcotics* or *exempt prescription products*. These criteria include:

- The pharmacist dispenses the product (although the actual sale can be completed by a nonpharmacist employee).
- The purchaser is at least 18 years of age.
- A limited amount can be purchased within a certain time frame.
- The pharmacy maintains a record book with information on the sale. The record book should include the purchaser's name and address, the name and

TABLE 6–2. Schedules for Controlled Substances According to Federal Law

Schedule	Classification Characteristics	Examples of Controlled Substances
Schedule I (CI)	No accepted medical use High potential for abuse Not available by prescription	Heroin and marijuana (including medical marijuana)
Schedule II (CII)	High potential for abuse or misuse, high risk of dependence, FDA-approved medical uses	Meperidine (Demerol), methadone, morphine, oxycodone (OxyContin, OxyIR), methylphenidate (Ritalin, Adderall, Concerta), hydrocodone with acetaminophen (Norco, Vicodin)
Schedule III (CIII)	Moderate potential for abuse, misuse, and dependence	Includes drug products that contain small quantities of controlled substances combined with other noncontrolled drugs such as acetaminophen and codeine (Tylenol #3)
Schedule IV (CIV)	Low potential for abuse and limited risk of dependence	Diazepam (Valium), lorazepam (Ativan), phenobarbital, and other sedatives and hypnotics
Schedule V (CV)	Lower potential for abuse, misuse, or dependence	Cough medications that contain a limited amount of codeine, antidiarrheal medications containing a limited amount of an opiate, such as diphenoxylate/atropine (Lomotil)

quantity of the product purchased, the date of purchase, and the name or initials of the dispensing pharmacist.

An example of a controlled substance that a pharmacist may dispense in some states is a Schedule V over-the-counter (OTC) cough syrup containing a limited amount of codeine. Some states, however, have stricter controlled substances laws and require that all controlled substances be dispensed by prescription only. In these states, because the state law is stricter than federal law, pharmacies must follow the state law.

Labeling of Controlled Substances

Federal law requires that the drug manufacturer's packaging for controlled substances is labeled with a specific symbol to indicate that it is a controlled substance. *The symbol to indicate a controlled substance is the letter* C *with the appropriate Roman numeral placed inside the* C *symbol.* A Schedule II controlled substance is denoted CII. Federal law requires that pharmacies place a specific caution message on the patient's container advising the patient that he or she may not give the controlled substance to any other person. The required statement is: *Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.*

Dispensing Controlled Substances

Prescribers and pharmacists both have responsibilities to ensure that only legitimate controlled substance prescriptions are issued and dispensed. For a controlled substance prescription to be valid:

- A licensed prescriber must prescribe it for a legitimate medical purpose in the normal course of the prescriber's professional practice.
- The prescribing practitioner must be registered with DEA (unless exempt from registration, such as Public Health Service physicians) and licensed by the state to prescribe controlled substances.

Pharmacists have a corresponding responsibility to dispense controlled substances pursuant to a valid prescription issued for a legitimate medical purpose in the course of the prescriber's practice. Prescribing a controlled substance or knowingly filling a controlled substance prescription in violation of laws and regulations may result in criminal or civil penalties.

Federal and state laws require specific information on prescriptions for controlled substances. Controlled substance prescriptions must include:

- Date issued
- Patient's full name and address

- Prescriber's name, address, and DEA registration number
- Drug name, strength, dosage form, and quantity prescribed
- Directions for use
- Number of authorized refills (if any)
- Prescriber's signature (unless a verbal prescription is permitted).

Pharmacists may dispense Schedule II controlled substances only pursuant to a written prescription signed by the prescriber unless an exception applies. For example, in an emergency, the prescriber may telephone or fax the prescription to the pharmacist. The prescriber must still provide the original written signed prescription to the pharmacist within 7 days and indicate that it was authorized for emergency dispensing.

Controlled substance prescriptions may also be transmitted to the pharmacy electronically. Some states require electronic transmission of controlled substance prescriptions. The computer software used to transmit and receive electronic controlled substance prescriptions must meet DEA's requirements.

Federal and state laws set specific requirements for refilling and transferring controlled-substance prescriptions. Schedule II prescriptions may not be refilled and are not transferable between pharmacies. Federal law allows Schedule III and IV prescriptions to be refilled up to five times within 6 months after the date that the prescription was issued by the prescriber. Schedule V prescriptions may be refilled more than five times, but have a 6-month time limit on refills.

Pharmacies are required to maintain complete and accurate records for all controlled substances that they purchase, receive, distribute, or dispense. Federal law requires the pharmacy to keep controlled-substance records for 2 years and have them readily available for DEA inspection if requested. State laws may require pharmacies to keep records for a longer time period. A separate inventory is required for each pharmacy location.

POP QUIZ!

Fentanyl is an example of what kind of controlled substance?

State Prescription Drug Monitoring Programs

Many states have enacted laws and regulations to institute prescription drug monitoring programs to monitor prescribing and dispensing of controlled substances. Most state prescription monitoring programs require pharmacies to report information on controlled substance prescriptions dispensed for drugs in Schedules II, III, IV, and V; however, some programs require reporting for dispensing of only Schedules II, III, and IV drugs. States use these programs to identify potential diversion and abuse of controlled prescriptions by the patient, pharmacy, or prescriber and to identify potential patients that would benefit from drug abuse treatment programs.

Restrictions on Sales of Products Containing Ephedrine or Pseudoephedrine

The sales of OTC drug products containing ephedrine and pseudoephedrine are subject to restrictions on their sales under federal law and laws enacted in many states. The federal law restricting sales of these products is called the *Combat Methamphetamine Epidemic Act of 2005 (CMEA).* It was enacted due to continuing concerns about the use of OTC products to illegally manufacture methamphetamine or amphetamine. Ephedrine and pseudoephedrine, which are the active ingredients in common cough, cold, and allergy products, are precursor chemicals to methamphetamine and amphetamine. The laws limit the amount of these products that a customer may purchase in a single transaction, in a single day, and over a 30-day period, and require that the products be locked up or otherwise not available for public access. Customers are also required to sign a logbook with details on the drug product and amount purchased. Federal law limits sales of these products to 3.6 grams daily and limits purchasers to 9 grams of these products in a 30-day period. The federal 3.6-gram daily limit for pseudoephedrine hydrochloride 30-mg tablets would be about 146 tablets or about 73 tablets of 60-mg pseudoephedrine hydrochloride.

Purchasers of ephedrine or pseudoephedrine must provide a valid photo identification and sign a logbook (which may be electronic) with their name, address, and date and time of purchase. The logbooks may be used by law enforcement to identify violations of the law.

BRAND NAME DRUGS AND GENERIC DRUGS

The FDA approves all drugs that are available for distribution in the United States to ensure that they are safe and effective. Before a new drug is approved, the drug manufacturer must submit a new drug application (NDA) to the FDA. The NDA includes information about the drug, including results from clinical trials in humans, results of animal studies, how the drug acts in the body, and how it is manufactured, processed, and packaged. If the FDA's review of the NDA is favorable and the drug is determined to be safe and effective, the FDA approves the drug for use in the United States.

Generic equivalents contain the same active ingredients and have the same dosage form, strength, and formulations as their brand name counterparts. Generic drug companies must submit abbreviated new drug applications (ANDAs). Generic manufacturers must meet the same standards for manufacturing, quality, and labeling as brand drug manufacturers; however, they do not need to repeat the original research. Instead, generic manufacturers must show that the generic drug is bioequivalent to the brand name drug, which means that the generic drug will deliver the same amount of the drug to the body in the same amount of time as the brand name drug.

Generic Drug Substitution

For drugs with an FDA-approved generic equivalent, pharmacists are permitted to substitute the generic equivalent drug for the brand name drug unless the prescriber prohibits generic substitution. Generic substitution by pharmacists is regulated by the state generic substitution drug laws and regulations. Depending on the state, the laws may instruct prescribers to indicate no substitution through various phrases on the prescription. Conversely, if the prescriber wants to permit substitution, state laws may instruct the prescriber to use terms such as "substitution permitted" or words of similar effect.

Not all drugs have a generic equivalent. If the drug company still has a patent on the drug, the brand name drug is the only one available. The Orange Book is used to find the FDA's determination that a particular manufacturer's generic drug is therapeutically equivalent to the brand name drug.

Biological Product Substitution

Biological products are large molecules that are often produced using biotechnology and include vaccines, monoclonal antibodies, and proteins. Different terminology is used when describing biological products. The original product approved by the FDA is called the reference product, and products that are similar to the reference product are called biosimilar products or biosimilars. However, biosimilar products are not the same as generic drugs. Variations can occur when manufacturing biological products, resulting in slight differences between similar products even though the two products produce the same effect. Because of these slight differences, the reference product and the biosimilar product are not considered interchangeable unless the biosimilar's manufacturer provides the FDA with additional information showing that there is no safety risk or change in efficacy for patients who switch between the reference product and the biosimilar product. If the biosimilar is approved as interchangeable with the reference product, then the biosimilar can be substituted for the reference product without the prescriber's approval, depending on state regulations. However, if the biosimilar product is not approved as interchangeable, then the prescriber will need to write the prescription for the biosimilar product. If the prescription is written for the reference product, the prescriber's approval would be needed before the biosimilar product can be dispensed. More information on biosimilar products is available from the FDA at www.fda.gov/biosimilars.

Prescription Drug Labeling and Package Inserts

Prescription drug products are labeled by the drug manufacturer. The prescription drug container label includes standard information such as

- Name and address of the drug manufacturer
- Drug name
- Strength and dosage form

- Manufacturer's expiration date for the drug
- Lot number
- Package size or quantity
- DEA schedule (if appropriate)
- *Rx Only* to indicate that the drug is for prescription use only

Prescription drugs are also called **legend drugs** due to a federal law enacted in 1951 (the Durham-Humphrey Amendment) that required certain drugs to require a prescription and be labeled with the statement (or legend), "*Caution: Federal law prohibits dispensing without a prescription*" or "*Rx only.*" Each product label must include a lot number and expiration date. The **lot number** is the number used by the drug manufacturer to identify each particular batch of the drug during the manufacturing process and is used to identify drug products that may need to be pulled from distribution in the event of a drug recall. The **expiration date** is derived from drug manufacturer's studies conducted on the drug's stability in the manufacturer's container. Drugs that have reached their expiration date may not be used or dispensed to patients.

Prescription drug products also include a **package insert**, which provides physicians, pharmacists, and other healthcare professionals with medical and scientific information about the prescription drug. The prescription drug package insert is not intended for patients.

Prescription Drug Information for Patients

Pharmacists provide patients with different types of written information for their dispensed prescription drugs. Patients are provided with printed information about their dispensed medication called *consumer medicine information (CMI).* In addition, the FDA requires pharmacists to provide patients with a *patient package insert (PPI)* when dispensing *certain* prescription drugs such as estrogens and oral contraceptives. PPIs must be provided with new and refill prescriptions when required.

Another type of written patient information used for certain prescription drugs is the *Medication Guide* or *Medguide.* Medication Guides contain FDA-approved information to help patients avoid serious adverse events, to inform patients about known serious side effects, or to promote patient adherence with their treatment.

Over-the-Counter Drug Labeling

OTC drugs are drugs that the FDA has approved to be safe for use by consumers without a prescription. Because they do not require a prescription, OTC drugs are labeled with information designed to help consumers use the medications correctly. The labeling for OTC drug products is intended to let the consumer know the uses for the drug, the recommended dosage, how often to use the drug, who should or should not take the medication, and to provide information on side effects and precautions for using the drug.

Poison Prevention Packaging Act

The federal Poison Prevention Packaging Act requires that prescription drugs, many OTC drug products, and other products such as household cleaners and furniture polish be sold in **child-resistant packaging**. The packaging must meet a test to show that it will prevent 80% of children from opening the package but allow 90% of senior adults to open the containers without difficulty.

The law allows consumers or the patient's prescriber to ask the pharmacist to dispense the medication in non-child-resistant packaging. Examples of exempt products include sublingual nitroglycerin tablets and oral contraceptives (birth control pills), which are packaged in numbered tablet dispenser packs.

POP QUIZ!

Give two examples of medications that are exempt from the Poison Prevention Packaging Act.

PATIENT PRIVACY

Pharmacies, pharmacists, and pharmacy technicians are required by federal and state laws to maintain the required privacy and confidentiality of patient health information. It is important to maintain privacy and confidentiality of patient health information and health

records. Failure to comply with the law may subject violators to penalties.

Virtually all pharmacy records contain private patient health information. Maintaining the privacy and confidentiality of patient health information requires appropriate safeguards for pharmacy patient records. Both state and federal laws establish requirements for maintaining privacy of patient health information. The primary federal law establishing health information privacy is the **Health Insurance Portability and Accountability Act (HIPAA)**. States also have laws protecting the privacy and confidentiality of patient health and medical information

HIPAA sets national standards for the privacy of medical records. HIPAA protects patients' individually identifiable health information, which is known as **protected health information (PHI)**. PHI is any health information that identifies the patient or could reasonably be used to identify the patient.

Pharmacies are permitted to use and disclose patient health information as necessary to provide patient healthcare services. HIPAA permits certain uses and disclosure of patient health information. HIPAA allows the use and disclosure of PHI for patient care, treatment, and healthcare operations. Such disclosures are necessary for providing pharmacy services including

- Dispensing prescriptions
- Patient treatment
- Billing for pharmacy services
- Managing patient care

LIMITED DISTRIBUTION DRUGS AND RISK EVALUATION AND MITIGATION STRATEGY

Limited distribution drugs (LDDs) have special requirements and are generally limited to drugs used to treat conditions that affect only a relatively small number of patients. Another term for the process associated with obtaining LDDs is **restricted access**. Because of their small market of patients, and sometimes because of FDA-imposed requirements, upon drug approval, manufacturers may choose to limit the distribution channel. This sort of limited distribution enables the manufacturer to keep track of the drug inventory and to ensure the proper education of pharmacists and that any required clinical monitoring of the patient occurs. The intent is to maximize patient benefit and minimize associated risks from the LDD therapy. In brief, the FDA, the manufacturer, and the distributor collaborate to establish tighter controls over LDD products.

If improperly administered, certain drugs can cause serious adverse effects such as blood disorders, birth defects, or changes in cardiovascular status. For example, the drug thalidomide can cause severe birth defects. If the clinical benefit of using a restricted access drug is perceived to outweigh the risks, the pharmacy can obtain it under prescription if proper screening, education, and monitoring requirements are satisfied. Often, these types of drugs carry what is known as a **risk evaluation and mitigation strategy (REMS)** requirement which is made by the FDA. The *REMS* is a strategy employed to manage known or potentially serious patient risks that may be experienced with a particular drug or biological agent. Generally, obtaining an LDD requires registration of the prescribing physician, dispensing pharmacy, patient-specific information, a patient agreement form, the specific indication for the medication, and its dose and quantity to be dispensed. It may also require a formal agreement to provide close clinical monitoring of the patient and related, de-identified patient data to be submitted for review. In some programs, laboratory results, adherence to a robust patient monitoring or outreach protocol, continuing education, and reimbursement information guaranteeing payment are required before the drug will be sent to the pharmacy. In some cases, pharmacies that dispense REMS products will be subject to an audit by the manufacturer, the FDA, or other third party. Examples of drugs with REMS include alosetron (Lotronex©), clozapine (Clozaril©, Fazaclo©), isotretinoin (Accutane©, Amnesteem©, Claravis©, Sotret©), thalidomide (Thalomid©), and dofetilide (Tikosyn©). Refer to **Table 6-3** for an example of REMS criteria pertaining to the LDD varenicline.

The FDA has designated other drugs that are required to be dispensed with Medication Guides. A

TABLE 6-3. REMS Criteria

Chantix (varenicline)	
a. Why is this medication required to have a REMS?	To inform patients about the serious risks associated with the use of CHANTIX, including the potential risk of serious neuropsychiatric symptoms in patients taking CHANTIX.
b. Do I or my hospital/pharmacy have to enroll in a certain program?	No
c. Does the patient have to enroll in a certain program?	No
d. Does the prescriber have to enroll in a certain program?	No
e. Do I have to verify that the patient and/or prescriber are enrolled?	No
f. Do I have to dispense a Medication Guide or any other material to the patient?	Yes
g. Is there monitoring involved with this medication?	No additional REMS monitoring currently required.
h. Can I order this medication through my usual supplier?	Yes
i. What do I have to document?	No REMS documentation currently required.
j. Am I required to complete CEs?	No
k. Are there restrictions on amount of this medication (i.e., quantity dispensed, refills)?	No
l. Am I or my pharmacy subject to an audit by the manufacturer/FDA/ or 3rd party?	No

CE = Continuing education requirement(s); FDA = Food and Drug Administration; REMS = risk evaluation and mitigation strategy

Source: REMS Database: Answers to 12 Basic Questions. https://www.ashp.org/Pharmacy-Practice/Resource-Centers/REMS/REMS-Database. ©ASHP. Accessed February 27, 2018.

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 (NSAIDs) and antidepressants.

POP QUIZ!

How many refills may be ordered for a prescription for alprazolam?

DRUG RECALLS

A **drug recall** effectively removes a manufactured product from the market. A manufacturer, on its own or at the direction of the FDA, will occasionally recall pharmaceuticals for such reasons as mislabeling, contamination, lack of potency, lack of adherence to the acceptable Good Manufacturing Practices, or other situations that may pose a significant risk to public health. The number of drug-related recalls has increased sharply since 2004, and the majority of these recalls were issued after 2012. A pharmacy must have a system for rapid removal of any recalled products.

Role of the U.S. Food and Drug Administration in Recalls

The FDA plays an active role in initiating the drug recall process. It coordinates drug recall information, helps manufacturers and distributors to develop specific recall plans, and performs health hazard evaluations to assess the risk facing the public by the recalled products. It also classifies recall actions in accordance with the level of risk and formulates recall strategies on the basis of the health hazard presented by the product in addition to other factors, including the extent of the distribution

of the product to be recalled. It decides on the need for public warnings and assists the recalling agency with public notification about the recall as needed. **Table 6-4** describes the various recall classes employed by the FDA and provides examples of each class.

Role of the Manufacturer/Distributor in Recalls

Because of their responsibility to protect the public consumer, manufacturers and distributors typically implement voluntary recalls when a drug product must be removed from the market. This method of recall is generally more efficient and effective in ensuring timely consumer protection than an FDA-initiated court action or seizure of the product.

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. To carry out a successful drug study, there are specific requirements and procedures that must be followed, including:

- Proper storage
- Record keeping
- Inventory control
- Preparation
- Dispensing
- Labeling of all investigational drugs

Quality Assurance Mechanisms

Quality control and continuous quality improvement (CQI) programs are also required by many of the accrediting agencies, such as the Joint Commission (TJC) and the Centers for Medicare & Medicaid Services (CMS; formerly the Health Care Financing Administration, or HCFA). Quality improvement is good practice, even if it is not required by regulatory oversight. The following are just a few examples of quality control and quality improvement activities:

- Completing refrigerator temperature logs
- Documenting inspections of nursing units and other medication stock areas
- Decreasing legibility errors by working with local physicians to provide electronic prescription transmission
- Improving medication turnaround time in the hospital by automating dispensing
- Decreasing wrong-drug/wrong-patient errors through the use of barcode identification systems
- Updating patient files at each prescription encounter to ensure that patient information is correct

Quality can be ensured through the use of quality control and through continuous quality improvement methods.

Quality Control

Quality control is a set of procedures followed during the manufacturing of a product or provision of a

TABLE 6–4. FDA Drug Recall Classes

	FDA Drug Recall Classes
Class I	The most serious of recalls; ongoing product use may result in serious health threat or death. **Examples:** food tainted with botulinum toxin, food containing undeclared allergens, a labelling mistake involving a lifesaving drug, or a faulty artificial heart valve.
Class II	Moderate severity concern; ongoing product use may pose slight threat of serious adverse events or irreversible consequences. **Example:** a drug that is subpotent but not generally used to treat a life-threatening condition.
Class III	Lowest severity concern; ongoing product use unlikely to cause adverse health threat; however, violates FDA product labeling requirements or manufacturing laws. **Example:** minor product container deficiencies.

FDA = Food and Drug Administration

service to ensure that the end product or service meets or exceeds specified standards. Checks and balances usually occur at critical points in the process. The start of any quality control program requires complete written procedures and training for all staff members involved in that procedure. Although quality control identifies and prevents errors or defects, it does not always identify or correct the underlying cause.

Quality Improvement

Quality improvement (QI) is a scientific and systematic process involving monitoring, evaluating, and identifying problems and developing and measuring the impact of the improvement strategies. It requires that decisions be based on facts (data). There are numerous QI models used today, including Six Sigma, Zero Defects, Total Quality Management (TQM), and Continuous Quality Improvement (CQI). There are also many tools used to identify problems, collect data, and analyze data. An example of a tool involving statistics is a run chart, which tracks patterns and trends over a period of time.

Technicians play key roles in many of the performance-improvement activities such as participating on performance improvement teams to collect and analyze data. Technicians may also assist in database management for quality improvement services such as adverse drug reaction reports, medication error reports, and medication-use evaluations.

SELF-ASSESSMENT QUESTIONS

1. Which of the following statements is **true** concerning the tasks that can be performed by pharmacy technicians?
   a. Pharmacy technicians can perform all pharmacy tasks when supervised by a pharmacist.
   b. Pharmacy technicians can perform tasks as permitted by federal and state pharmacy laws and regulations.
   c. Pharmacy technicians can perform any task without supervision of a pharmacist.
   d. Pharmacy technicians can perform any task requested by a pharmacist.

2. When state and federal laws regulating the practice of pharmacy differ,
   a. Only the state law needs to be followed.
   b. You can choose which law to follow.
   c. Only the more stringent law needs to be followed.
   d. Both state and federal laws must be followed, including the more stringent law.

3. Which of the following is **NOT** normally required to become a registered or licensed pharmacy technician?
   a. A degree from a school of pharmacy
   b. A minimum age
   c. Completion of a training program, including pharmacy employer training programs
   d. High school diploma or equivalent

4. Which of the following statements is **true** about controlled substances?
   a. Special forms are not required to order Schedule II controlled substances.
   b. Records for Schedule II drugs may be kept with the records for Schedule III, IV, and V drugs.

c. Theft and significant loss of controlled substances do not need to be reported to the Drug Enforcement Administration.
d. Only pharmacists can complete the DEA Form 222 for ordering Schedule II drugs.

5. There are federal and state laws and regulations concerning the dispensing of controlled substances, especially Schedule II drugs. Which of the following is **true** about prescriptions for Schedule II drugs?
   a. Faxed prescriptions for Schedule II drugs are allowed for all patients.
   b. Schedule II prescriptions cannot be transmitted electronically.
   c. Prescriptions for Schedule II drugs must include the prescriber's name, address, and DEA registration number.
   d. Prescriptions for Schedule II drugs can be refilled once within 6 months after the date the prescription was written.

6. Sale of products containing ephedrine and pseudoephedrine are restricted under the Combat Methamphetamine Epidemic Act of 2005. Which of the following is **NOT** a provision of that law?
   a. Products containing ephedrine and pseudoephedrine can only be dispensed with a prescription.
   b. There is a limit to the amount of ephedrine and pseudoephedrine that can be purchased daily and within a 30-day period.
   c. Pharmacies are required to keep records on the sales of ephedrine and pseudoephedrine products.
   d. Purchasers must provide a valid photo identification and need to sign a logbook.

7. Concerning brand name and generic drugs, which of the following statements is **true**?
   a. Generic manufacturers need to demonstrate that the generic drug is bioequivalent to the brand name product.
   b. Brand name manufacturers do not receive exclusive rights to market the drug while it is under patent.
   c. Generic drugs must look identical to the brand name drug.
   d. Both brand name manufacturers and generic manufacturers must submit NDAs to the FDA for approval.

8. When a generic equivalent is available for a brand name drug,
   a. The generic equivalent must always be dispensed regardless of the prescriber's or patient's preference.
   b. Only patients on Medicaid can receive generic drugs.
   c. Prescribers cannot indicate on the prescription that only the brand name should be dispensed.
   d. The Orange Book contains a list of generic drug products that are equivalent to the brand name drug.

9. Patient package inserts must be provided with which type of medications?
   a. All new prescriptions
   b. Over-the-counter medications
   c. New or refill prescriptions of oral contraceptives
   d. Sublingual nitroglycerin tablets

10. Patient privacy is protected by federal and state laws, most notably HIPAA. Which of the following is **true** about patient health information?
    a. All patient health information, even de-identified information, is PHI.
    b. HIPAA permits use of patient health information to provide pharmacy services.
    c. HIPAA does not apply to physicians or nursing home personnel.
    d. Patient health information can be discussed in the pharmacy, even if non-pharmacy personnel are present.

11. Quality control programs make sure that processes are working the way they are expected to, whereas quality improvement programs strive to make processes work better than before.
    a. True
    b. False

12. Which of the following medications are exempt from the Poison Prevention Packaging Act?
    a. All blood pressure medications
    b. Nitroglycerin
    c. All aspirin-containing products

13. Schedule I drugs have a high abuse potential and are only rarely used medically.
    a. True
    b. False

14. Benzodiazepines such as diazepam, lorazepam, and triazolam are Schedule _____drugs.
    a. II
    b. III
    c. IV
    d. V

15. What does OBRA 90 require?
    a. That pharmacists make the offer to counsel
    b. That the offer to counsel be made in writing
    c. That there be a minimum of two pharmacists on duty at all times so that one is available to do counseling
    d. That someone provide counseling, but that person can be a pharmacist or a technician—whoever is free at the time

16. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) strengthened patient privacy protection for health information.
    a. True
    b. False

17. Record retention rules vary by state, but the minimum amount of time most records should be retained is 7 years.
    a. True
    b. False

18. Laws that govern pharmacy technicians are the same in all 50 states.
    a. True
    b. False

19. _____ have/has the regulatory authority to license pharmacies.
    a. The Drug Enforcement Administration
    b. State Departments of Commerce
    c. State Boards of Pharmacy
    d. The FDA

20. Registration or licensure of pharmacy technicians is the responsibility of
    a. Pharmacy Certification Board
    b. National Boards of Pharmacy
    c. State Boards of Pharmacy
    d. Drug Enforcement Administration

21. Antidiarrheal medications that contain a limited amount of an opiate are
    a. C-III substances
    b. C-IV substances
    c. C-V substances
    d. Available OTC

22. Pharmacy logbooks containing information of pseudoephedrine sales are not permitted to be used by law enforcement.
    a. True
    b. False

23. Biosimiliar products are the same as generic drugs.
    a. True
    b. False

24. Disclosure of PHI is permitted for which of the following?
    a. Treatment
    b. Billing for pharmacy services
    c. Spouse healthcare purposes
    d. Never permitted

25. What does the acronym REMS mean?

26. The most serious drug recall is
    a. Class IV
    b. Class III
    c. Class II
    d. Class I

27. A continuous quality improvement program is designed to
    a. ID the technician or RPh making a drug error
    b. ID problems in the system that may be contributing to drug errors
    c. Only be utilized by supervisors when evaluating technicians or staff pharmacists

28. In states that have legalized medical use of marijuana, pharmacies may now dispense it.
    a. True
    b. False

29. Methylphenidate, used by ADHD patients, may
    a. Be refilled 5 times in 6 months
    b. Be refilled 6 times in 5 months
    c. Be refilled for up to a year
    d. Not be refilled

30. DEA form _____ is used to report theft or loss of controlled substances.
    a. 106
    b. 222
    c. 224
    d. 223

SELF-ASSESSMENT ANSWERS

1. b.
2. d.
3. a.
4. d.
5. c.
6. a.
7. a.
8. d.
9. c.
10. b.
11. a.
12. b.
13. b.
14. c.
15. a.
16. a.
17. b.
18. b.
19. c.
20. c.
21. c.
22. b.
23. b.
24. a. and b.
25. Risk Evaluation and Mitigation Strategy
26. d.
27. b.
28. b.
29. d.
30. a.

CHAPTER 7

MEDICATION DOSAGE FORMS, ROUTES OF ADMINISTRATION, AND DRUG USAGE



Learning Outcomes

After completing this chapter, you will be able to

- Explain why medications are often available in more than one dosage form.
- List three advantages of liquid medication dosage forms.
- List three disadvantages of solid medication dosage forms.
- Outline characteristics of solutions, emulsions, and suspensions.
- Explain the differences in use among solid medication dosage forms such as tablets, capsules, lozenges, powders, and granules.
- List six routes of administration by which drugs may enter or be applied to the body.
- Identify special considerations for five routes of administration.
- List five parenteral routes of administration.
    - Distinguish between sublingual, subgingival, and buccal routes.
- Define the study of biopharmaceutics.
- List and describe the four major processes that make up the study of pharmacokinetics.
- Describe factors that can alter the absorption of a medication.
- Describe how medications are distributed within the body, including factors that affect medication distribution in the body.
- List and describe the two most common types of drug interactions.
- Define pharmacodynamics.
- Describe how medications are eliminated from the body, including factors (e.g., disease states) that can increase or decrease elimination of a medication.
    - Define pharmacogenomics.
    - Describe the steps that must occur before a medication can exert its effect on the body.

This chapter is an introduction to commonly, and not-so-commonly, used medication dosage forms and administration routes. Pharmacy technicians must be familiar with these dosage forms and routes of administration because they work with them every day as they prepare, dispense, store, and otherwise manage medications. Additionally the pharmacy technician is often the first person in the pharmacy to handle a patient's medication, often filling multiple prescriptions for a single patient. Thus, the pharmacy technician who prepares prescriptions for dispensing should have a basic understanding of biopharmaceutics, pharmacokinetics, and pharmacodynamics, which collectively describe how a particular medication is prepared, is handled by the body, and affects the body.

MEDICATION DOSAGE FORMS

The most common medication dosage forms are liquids and solids. Liquid dosage forms deliver medication in a fluid and may be poured from a bottle or vial; solid medication dosage forms hold their original shape. Both dosage forms are usually administered into the mouth (orally), but may be administered by other routes.

✓ **A local effect refers to an action of a medication that happens where the medication comes in contact with the body. A systemic effect is an action of a medication that occurs throughout the body or in a place far from where the medication first contacts the body.**

Liquid Medication Dosage Forms

Liquid medication dosage forms deliver medication in a fluid. The fluid serves as a carrier, or delivery system, for the medication and is referred to as the *vehicle*. Medications can be dissolved in the vehicle or can float as very fine solid particles that are suspended, or hang, in the vehicle. Liquid medication dosage forms may pour as easily as water or be as thick as molasses. They may be taken by mouth (orally) or used in, or on, other parts of the body.

Liquid medication dosage forms offer the following advantages over other medication dosage forms:

- Oral liquid medication dosage forms are usually faster-acting than solid medication dosage forms.
- Patients who have difficulty swallowing may find oral liquid medications easier to take than medications in solid dosage forms.
- Liquids have more dosage flexibility than some other dosage forms because liquid medications are usually dispensed in bulk containers rather than individual dosage units.
- Liquid medications may be used where solid medication dosage forms are not practical.

There are also disadvantages to liquid medication dosage forms:

- Liquid medication dosage forms often have shorter expiration times than other dosage forms.
- Many drugs have an unpleasant taste.
- Patients sometimes find liquid medications inconvenient.

Table 7-1 gives examples of liquid medication dosage forms that are classified as solutions, emulsions, and suspensions.

TABLE 7–1. Liquid Medication Dosage Forms

Dosage Form	Examples
Solutions	Aqueous (water is the vehicle for the medication) Nonaqueous (the vehicle for the medication is not water)
Extractives	Extracts, tinctures, fluidextracts, and oil-in-water
Suspensions	Lotions, magmas and milks, gels
Emulsions	Mixtures of two liquids that normally do not mix

Solutions

Solutions are mixtures of medication particles evenly dissolved in a liquid.

Aqueous Solutions

These solutions use purified water as the vehicle and can be taken orally, applied externally (topically) on the skin, or injected into the bloodstream.

Viscous aqueous solutions are sticky, thick, sweet solutions that are either liquid or semisolid. A *syrup* is a mixture of sugar and purified water. A high sugar

content makes syrups a poor choice for patients who have diabetes mellitus.

The advantage of syrups is that their sweet taste can disguise the unpleasant taste of medications. Because syrups are thicker than aqueous solutions, they are commonly used for medications taken by children.

Jellies are semisolid solutions that have a high liquid content, usually water.

Nonaqueous Solutions

These solutions are those that use solvents, or dissolving liquids, other than water. Commonly used nonaqueous solvents include alcohol (ethyl alcohol or ethanol), glycerin, mineral oil, and propylene glycol.

Hydroalcoholic solutions differ from aqueous solutions in that they contain alcohol as well as water. Elixirs and spirits are examples of hydroalcoholic solutions. *Elixirs* [i-lick-serz] are clear, sweet, flavored water-and-alcohol mixtures for oral use. *Alcoholic solutions, also known as spirits* or essences, are alcoholic or hydroalcoholic solutions that contain volatile, or easily evaporated, substances. Because the volatile substances dissolve more easily in alcohol, spirits can contain greater amounts of these substances than aqueous solutions.

Extractives

Extractives are concentrated preparations of materials found in plant or animal tissue. The raw drug is removed from the dried plant or animal tissue by soaking it in a solvent. The solvent is then evaporated and leaves behind the parts containing medical activity. Extracts, tinctures [tingk-cherz], and fluidextracts are examples of dosage forms prepared this way. They differ only in their strength or potency.

Extracts

These are prepared the same way as tinctures and fluidextracts and are two to six times as potent as the raw drug.

Tinctures

Tinctures are alcoholic or hydroalcoholic solutions whose strength is adjusted so that each milliliter of tincture contains the equivalent of 100 mg of raw drug.

POP QUIZ!

What liquid dosage form has an alcohol base?

Emulsions

Emulsions are mixtures of two liquids that normally do not mix. In an emulsion, one liquid is broken into small droplets and evenly scattered throughout the other.

Oil-in-Water (O/W) Emulsions

In most emulsions, the two liquids are oil and water. An O/W emulsion occurs when small oil droplets are scattered throughout water.

Water-in-Oil (W/O) Emulsions

In W/O emulsions, water droplets are spread throughout the oil. W/O emulsions are often used on unbroken skin.

The choice of O/W or W/O emulsion for products used on the skin depends on several things. Medications that are irritating to the skin feel better when applied as small particles in the *internal phase*. The *external phase* keeps them from contacting the skin and causing irritation. O/W emulsions may be better in some cases because they are washed off with water and do not stain.

Suspensions

Suspensions are mixtures of fine particles of an undissolved solid spread through a liquid or, less commonly, a gas. The difference between a solution and a suspension is that the particles are dissolved in a solution, while in a suspension they are not. All suspensions must be shaken.

Lotions

Lotions are suspensions that are meant to be applied to the skin.

Magmas and Milks

These are thick, jelly-like suspensions of undissolved drugs in water.

Gels

Gels are similar to magmas and milks except that the suspended particle size in gels is smaller.

Solid Medication Dosage Forms

Medications are commonly formulated in a solid form. Examples of solid medication dosage forms include tablets, capsules, suppositories, and lozenges. Solid medication dosage forms allow for medications to be taken orally, rectally, or vaginally. **Table 7-2** summarizes the solid medication dosage forms that are discussed in this chapter.

Tablets

Tablets are compacted solid medication dosage forms. They may be further classified by how they are manufactured.

Molded Tablets

These tablets are made from wet materials made into a paste, which is then placed in a mold, shaped to the mold, and allowed to dry.

Compressed Tablets

They are formed by pressing powders, crystals, or granules into a solid shape using a high pressure die punch.

Other ingredients that have no medicinal activity may be included in a compressed tablet:

- Binders hold the compressed tablet together to keep it from crumbling.
- Diluents are fillers that are added to the active medication to make the tablet a practical size.
- Lubricants help to remove the tablet from the die punch.
- Colorants add color to the product.
- Disintegrators help the tablet break apart so it can dissolve more quickly in the stomach, small intestine, or elsewhere in the body.

Compressed tablets may have a *sugar, film,* or *enteric coating* on the outside. *Sugar coating* or *film coating* may be used to mask foul-tasting or foul-smelling drugs, to add color to the tablet, or to protect the drug from exposure to air and humidity. *Enteric-coated oral tablets* have a coating that protects the lining of the stomach from irritation by the drug. Tablets that are enteric coated should not be crushed, chewed, or cut. Doing so destroys the purpose of the coating.

TABLE 7–2. Solid Medication Dosage Forms

Dosage Form	Examples
Tablets	Molded
	Compressed
	■ Sugar-coated
	■ Film-coated
	■ Enteric-coated
	Sublingual
	Buccal
	Effervescent
	Chewable
	Vaginal
Capsules	Hard gelatin
	Soft gelatin
Caplets	
Lozenges	
Suppositories	Rectal
	Vaginal
	Urethral
Semisolids	Ointments
	Creams
	Pastes

Sublingual and Buccal Tablets

These are small tablets that dissolve almost instantly when placed under the tongue (sublingual) or in the pocket between the cheek and gum (buccal). The medication is absorbed into the bloodstream through the mucosal lining under the tongue or of the cheek and begins to work much faster than if it were swallowed as an oral tablet. Medications that are destroyed by stomach acid may also be formulated as sublingual or buccal tablets.

Effervescent Tablets

These tablets contain ingredients that bubble and release the active drug when placed in a liquid. Their advantage is that they break down and dissolve before administration and the drug can be absorbed quickly after it is taken.

Chewable Tablets

These are tablets that do not need to be swallowed whole and may, or even should, be chewed.

Vaginal Tablets

They are inserted into the vagina and dissolve. The medication may be absorbed through the vaginal mucous lining into the bloodstream or remain in the vagina to work within the vagina.

Capsules

Capsules are solid medication dosage forms where a drug, with or without inert ingredients, is packaged into a gelatin shell. The gelatin shells are made of animal protein.

Hard Gelatin Capsules

These are two-piece oblong shells filled with powdered ingredients.

Soft Gelatin Capsules

Soft gelatin capsules have ingredients added to the gelatin to give it a soft, squeezable, elastic character.

Caplets

Caplets are solid, capsule-shaped tablets that are generally coated for easy swallowing. They were designed to be more tamper-resistant than hard-shelled gelatin capsules.

Lozenges

Lozenges, also known as *troches* or *pastilles*, are hard, disk-shaped solid medication dosage forms that contain medication in hardened sugar. The lozenge is held in the mouth and sucked. As it dissolves, the lozenge releases the medication.

Suppositories

Suppositories are solid medication dosage forms that are inserted into the rectum, the vagina, or, very rarely, the urethra. Most often, suppositories are molded from a soft, solid material (called a *base*), such as cocoa butter or glycerin. Suppositories are designed to melt at body temperature. Patients should be instructed to allow suppositories to warm to room temperature before use and to remove the wrappers before insertion.

POP QUIZ!

What are some advantages to oral tablets?

Semisolid Medication Dosage Forms

Ointments

Ointments are semisolid medication dosage forms that are applied to the skin or mucous membranes. They lubricate and soften or are used as a base for drug delivery. The main types of ointment bases are *oleaginous, anhydrous, emulsion,* and *water-soluble*. Not all ointments contain medication. Ointments are categorized based on their characteristics.

Creams

Creams are semisolid O/W or W/O emulsions that may or may not contain medication. They are easily worked into the skin, or vanish, and feel lighter than ointments.

Creams and ointments are not always interchangeable. If a product is available as a cream and as an ointment, the prescriber will select the one which is most appropriate for the patient. A pharmacist cannot substitute a cream for an ointment or an ointment substituted for a cream without the prescriber's authorization.

Pastes

Pastes are semisolid medication dosage forms that contain medication intended for topical application.

Extended-Release Dosage Forms

In some cases, having a medication dosage form that slowly and consistently releases a drug over a period of time, instead of all at once, is desirable. These medication dosage forms are called *extended-release, sustained-release, long-acting,* or *controlled-release.* Although the exact meanings of these terms differ slightly, each of these terms indicates a slow release of medication over a longer period of time than standard dosage forms. **Box 7-1** lists common abbreviations used for extended-release products.

BOX 7–1. Common Abbreviations for Extended-Release Medications

CD	Controlled-diffusion
CR	Controlled-release, continuous-release
CRT	Controlled-release tablet
ER	Extended-release
LA	Long-acting
SA	Sustained-action
SR	Sustained-release, slow-release
TD	Time-delay
TR	Time-release
XL	Extra-long
XR	Extended-release

Extended-release dosage forms offer several advantages:

- They deliver medication in a slow, controlled, and steady way so the patient absorbs the same amount of medication throughout a particular time period.
- The chance of drug side effects is reduced.
- Patients may take the medication less frequently.
- Patients are more likely to take their medications properly.
- The daily medication cost to patients may be decreased.

There are disadvantages to extended-release dosage forms:

- There may be a delay between the time the patient takes the medication and the time it takes effect.
- If a patient experiences a side effect, it may take time for the effect to go away because some of the medication may remain in the body for a while.
- Most extended-release products cannot be cut, crushed, or chewed.
- The medication may be more expensive than an immediate-release product.

Some medications may leave ghost tablets. Patients should be warned that they may find these ghost tablets or remnants in feces. They may become concerned that the medication has passed through their bodies without having an effect. You can assure them that this is normal and that the medication has worked as it should have for drugs made with a matrix core.

Extended-release products should not be cut, crushed, or chewed. The extended-release properties of most extended-release products rely on the dosage form remaining intact and unbroken.

POP QUIZ!

What are some advantages to extended-release dosage forms?

Powders

Powders are finely ground particles of dry medication that can be used externally or internally.

Powders for injection must always be reconstituted before use. The powder should be totally dissolved in fluid and the resulting product inspected to be sure that there are no visible particles in the solution before giving it to the patient.

Granules

When powders are wetted, dried, and ground into coarse pieces, the resulting medication dosage form is called a *granule.*

Inhalants

Inhalants are fine powders or solutions of drugs delivered as a mist through the mouth into the respiratory tract. Many drugs used to treat respiratory conditions, such as asthma or chronic obstructive pulmonary disease (COPD), are formulated as inhalants.

Aerosols

Aerosols are suspensions of very fine liquid or solid particles spread through a gas and packaged under pressure. They need to be shaken before use.

A *nebulizer* works similarly to produce a fine mist that is inhaled by a patient. Compressed air is pumped through a liquid to make small droplets. These are then inhaled through a mask or mouthpiece.

Liniments

A liniment is a medication dosage form that is applied to the skin with friction and rubbing. Liniments may be solutions, emulsions, or suspensions. Some lini-

ments contain ingredients that cause a mild irritation or reddening of the skin.

Transdermal Patches

Adhesive transdermal patches, similar to plastic bandages, contain drugs in a small reservoir. Patches are convenient to use. Depending on the patch, it may be applied to the skin from once a day to once a week or longer.

Transdermal patches are formulated in one of two ways: (1) The patch itself controls the rate of delivery of drug to the skin. A membrane in the patch is in contact with the skin. The membrane controls the amount of drug delivered from a drug reservoir in the patch, through the membrane and skin, and into the bloodstream; or (2) The skin controls the rate of drug delivery. The drug moves from an area of high concentration of medication (the drug reservoir) into an area of low concentration (the skin and bloodstream). The disadvantage of this type of patch is that the release of drug is less controlled and a large amount of drug could suddenly be released from the patch into the blood.

Implants

An implant is a medication pump or device inserted semi-permanently or permanently into the body. Medication is released from the implant and delivered in a controlled fashion. Implants are often used to treat chronic (long-term) conditions or diseases. Some diabetic patients have a small pump implanted in their bodies that delivers insulin. Certain types of cancers may be treated with chemotherapeutic (anti-cancer) agents delivered into the arteries that enter the cancerous organ.

ROUTES OF ADMINISTRATION

Drugs can be administered by several different routes (see **Table 7-3**). Although the oral route is most common, it may not always be the most convenient or practical. Drugs may be administered into or through any body orifice or opening (e.g., mouth or rectum), through the skin (e.g., using creams, ointments, or transdermal patches), or into an artificially made opening (e.g., feeding tubes inserted directly into the stomach through the abdominal wall).

Oral

Medications taken by the oral route are introduced into the body through the mouth. The oral route is abbreviated **PO**, from the Latin *per os* (by mouth). Tablets, capsules, solutions, suspensions, and emulsions are some of the medication dosage forms that may be taken orally.

Sublingual, Buccal, Transmucosal, and Subgingival

The terms **sublingual** (under the tongue) and **buccal** (inside the cheek) refer not only to types of tablets, but also to routes of oral medication administration. To administer a sublingual drug, the drug is placed under the tongue where the medication dissolves and is absorbed into the bloodstream through the skin lining under the tongue.

Buccal tablets and *films* are placed inside the pouch of the cheek and stick to the inside lining of the cheek. Medication dissolves and is absorbed over time through the cheek lining (mucosa) into the bloodstream.

Sometimes, a patient may have difficulty swallowing or may not be alert enough to swallow. In this case, **transmucosal** drug administration, where drug enters the body through, or across, a mucous membrane, may be a practical option.

A **subgingival** medication is deposited into the subgingival space (the space between the tooth and gum) to treat gingivitis (inflammation of the gums).

Enteral

There may be times when patients cannot swallow a medication. Enteral medications might then be given via a route which avoids using the patient's mouth and need to swallow.

Parenteral

Parenteral routes of administration are those that do not use the digestive tract. Medications administered parenterally are most commonly introduced into the body intravenously, intramuscularly, or subcutaneously.

TABLE 7–3. Routes of Medication Administration

Route	Methods	Definition/Description
Oral	Oral	Through the mouth (PO)
	Buccal	Inside the cheek
	Lingual	On the tongue
	Sublingual	Under the tongue (SL)
	Subgingival	Under the gums
	Transmucosal	Across mucous membranes
Enteral	Enteral	By way of the intestine
	Nasogastric (tube)	A feeding tube inserted through the nose into the stomach (NG or NGT)
	Gastrostomy (tube), percutaneous endoscopic gastrostomy (tube)	A feeding tube inserted through the abdominal wall into the stomach (GT, PEG)
	Jejunostomy (tube)	A feeding tube inserted into the jejunum (small intestine) (JT)
Inhalation	Inhalation	Drawn through the mouth into the lungs
Parenteral	Parenteral	Bypassing the digestive (or gastrointestinal) tract
	Implant	A device inserted into or under the skin
	Intra-arterial	Into an artery (IA)
	Intra-articular	Into a joint (IA)
	Intracardiac	Into the heart muscle (IC)
	Intradermal	Into the top layers of the skin (ID)
	Intratracheal, endotracheal	Into the trachea (IT)
	Intramuscular	Into a muscle (IM)
	Intraperitoneal	Into the peritoneal (abdominal) cavity
	Intrapleural	Into the pleura (sac that surrounds the lungs)
	Intrathecal	Into the space around the spinal cord
	Intrauterine	Into the uterus
	Intravenous	Into a vein (IV)
	Intraventricular	Into the ventricles, or cavities, of the brain
	Intravesicular	Into the urinary bladder
	Intravitreal or intravitreous	Into the eye
	Subcutaneous, subdermal	Immediately under the skin (subcut, sub-Q)
Nasal	Intranasal	Into the nose
Ophthalmic		Into the eye
Otic, aural		Into the ear
Percutaneous		Through the skin
Rectal		Through the anus into the rectum
Topical		Applied to skin or mucous membranes
Transdermal		Through the skin
Vaginal		Into the vagina

A disadvantage of parenteral routes is that they are invasive—that is, a needle or other device penetrates the skin to enter veins, arteries, and other areas of the body.

Intravenous (IV)

IV medications are introduced into the body through a needle inserted into a vein. These drugs are usually given as solutions, which must be sterile and particle-free. IV drugs act immediately in the body.

IV drugs may be given as a *bolus,* by *short infusion,* or by *continuous infusion.* A *bolus dose* is injected into the body over a relatively short period of time—seconds to minutes—to produce an almost immediate effect in the body. The term *IV push* also refers to this administration technique—the drug is pushed into the body using a syringe and needle.

Intramuscular (IM)

IM administration involves injection of medication directly into a large muscle, such as the upper arm, thigh, or buttock. The drug is absorbed from the muscle tissue into the bloodstream.

Disadvantages of the IM route: It is difficult to reverse the drug's effects once the injection has been given, the injection is painful to receive and may cause bruising, and drug absorption from the muscle into the bloodstream may be unpredictable and incomplete.

Subcutaneous

Solutions or suspensions injected subcutaneously (sub-Q) are deposited in the tissue just under the skin. Patients can be taught to give subcutaneous injections to themselves.

Intradermal (ID)

The ID, or subdermal, route involves injecting a drug into the top layers of the skin. ID injections are not as deep as subcutaneous injections. The ID route is used to administer drugs for skin testing, such as tuberculin purified protein derivative (PPD), which is a test for tuberculosis.

Topical

The topical route usually refers to the application of medications to the skin or mucous membranes, although it also applies to other external parts of the body, such as fingernails and toenails and hair.

The **transdermal**, or **percutaneous** [pur-kyoo-tay-nee-uhs], route of medication administration delivers drugs through the skin. *Transdermal medications* are applied to the skin, released from a vehicle, and absorbed continuously into the bloodstream and delivered throughout the body.

Rectal

Drugs delivered by the rectal route are inserted through the anus into the rectum. Rectally administered drugs can be formulated as solids (suppositories), liquids or suspensions (enemas), or aerosol foams.

Otic

The otic route is used to deliver drugs into the ear canal. Otic drugs can be made as solutions or suspensions.

Ophthalmic

Drugs given via the ophthalmic route are administered to the outside surface of the eye. The ophthalmic route differs from the intravitreous route in that medications administered ophthalmically are applied only to the eye surface. They are not directly injected *into* the eyeball like those administered intravitreously. Ophthalmic products will be marked "sterile." Ophthalmic drops may be used optically, but otic drops may not be used ophthalmically because they are prepared in a sterile environment.

Nasal

Drugs are administered into the nostrils by the nasal route. Solutions can be nasally administered as sprays or drops. This route enables conditions of the nose, such as nasal congestion or allergic rhinitis, to be treated without administering the drug systemically.

Inhalation

Drugs can be inhaled through the mouth into the lungs. The inhalation route is used when a rapid drug effect is desired to treat lung conditions or when a local effect in the lungs is desired.

BIOPHARMACEUTICS

Biopharmaceutics is the study of the manufacture of medications for effective delivery into the body. It includes the relationships between the physical and chemical properties of a drug, the dosage form in which the drug is given, the route of administration, and the effects of properties and dosage on the rate and extent of drug absorption. It has long been recognized that the method by which a medication is prepared and formulated can affect its action. The study of biopharmaceutics has led to the improved design of drug products to enhance the delivery of medication and ultimately to optimize the clinical effects of medication.

Before most medications can exert a pharmacologic response, they need to be released from their formulations so they can be absorbed (taken up by the bloodstream). A medication in a tablet formulation, for example, is more than just the active drug. Any given tablet will contain not only active drug but also nondrug ingredients, such as binders that keep the tablet from falling apart, fillers that add bulk to the tablet, and preservatives. Two processes—disintegration and dissolution, in that order—usually need to occur before the medication can be absorbed. **Disintegration** is the breakdown of the medication from its original solid formulation, and **dissolution** is the dissolving of medication into solution, usually in the stomach and intestinal tract. Disintegration aids dissolution, as smaller particles dissolve more easily than larger particles. Once a medication is disintegrated and dissolved, it can be absorbed into the bloodstream. Some product formulations are disintegrated and dissolved more slowly or more rapidly than others, which may ultimately affect the rate of onset of therapeutic effect.

Medications that are given IV have a very rapid onset of action because the medications are already in solution (therefore disintegration and dissolution do not need to occur) and are placed directly into the bloodstream.

PHARMACOKINETICS

Pharmacokinetics is defined as the study of the movement of a drug through the body during the following phases: **absorption, distribution, metabolism**, and **excretion**. These processes are often referred to as *ADME*.

Absorption

Absorption refers to the amount of medication that enters the bloodstream, or systemic circulation. Not all the medication in a tablet, capsule, suppository, inhaler, or IM or sub-Q syringe enters the bloodstream, and, therefore, not all of it is absorbed. Except for topical products that are applied for a local effect, such as anti-inflammatory creams, only absorbed medication has the potential to exert a systemic pharmacologic effect.

The term **bioavailability** refers to the percentage of an administered dose of a medication that reaches the bloodstream. The bioavailability of an agent depends on many factors including the amount of drug dissolved, its dosage form, and its route of administration.

Some medications that are ingested orally are metabolized (broken down) before they reach the main bloodstream, which is referred to as **first-pass metabolism**. This often results in a small percentage of the medication metabolized on the first pass through either the intestine wall or the liver. Medications that undergo a high first-pass metabolism have a high amount of drug metabolized, and therefore a lower percentage is available to reach the main systemic circulation.

There are some routes of drug administration, such as rectal, inhalation, and sublingual, that avoid first-pass metabolism because they bypass the small intestine and liver, and the drugs are absorbed directly into the main bloodstream.

Medications given IV are administered directly into the vein and therefore enter the bloodstream directly. Thus, they have 100% bioavailability, meaning that 100% of the dose administered is available in the bloodstream and has the potential to exert a pharmacologic effect.

Distribution

Once absorbed into the bloodstream, medication either leaves the bloodstream or enters the tissues—including, but not limited to, the **site of action** (the tissue organ site where the medication is to exert its intended phar-

macologic response). Or, it remains in the blood, bound to protein components. Therefore, for any given dose of medication, some of it will travel to tissues and some will remain in the bloodstream. Some medications are highly bound to blood proteins, in some cases greater than 90%. The medication bound to blood proteins is inactive and does not exert any pharmacologic effect until it is released from the protein. Only medication that is *free,* or not bound to proteins, can leave the bloodstream and enter the tissues to exert a pharmacologic effect.

The apparent **volume of distribution** for a drug describes the extent of its outreach to various tissues and spaces throughout the body. In general, medications with a large volume of distribution will have a lower blood concentration, whereas medications with a small volume of distribution will have a higher blood concentration.

Certain other factors can also affect the extent of distribution of a drug throughout the body. Some medications that are highly bound (attracted) to proteins found in the bloodstream often have low volumes of distribution because they tend to stay in the bloodstream. These medications often have very high blood concentrations, and the amount (dose) of medication is relatively small compared with other drugs. Conversely, medications that have a high affinity to body fat and medications that either are bound to proteins in tissue or are not highly bound to plasma proteins tend to have high volumes of distribution—that is, they tend to be widely distributed throughout the body. The doses of these medications can be very high, sometimes upwards of 1–2 grams per day.

Knowing the volume of distribution of a certain medication can help the prescriber to approximate the dose of medication needed to attain the desired level of drug in the body for it to be effective or to start working quickly. If a medication is widely distributed through the body and the prescriber wants the medication to start working quickly, sometimes a *loading dose* of the medication (a larger first dose) will be given to more quickly achieve a higher drug concentration in the body.

Metabolism

The breakdown and elimination of drugs from the body occur by metabolism and excretion. The **metabolism** of medication is the breakdown of medication in the body. Here, the drug molecule is changed or altered in some way to create a secondary molecule called a **metabolite**. Some drug molecules are not susceptible to metabolic breakdown and may travel directly to the kidneys to be excreted. The liver is the major organ in which drug metabolism occurs, although significant metabolism can occur in the small intestine. Very little metabolism occurs in other organs, such as the kidneys and lungs. Metabolism is most often accomplished by protein substances called *enzymes.* The most common enzymes that metabolize drugs belong to a family of enzymes called the **cytochrome P450 (CYP)** system. These enzymes are very active in converting a drug to its metabolites.

In rare cases, metabolism can result in the formation of an *active metabolite* that may be more pharmacologically active than the parent (original) drug, or even toxic. It is therefore important to know whether the active metabolite acts in the same manner as the parent drug. There are also a few examples where a drug is administered in an *inactive* form, which is metabolized or converted to the active component. This inactive form is called a *prodrug*.

Excretion

Excretion refers to the irreversible removal of a drug or metabolite from a body fluid. The most common location of drug excretion in the body is the kidneys, with the biliary tract being another important route of excretion. In the kidney, some medications are excreted from the blood by a filtering process whereby drug is eliminated into the urine without being metabolized. After drug metabolism, many metabolites are water soluble, making them very susceptible to excretion by the kidneys.

The total removal of a drug via metabolism and/or excretion from the bloodstream per unit of time can also be referred to as drug *clearance*, which combines elimination rate with the flow of a drug through the organs of elimination (i.e., liver and kidneys). This term is often used to compare various drug pharmacokinetics based on organ blood flow values (in units of mL/min or L/hr).

The **half-life**, often designated by the term $T_{1/2}$, of a drug is also related to clearance and elimination. Here, half-life refers to the time that it takes for 50% of an amount of drug to be eliminated from the body. A drug with low clearance, meaning one that is not effectively metabolized or excreted, will typically have a long half-life. This means that it will take a long time to eliminate a dose of the drug from the body.

POP QUIZ!

What are the four steps in the ADME process?

DRUG INTERACTIONS

Drugs (and some foods) can compete with other drugs for metabolism within the system or alter the metabolic system altogether, resulting in **drug interactions**. A drug interaction is defined as the impact of a drug or food product on the amount or activity of another drug in the body. This drug-drug (or drug-food) interaction can result in enhanced, reduced, or new activity of the drug in the body. Some medications, foods, and herbal products can *inhibit* (or slow down) CYP enzyme activity, which results in reduced drug metabolism of other medications. Conversely, some drugs can *induce* (or speed up) the metabolism of other medications. These two mechanisms are the most common forms of drug interactions.

Some examples are:

- *Drug-drug interaction*—a potentially serious drug-drug interaction is that of valproic acid with the anti-seizure medication lamotrigine. Valproic acid inhibits the metabolism of lamotrigine, resulting in a 2-fold increase of lamotrigine blood levels, which could lead to a severe skin reaction.
- *Drug-food interaction*—an important drug-food interaction is grapefruit juice (a CYP enzyme inhibitor) with the lipid-lowering statin drug, simvastatin (metabolized by CYP). This interaction can lead to higher blood levels of simvastatin and potentially greater side effects, such as muscle soreness and liver abnormalities.
- *Drug-food interaction*—green leafy vegetables that contain high amounts of vitamin K, such as spinach and kale, can block the blood-thinning effects of warfarin (Coumadin), thereby increasing the risk of stroke or clot formation.

PATIENT VARIABLES AFFECTING PHARMACOKINETICS

Several factors can affect the normal processes of ADME, leading to altered pharmacokinetics. For example, drug absorption can be altered by a change in the speed of the GI tract, such as constipation or diarrhea. The diseases of the kidney and liver, such as cirrhosis, can impact elimination or clearance of a drug. Reduced elimination can then lead to a prolonged half-life of the drug when compared with patients without organ dysfunction. Changes in heart function or cardiac output can lead to changes in delivery of drugs via the bloodstream. Severe heart failure, in which there is low cardiac output, can lead to decreased blood flow to the kidneys and liver and therefore to decreased clearance of medications. Other patient factors include pregnancy, age of patient, and genetics.

PHARMACOGENOMICS

Over the past 10 years, much new information has been learned about how a person's genetics can influence the pharmacokinetics of drugs. The most important area related to drugs is the role of genetic variability on a few enzymes within the CYP enzyme that metabolize drugs in the liver. For example, one of the CYP enzymes called *CYP 2D6* metabolizes some opioid analgesic drugs such as codeine, oxycodone, and tramadol. This is important because codeine needs to be metabolized to morphine to become active (i.e., provide relief from pain). For people who have low genetic expression of CYP 2D6, this can mean that there is lower activation of codeine and little pain relief. In the future, use of genetic testing may help identify people who are "poor metabolizers" of CYP enzymes such as CYP 2D6, as a way to predict those who may not respond to some drugs or have side effects from others.

POP QUIZ!

What is the major organ of metabolism?

PHARMACODYNAMICS

Just as pharmacokinetics can be thought of as what the body does to the drug, pharmacodynamics can be considered what the drug does to the body. Pharmacodynamics refers to the study of the relationship between the concentration of a drug in the body and the response or outcome observed or measured in a patient. Examples of pharmacodynamics responses include an increase in bone mass with a bisphosphonate used for osteoporosis, a decrease in blood pressure with an antihypertensive agent, and a decrease in blood glucose with a sulfonylurea used in the management of diabetes.

For a pharmacologic effect to occur, a drug needs to be absorbed into the systemic circulation and travel to its intended site of action, or target organ, as described earlier. Next, it needs to bind to a specific receptor, like a key fitting into a lock. A receptor is a protein that is embedded on the surface of the cell and that allows communication between the outside and the inside of the cell. Once the drug binds to the receptor, this triggers a cascade of events that leads to the drug's response. The time that it takes to detect a drug's response, whether it be very rapid or delayed, is related to the drug-receptor binding process and to any subsequent chemical reactions that take place inside the target cell or organ.

By binding to the receptor, medications can either promote or block the signal that would ordinarily be generated by binding of the normally occurring substance to the receptor. Medications that augment or enhance a signal normally communicated in a cell are called *agonists.* Medications that block the transmission of a signal normally communicated in a cell are called *antagonists.*

The *drug-receptor complex* forms the basis of medication effects on the body. This drug-receptor interaction is what makes medications work—what makes the anti-heartburn medication soothe the stomach, the antibiotic help fight infection, and the pain medication relieve pain.

CONCLUSION

Medications are available in many dosage forms and may be administered by a variety of routes. By carefully considering the desired effects of a medication, its potential undesired effects, and a patient's characteristics and situation, the best combination of dosage form and route of administration route is selected. This results in optimal use of the medication and guarantees that the patient will receive the maximal benefit with minimal side effects.

Biopharmaceutics, pharmacokinetics, and pharmacodynamics collectively describe how medications are specially formulated, are handled by the body, and exert their actions in the body. Drugs must be used very cautiously in special cases, such as kidney disease, liver disease, elderly, and pediatric patients, to ensure that the desired clinical effects are achieved and side effects are avoided or minimized. The role of genetic variability in drug handling in the body is also important. A pharmacy technician must become familiar with the basic principles of these important areas to appreciate their contribution to the clinical effects, drug interactions, and toxicity of medications. When the technician is asked if a medication can be crushed, he or she will know why this seemingly simple question is a very important one with potentially problematic consequences if wrong directions are given. When the computer system alerts the technician to a drug interaction between an enzyme inducer and another medication, he or she will have a basic understanding of the mechanism of the interaction. Knowledge about loading doses will help the technician understand why there might be two doses given in a short period of time for the same drug. Knowledge of differences in dosing in special populations will help the technician assist in recognizing when doses make sense and when they should be questioned.

SELF-ASSESSMENT QUESTIONS

1. Which of the following liquids could be used to make a nonaqueous solution?

    1. Ethyl alcohol
    2. Water
    3. Propylene glycol
    4. Glycerin

    a. 1, 2, 3
    b. 1, 2, 4
    c. 1, 3, 4
    d. 2, 3, 4

2. A patient is recovering from a serious car accident in which he suffered a broken jaw and a broken arm. He is taking pain medication every 6 hours. He is home alone during the day while his wife is at work. Which of the following medication dosage forms is the best for his pain medication?

    a. A foil-wrapped rectal suppository
    b. A liquid solution dispensed in a bulk bottle
    c. A sublingual tablet
    d. An oral, hard gelatin capsule

3. All of the following statements are advantages of the oral route of administration compared to the IV route except _____:

    a. There is less chance of contamination by bacteria in the bloodstream.
    b. The effects of an orally administered drug may be more easily reversed if too high a dose is given.
    c. They are generally less expensive and are more convenient to administer.
    d. A drug given orally is available to act immediately in the body when used to treat serious conditions such as a heart attack or a severe allergic reaction.

4. A pharmacy technician reviews a prescription for vancomycin 500 mg IV to be given every 12 hours. Where is the vancomycin (an antibiotic) to be administered to the patient?

    a. Into a ventricle of the heart
    b. Into the urinary bladder
    c. Into a vein
    d. Into a ventricle of the brain

5. A _____ route of medication administration is one that bypasses the digestive tract.

    a. Parietal
    b. Parental
    c. Parenteral
    d. Parenthetical

6. Drugs that are administered through the mouth and swallowed are given by the _____ route.

    a. Oral
    b. Buccal
    c. Otic
    d. Aural
    e. Topical

7. For which patient would an oleaginous ointment be preferred over a cream?

    a. A patient who has a rash that is itchy and feels "hot" on his arms.
    b. A patient with very dry skin on his heels; the skin often cracks and bleeds, which makes it painful for the patient to walk.
    c. A teenager who has severe facial acne who was prescribed a topical anti-acne medication.
    d. A patient who has a "weepy" rash with watery discharge.

8. A local effect is one that occurs _____.

    a. At a site distant from the point at which the medication enters the body.
    b. Throughout the body.
    c. As a result of absorption of the medication into the body.

d. In the area where the medication is applied or administered.

9. Which of the following dosage forms must be shaken before use?
   a. Magmas
   b. Gels
   c. Emulsions
   d. Lotions
   e. All of the above

10. Which of the following routes of administration refers to application of a drug to the outside surface of the eye?
   a. Ophthalmic
   b. Otic
   c. Intravitreous
   d. Intravesicular

11. Which of the following is the FIRST process that a solid dosage form must undergo to exert a pharmacologic effect?
   a. Disintegration
   b. Dissolution
   c. Distribution
   d. Metabolism

12. The process of first-pass metabolism occurs in which of the following organs?
   a. Kidney
   b. Liver and small intestine
   c. Heart
   d. Pancreas

13. Which of the following pharmacokinetic processes is most impaired in the presence of renal disease?
   a. Absorption
   b. Distribution
   c. Metabolism
   d. Excretion

14. Administering a drug by which of the following routes most likely results in less than complete (<100%) bioavailability into the systemic circulation?
   a. Intravenous
   b. Subcutaneous
   c. Intramuscular
   d. b. and c.

15. What does an enzyme inducer do?
   a. It increases the metabolism of other medications.
   b. It increases the absorption of other medications.
   c. It increases the distribution of other medications.
   d. It increases the bioavailability of other medications.

16. A patient is currently taking simvastatin to treat high blood cholesterol. Simvastatin is known to be metabolized by the CYP enzyme system. After 2 weeks of taking simvastatin, the patient starts consuming large amounts of grapefruit juice, which is known to inhibit CYP enzymes in the liver. Which of the following is likely to occur when these two substances are given together?
   a. Blood levels of simvastatin will be increased.
   b. Blood levels of simvastatin will be reduced.
   c. Blood levels of grapefruit juice will be increased.
   d. Blood levels of grapefruit juice will be reduced.

17. Which of the following involves studying how a medication moves through the body?
   a. Biopharmaceutics
   b. Pharmacoepidemiology
   c. Pharmacokinetics
   d. Pharmacodynamics

18. Drug binding to a _____ is required to produce a clinical effect.
    a. Plasma protein
    b. Receptor
    c. Tissue
    d. Blood cell

19. A patient with large amounts of edema (swelling) may be expected to have increased drug _____.
    a. Absorption
    b. Distribution
    c. Metabolism
    d. Renal excretion

20. An order reads "1 PR q 4h prn nausea/vomiting." What dosage form would be dispensed?
    a. SL tablet
    b. Troche
    c. Suppository
    d. Buccal tablet

21. You receive an order for Gentamycin Otic solution. Your pharmacy formulary only stocks Gentamycin Ophthalmic solution.
    a. You dispense the ophthalmic solution since it is OK to use in the ear.
    b. You notify the patient you will have to procure the otic solution from your vendor and will deliver the prescription the next day.
    c. You dispense neomycin otic solution since that is the only otic antibiotic in stock.
    d. None of the above; you call the physician.

22. Medications that augment or enhance a signal normally communicated in a cell are called _____.
    a. Antagonists
    b. Agonists
    c. Receptors
    d. Enzymes

23. Pharmacodynamics refers to _____.
    a. The study of the movement of a drug through the body
    b. The study of the relationship between the concentration of a drug in the body and the response or outcome observed or measured in a patient
    c. The study of medication breakdown in the body
    d. The percentage of an administered dose of a medication that reaches the bloodstream

24. The major organ of metabolism is the _____.
    a. Pancreas
    b. Bladder
    c. Liver
    d. Heart

25. _____ is the route by which drugs are injected into the space around the spinal cord.
    a. Intra-articular
    b. Intraperitoneal
    c. Intravesicular
    d. Intrathecal

SELF-ASSESSMENT ANSWERS

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

CHAPTER 8

PROCESSING MEDICATION ORDERS AND PRESCRIPTIONS



Learning Outcomes

After completing this chapter, you will 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.
- 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.
- List the information that is typically contained in a patient profile.
- Describe the differences between a centralized and decentralized pharmacy in an institutional setting.
- Define medication reconciliation and medication therapy management.
- Describe the differences among various types of community and ambulatory practice care settings.
- Describe the technician's evolving role in community practice settings.
- Differentiate between questions technicians can answer and those reserved for a pharmacist.

This chapter describes the pharmacy technician's role in evaluating and processing medication orders and prescriptions from the time they are received until the medications leave the pharmacy.

PROFESSIONAL ROLES IN THE PHARMACY

The pharmacist is solely responsible for the proper acquisition, compounding, dispensing, and storage of drugs. The pharmacist is also an educator, responsible for instructing the patient and/or patient's caregiver(s) and the nurse on the drugs being administered.

Pharmacy technicians support the pharmacist by performing the majority of the technical pharmacy functions. These functions consist of generating medication labels; compounding, preparing, and labeling medications; and maintaining the compounding room and drug storage areas. The technician is the coordinator of the intravenous (IV) room, working with the pharmacist to arrange the mixing schedule, ordering and maintaining drug and mixing supplies, and performing quality assurance on compounding activities. Pharmacy technicians are often responsible for managing the warehouse and inventory of nondrug supplies, keeping track of accounts receivable, picking and packaging supplies for shipment to patients, and arranging for delivery of supplies to patients. In smaller companies, the pharmacy technician may wear many of these "hats."

See Chapter 5 in the *Manual for Pharmacy Technicians, 5th edition,* for more specialty pharmacy examples.

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: "**Rx Only**" previously was "Federal law prohibits dispensing this medication without a prescription." **Over-the-counter (OTC) 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 the pharmacy stocks and are approved for use in the facility. In the retail setting, the term generally applies 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 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).

RECEIVING AND PROCESSING MEDICATION ORDERS IN A HOSPITAL

Medication orders come to the hospital pharmacy in various ways. Written orders may be delivered to the pharmacy or one of its satellites in person or via a

mechanical method, such as fax transmission or pneumatic tube. Orders may also be telephoned to the pharmacy by either the prescriber or an intermediary, such as a nurse. Legal restrictions are placed 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 (it is recommended that generic drug names be used, 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 it is clear and complete. If information is missing—for example, the room number for the patient—the technician may be allowed to clarify the order on behalf of the pharmacist. Some clarifications, however, must involve the pharmacist.

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 the most critical or time-sensitive orders 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. Orders designated as **STAT** (abbreviation of statim, Latin for immediately), indicates an urgent need. A prescriber may also designate that a medication is to be started "now" or "ASAP" (as soon as possible), or simply state "start today" or "start this morning." A typical turnaround time for filling an order in an institutional setting might be 15 minutes for a STAT order and 1 hour for a routine order.

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 barcode technology and electronic charting to facilitate accuracy. In an institutional setting, **patient identification numbers** are generally used. Most commonly, patients are identified by two numbers: a *unique medical record number* that distinguishes patients from one another, and an *account number* that is specific to a transaction or set of transactions, such as an individual hospitalization or encounter. A patient's medical record number never changes, but account numbers change every time a patient is admitted to an institution.

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, 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 typically found in the hospital pharmacy's patient profile, although system settings may limit access to some components:

- Patient name and identification numbers
- Date of birth or age
- Sex
- Height and weight
- Certain laboratory 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
- Medication history (current and discontinued medications; medications from a previous admission, if applicable)
- Special considerations (e.g., foreign language, disability)
- Clinical comments (e.g., therapeutic monitoring, counseling notes)

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, 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 drug 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 to 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 IV medication is 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 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 on 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 (either paper or electronic **eMAR**).

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 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 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.

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 (Drug Enforcement Administration) 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 dispensed. The technician must know the requirements of their state.

POP QUIZ!

If a prescription were ordered 1 tab qid, ac and at bedtime, how would you write the label?

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. Forged prescriptions may also be telephoned in to the pharmacy.

To help prevent prescription forgery, a technician can 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 × even group (14 × 2)

= 19 + 28 = 47

The last digit of this odd/even group sum is the same as the last digit of the DEA number.

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
  - Principle diagnoses of patient
  - Primary healthcare providers
  - Third-party payer(s) and other billing information
  - OTC medications and herbal supplements used by the patient
  - Prescription and refill history
  - Patient preferences (e.g., child-resistant packaging waiver, preference for receiving prescriptions by mail)

- *Selecting the appropriate drug product*: 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.
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

Most prescriptions are now electronically filed with a third-party payer at the time they are entered into the pharmacy information system; this is called electronic claims adjudication. 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 (e.g., 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. 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)
    - Expiration date and physical description of the medication, if required

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 at least the following:

- Administration directions (e.g., "Take," "Insert," "Apply," "Instill")
- Number of units constituting one dose and the dosage form (e.g., two tablets)
- Route of administration (e.g., "by mouth," "vaginally")
- How frequently or at what time (e.g., "twice daily," "daily at 9 a.m.")
- Length of time to continue, if applicable (e.g., "for 10 days," "until finished")
- Indication of purpose, if applicable (e.g., "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 language barriers, such as illiteracy or a primary language other than English.

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.

POP QUIZ!

What does the first letter of the DEA number signify?

TRANSFERRING PRESCRIPTIONS

The laws regarding the transfer of prescriptions between pharmacies vary among states and among different classes of drugs. However, the pharmacist is 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 pharmacist's responsibility.

The same is true for prescriptions 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 as much information as possible from the patient 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.

HANDLING RESTRICTED-USE MEDICATIONS

Certain medications can only be prescribed and dispensed in a community or ambulatory care pharmacy, under specific conditions, due to special precautions regarding their use. The U.S. Food and Drug Administration (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 (Clozaril®, Fazaclo), isotretinoin (Accutane®, Amnesteem®, Claravis®, Sotret®), dofetilide (Tikosyn®), thalidomide (Thalomid), and transmucosal immediate-release fentanyl (TIRF) products.

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 (NSAIDs), antidepressants, opioids, amphetamines, antiepileptic, and hypoglycemic agents.

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, including:

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

INPATIENT PHARMACY SERVICES

Inpatient pharmacy services or hospital pharmacies are classified in many ways, one of which is where the dispensing and drug preparation takes place.

Centralized pharmacy services handle pharmacy personnel, resources, and functions from a central location. A typical centralized pharmacy contains a sterile preparation area or clean room, which is designed for the aseptic preparation of IV medications (e.g., antibiotic piggybacks, large-volume parenteral solutions with additives, total parenteral nutrition, chemotherapeutic agents), a medication cart filling area, and a storage area for medications and supplies. There are many advantages and disadvantages to centralized pharmacy services.

Technicians have several responsibilities in the central pharmacy, including:

- Preparing medications
- Filling patient medication carts
- Restocking automated medication dispensing devices
- Delivering medications to nursing units, including chemotherapy and controlled substances
- Extemporaneous compounding (i.e., preparing products not available from a manufacturer)
- Performing functions related to quality control and quality improvement
- Pulling expired or recalled medications
- Billing and miscellaneous paperwork
- Filling missing dose requests

Decentralized pharmacy services do not replace centralized pharmacy services; rather, they are used in conjunction with a central pharmacy. **Decentralized pharmacy services** are provided from patient care areas. One significant disadvantage to decentralized services is that they may require additional resources including personnel, equipment, stock, and inventory management. **Pharmacy satellites** are designated areas on a hospital floor or patient care unit where drugs are stored, prepared, and dispensed for patients.

Some advantages of decentralized pharmacy services include:

- Face-to-face interactions with patients and healthcare providers
- Shorter time to deliver medications
- Enhanced focus on the areas being served

Due to the increased availability of technology (e.g., automated medication dispensing cabinets and

the requirement for more resources compared to a centralized model), the use of pharmacy satellites has become less common. Many institutions either have limited satellites to specialized areas such as the operating room, pediatrics, or for preparing chemotherapy, or have decided not to use satellites.

MEDICATION MANAGEMENT

Medication management involves the entire medication-use process, including:

- selection and procurement of drugs
- storage
- prescribing
- preparation and dispensing
- administration
- monitoring the effects of the medication
- evaluation of the effectiveness of the entire system

To guide the pharmacy regarding which drugs to order and keep in stock, the hospital's **Pharmacy and Therapeutics (P&T) Committee** establishes a hospital formulary. Formulary medications are approved based on several criteria such as indications for use, effectiveness, drug interactions, potential for errors and abuse, adverse effects, and cost. This contrasts with community pharmacy in which most of the common drugs in a therapeutic class are available.

DRUG DISTRIBUTION IN INSTITUTIONAL PHARMACY

Two primary methods—automated medication dispensing devices and manual processes using medication carts or cassettes—are used in hospitals to dispense maintenance medications to patient care areas. The first method utilizes *automated medication dispensing devices*. **Automated medication dispensing devices** (e.g., Pyxis® MedStation™, Omnicell®) can help hospitals improve the availability of medications for administration to patients. The second method of dispensing maintenance medications usually requires the use of medication carts or cassettes. In this system, each patient is assigned to a medication drawer, usually arranged by bed number. All medications scheduled to be given during the selected fill-list time print, usually within a 24-hour period. Once these cassettes are filled, the pharmacist or technician checks the carts for accuracy.

Administration

Procedures are in place to ensure that medications are administered appropriately to patients, which includes providing them in a timely manner. Nurses perform a series of checks to ensure that the **right medication**, in the **right dose**, is given to the **right patient** at the **right time**, and by the **right route**. This is referred to as the **5 rights of medication administration**. The use of **barcode-assisted medication administration (BCMA)** allows the nurse to scan the patient's wristband and then the medication label to confirm that the right drug is given to the right patient.

TRANSITIONS OF CARE

Transitions of care refer to the movement of patients between healthcare practitioners, settings, and home as their conditions and care needs change. The review of medications at transition points is key to preventing medication errors and hospital readmissions.

Medication reconciliation is the process of creating the most accurate list possible of all medications a patient is taking—including drug name, dosage, frequency, and route—and comparing that list against the prescriber's admission, transfer, and/or discharge medication orders, with the goal of providing correct medications to the patient at all transition points. The importance of reconciling medications to prevent medication-related errors is well recognized and, over the last several years, it has become a task pharmacists routinely perform at many institutions. Pharmacy technicians may participate in this process by helping the pharmacist obtain a complete and accurate medication list.

Pharmacists and pharmacy technicians may also be involved in the discharge medication process. Once the decision is made to discharge a patient from the hospital, a series of activities needs to occur including writing, printing, or electronically submitting prescriptions for medications to outpatient pharmacies.

Some hospitals may have an outpatient pharmacy located inside the hospital that may offer a **meds-to-bed service** where patients can have their medications filled prior to discharge and either delivered to the beside or picked up by the patient before they leave.

ACCREDITING AND REGULATORY AGENCIES

Every hospital pharmacy is dedicated to offering the best pharmacy services possible and is committed to providing safe and effective medication therapy to all its patients. These agencies exist to ensure that each facility provides a safe and effective standard of care to patients. They are dedicated to helping hospitals provide the best care through meeting various standards or elements of care. Regulatory and accrediting agencies make site visits to inspect and verify that their published standards of care are met.

Examples of regulatory agencies include The Joint Commission (TJC; formerly known as the Joint Commission on the Accreditation of Healthcare Organizations, or JCAHO), Healthcare Facilities Accreditation Program (HFAP), and Det Norske Veritas Healthcare, Inc (DNV).

COMMUNITY PHARMACIES

Community pharmacies are generally broken down into two groups: *independent* and *chain pharmacies*. **Independent pharmacies** are generally owned and staffed by one or two individual pharmacists. An independent pharmacy owner may own a small number of pharmacies in a limited geographic area, but they are still generally considered to be independent. Originally, all pharmacies were independent, with chain pharmacies beginning to develop in the 20th century.

Chain pharmacies developed when companies began to own larger numbers of pharmacies that all used the same name and logo and carried similarly branded OTC products. As manufacturers began producing more pharmaceuticals, chain pharmacy companies gained a financial advantage by buying in bulk to supply their stores.

Mass merchandising and food store pharmacies are the most recent additions to community pharmacies. These retailers offer a wide variety of products from food to clothing, furniture, appliances, and other sundry items. Often called a **one-stop shop,** patients can have their prescriptions filled while they complete their other shopping needs.

Clinic Pharmacies

Clinic pharmacies are ambulatory care pharmacies that are located in clinics or medical centers to serve the needs of outpatients. These pharmacies may be owned and operated by the facility, owned independently, or may be a chain pharmacy that is located in the facility.

Ambulatory Care Pharmacists

The term **ambulatory** has such a broad definition that it is often used interchangeably with the term *community*. It is important to note that some ambulatory care pharmacists may work within a physician's office or medical clinic providing direct patient care. These pharmacists work closely with physicians to manage patients' disease states such as hypertension, diabetes, anticoagulation, asthma, and others.

Managed Care Pharmacies

Managed care pharmacies may be ambulatory pharmacies that are owned and operated as part of a managed care system, such as a health maintenance organization (HMO). They resemble clinic pharmacies but are operated by the managed care company for the patients they serve. As with clinic pharmacies, they are typically located in proximity to a medical facility.

Some managed care pharmacists and technicians may work directly for a **pharmacy benefits manager (PBM)** in a more corporate setting. The pharmacists are still providing ambulatory care services to patients by phone, but will send the product dispensing activities to one of their managed care pharmacies. There are opportunities for a pharmacy technician to work in a managed care PBM environment.

Mail-Order Pharmacies

Although classified as ambulatory pharmacies as they generally serve ambulatory patients, mail-order phar-

macies look and operate differently from other types of community and ambulatory care pharmacies. **Mail-order pharmacies** usually fill very large volumes of prescriptions and specialize in maintenance medications. Because of their high prescription volume, the prescription filling process is often highly automated, and there is generally less direct contact with patients, except by telephone and electronically via websites and the Internet. Mail-order pharmacies are more like warehouses with pharmacists and technicians.

PRACTICE TRENDS

As community and ambulatory pharmacy practice continues to evolve, pharmacies are finding new ways to serve their patients while also generating revenue to offset the financial pressures from reduced third-party payer reimbursement.

Newer practice trends include providing services as follows:

- medication therapy management
- health screenings
- immunizations
- dietary supplements
- specialty compounding

MEDICATION THERAPY MANAGEMENT

As community and ambulatory care pharmacies have evolved from a focus on dispensing to a focus on clinical management of medication therapies, many pharmacists have developed specialties in disease state management. The ability of skilled technicians to assume many of the important dispensing functions that pharmacists previously performed has allowed pharmacists to participate in medication therapy management (MTM). Disease state management or MTM is most common in the management of chronic conditions such as hypertension, hyperlipidemia, asthma, and anticoagulant therapy. Technicians may also be involved in this process by helping collect and manage the data and records necessary for pharmacist monitoring.

IMMUNIZATIONS

Many pharmacies provide immunizations for the prevention of various conditions. Probably the most common vaccine pharmacies offer is the influenza vaccine or the "flu shot," pneumonia, shingles, and travel vaccines. All states now allow pharmacists with special training to administer vaccines. In Idaho, pharmacy technicians who receive specialized training can also immunize patients. In general, technicians may assist with immunizations by registering patients, ordering, storing, preparing vaccine doses, and keeping required records.

DIETARY SUPPLEMENTS

With the decline in reimbursement from third-party payers for prescription drugs, many pharmacies have found an opportunity by specializing in dietary supplements, which generally include vitamins and minerals, amino acids, and herbs. More and more medically credible resources are becoming available to help pharmacists make informed recommendations and provide important warnings. As with OTC drugs, pharmacy technicians should be familiar with the products that the pharmacy stocks and be able to help patients locate specific products they request. It may also be necessary to direct a patient to the pharmacist for more information or to answer questions about a product.

HOME CARE

The primary members of the home care team are actively involved in the care of the majority of home infusion patients. Secondary members are involved only when a particular patient requires their service. Examples of secondary members include registered dietitians, respiratory therapists, social workers, physical and occupational therapists, and certified nursing assistants (CNAs).

DRUG INFORMATION

Pharmacy technicians are challenged with drug information questions frequently throughout the work day

and are called on to become knowledgeable about the handling, availability, and uses of medications. 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. Classifying the type of request helps to narrow the search and makes the search process more efficient. **Table 8-1** lists common types of questions that technicians may answer, with examples of each. Technicians should not interpret a patient-specific question or provide information that may require professional judgment.

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 by a pharmacist. **Table 8-2** has examples of questions that need to be referred to the pharmacist. A simply stated question can actually be a complex patient-specific situation. 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 (e.g., the Internet), which are available in all practice settings, often hold answers to typical day-to-day practice-related questions. **Table 8-3** contains some of the common reference sources, many of which are available in electronic formats.

TABLE 8-1. Classifications of Drug information Questions

Question Classification	Examples
General Drug Information	What is the brand name of warfarin? Do Naprosyn and Aleve contain the same active ingredient? Who manufactures Enbrel? Is Prilosec available as a generic? Is it a prescription or over-the-counter product?
Availability and Cost	What dosage forms of Imitrex are available in your pharmacy? Is Zoloft available as a liquid? If so, what size and concentration are available? What are the prices of Adalat CC and Procardia XL? How long is the shortage of albumin expected to last?
Storage and Stability	Should Lovenox be stored in the refrigerator? How long is a flu shot stable after it is drawn up in a syringe?
Calculations	How many milliliters are in an ounce?
Preparation	How should ampicillin be reconstituted?
Pharmacy Law	In what controlled substance schedule is zolpidem (Ambien)? Can Tiazac be substituted for Cardizem CD (is it AB rated)? How many times can a prescription be transferred from one store to another?
Miscellaneous	Where can I find the phone number for Sanofi Aventis? When will the patent for Lipitor expire? Where can I get more Lovenox teaching kits? Where can I find the Vaccine Information Sheet for the influenza vaccine?

TABLE 8–2. Drug Information Questions Appropriate for Pharmacists

Question Classification	Examples	Rationale
Identification and Availability	What is paracetamol and what is its U.S. equivalent?	Although it is appropriate for a technician to obtain technical information about availability (e.g., anticipated length/reasons for a shortage), questions that require clinical knowledge, such as therapeutic alternatives, must be answered by a pharmacist.
Allergies	Which narcotic is safe to use in a patient with a codeine allergy?	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.
Dosing and Administration	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?	Answers to dosing and administration questions depend on many factors, especially the indication for use and patient-specific information (e.g., age, weight, kidney, liver function).
Compatibility	Is Primaxin compatible with dopamine?	More information is needed (e.g., doses, concentrations, fluids, type of IV lines), and a pharmacist must interpret information found in a reference and apply it to the situation.
Drug Interactions	Is it OK to take aspirin with warfarin?	Drug interaction questions are complex and require patient-specific information and interpretation by a pharmacist to apply the significance of a potential interaction to a specific patient.

Question Classification	Examples	Rationale
Side Effects	What are the side effects of Lexapro? Can Celebrex cause renal failure?	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 made because an adverse event is suspected with one or more medications.
Pregnancy and Lactation	Is albuterol safe to use in pregnancy? Can I get a flu shot if I am breastfeeding?	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.
Therapeutic Use	Has clonidine been used to treat opiate withdrawal?	The use of drugs for non-FDA approved uses often requires evaluation and interpretation of the literature and clinical judgment.

IV = intravenous; U.S. = United States

TABLE 8-3. Common Drug Information Requests and Reference Sources

Type of Information Needed	References Likely to Have the Information
Product Availability Dosage form, product strength, brand and generic name, manufacturer indication	Facts & Comparisons Drug Information Handbook; Internet *PDR*; *Micromedex Clinical Pharmacology USPDI Pharmaceutical Manufacturer*
Product Identification Dosage form, product strength, brand and generic name, manufacturer, colored photographs of tablets/capsules	Facts & Comparisons; *PDR Clinical Pharmacology; USPDI Micromedex*
Drug Uses FDA-approved indications; other uses of the agent	*AHFS Clinical Pharmacology*; Facts & Comparisons Drug Information Handbook; *PDR* (FDA-approved indications only) *Micromedex USPDI*
Drug Monographs General drug information, pharmacology, indications and uses, drug interactions, admixture information, doses, adverse effects, drug interactions	*AHFS Clinical Pharmacology; Facts & Comparisons Drug Information Handbook*; *Micromedex PDR USPDI*
Injectable Drug Compatibility/Stability Information Drug diluent and solution compatibilities, drug compatibility, conditions for handling and storing products (i.e., glass vs. plastic container, protection from light, filters, refrigeration, expiration)	*AHFS; King's Guide to Parenteral Admixtures;* Handbook on Injectable Drugs; package inserts; *PDR Micromedex*
Preparation	*AHFS*; *King's Guide to Parenteral Admixtures;* Handbook on Injectable Drugs; *Micromedex;* package inserts; *PDR*
Calculations	*Drug Information Handbook*; *Micromedex*
Hazardous Chemicals and Drugs Specifies hazards of the chemicals or drugs used at the worksite, guidelines for their safe use, recommendations to treat or clean up an exposure	Material Safety Data Sheets; *Micromedex*
Pharmacy Law Generic substitution (bioequivalence), federal regulations regarding handling and dispensing	USPDI Volume III Orange Book
Patient Information	*Clinical Pharmacology Facts & Comparisons* Internet *Lexi-Comp*; *MedlinePlus; Micromedex*; patient package inserts, Medication Guides; *USPDI Volume* I

SELF-ASSESSMENT QUESTIONS

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. prn
   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
   d. In some states when they refuse counseling
   e. All the above
   f. Only a, c, and d

8. Examples of drugs with REMS include clozapine, thalidomide, and _____.
   a. Isotretinoin and fentanyl
   b. Isotretinoin and sildenafil
   c. Alosetron and methadone
   d. Sildenafil and fentanyl

9. 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 I store this antibiotic suspension in the freezer?
   d. Does simvastatin interact with grapefruit juice?
   e. What should I substitute for morphine if my patient is allergic?

10. Anyone who has worked in a pharmacy for a minimum of 2 years may receive a telephone prescription from a physician's office.
    a. True
    b. False

11. Generally, the first step when a prescription is received is to review the prescription for completeness and accuracy, and the second is to

prioritize the prescription in relation to the other work to be done.

a. True
b. False

12. An outpatient pharmacy generally has a single formulary that is used for all patients, regardless of the third-party payer.

a. True
b. False

13. Which of the following pieces of information should be on a prescription in an outpatient pharmacy and are also required on a medication order for a hospitalized patient?

a. Patient's address
b. Prescriber's address and telephone number
c. Refill information
d. Patient's name

14. When searching for a medication name in a pharmacy computer system search screen, typing fewer letters will result in a shorter list and is therefore less likely to result in a mispicked item.

a. True
b. False

15. Any suspicious prescription should be brought to the attention of the pharmacist because it may be a forgery.

a. True
b. False

16. Which of the following medications are often required urgently in a hospital setting?

a. Docusate
b. Norepinephrine
c. Naloxone
d. Both b and c
e. None of the above

17. Many hospitals have default times of the day associated with common dosing frequencies.

a. True
b. False

18. Patient identification is a significant concern in an outpatient pharmacy, because the technician needs to make sure that medications are delivered to the correct patient.

a. True
b. False

19. Barcoding technology eliminates the chance of errors with regard to medication administration.

a. True
b. False

20. A thorough review of a well-kept patient profile in an outpatient pharmacy will generally allow the technician to identify all of the following *except:*

a. Existing orders for the same medication.
b. Allergies that may indicate that the medication should not be used.
c. A disability, such as blindness, that requires special attention.
d. Credit card information.

21. Common screening options during a pharmacy- or nursing-operated computerized order entry process in a hospital include all of the following *except:*

a. Therapeutic duplication
b. Insurance information
c. Allergy screening
d. Dose range checking
e. Drug interactions with existing orders

22. Special instructions for nurses may be included on a hospital medication label.

a. True
b. False

23. In the outpatient setting, appropriate medication administration times must be discussed with the patient or family member to ensure optimal benefit.

a. True
b. False

24. In the case of a prescription with complex directions, such as "tid for 3 days, bid for 3 days, qd for 3 days, and dc," it is acceptable to use the Latin abbreviations on the label as long as they are carefully explained to the patient.
    a. True
    b. False

25. Which of the following statements about prescription labeling is *false*?
    a. Some prescriptions require labeling beyond what will fit on the label itself.
    b. Auxiliary labels are often used to clarify or elaborate on directions for use.
    c. If the patient is in a hurry, it is acceptable to dispense the prescription without an affixed label as long as you talk to the patient about how to use the medication and he or she understands.
    d. Most states have specific requirements about what information must be included in prescription labeling.

26. Which of the following best incorporates all recommended components of label directions for outpatient use?
    a. Take one tablet by mouth three times daily.
    b. Take one tablet three times daily.
    c. Take one tablet by mouth three times daily for 10 days.
    d. Take one tablet by mouth three times daily for 10 days as needed for pain.

27. Inpatient pharmacies may become more efficient by implementing decentralized dispensing automation, thereby moving more of the filling functions to batch runs.
    a. True
    b. False

28. Which of the following is *not* true of hospital pharmacy dispensing automation?
    a. Dispensing automation may be centralized in the pharmacy or decentralized at the point of care.
    b. Decentralized automation is superior to centralized automation.
    c. Both centralized and decentralized automation make dispensing more efficient.
    d. Some institutions combine both centralized and decentralized automation to incorporate advantages of both systems.

29. When a filling label seems to indicate an error, which of the following would be an appropriate *initial* action for the technician?
    a. Alert the pharmacist that an error has been made.
    b. Check the label against the original order to determine if an error was made.
    c. Call the physician to clarify the order.
    d. Fill the prescription to the best of your ability, and then clarify it with the pharmacist.

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

31. Which of the following statements about drug diversion is true?
    a. A pharmacy technician can help to prevent diversion by keeping complete and accurate records of transfer of controlled substances both in and out of the pharmacy.
    b. If you witness a coworker not following department drug diversion policies or procedures, call the local police department nonemergency line to report potential diversion.

c. If your doctor prescribes a controlled substance for you and you need a dose at work but didn't bring your supply with you, you may take a dose from the pharmacy.
d. Drug diversion rarely occurs and is easily preventable.

32. All the following are components of the medication-use process in the hospital except _____.
a. Administration
b. Prescribing
c. Monitoring
d. Insurance verification

33. Advantages of decentralized pharmacy services include the following:
a. Face-to-face interactions with healthcare providers and patients
b. Shorter time to deliver medications
c. Enhanced focus on the areas being served
d. All the above

34. Nontraditional technician roles include the following:
a. Participating in medication reconciliation activities
b. Serving as an informatics specialist to manage stock in automated dispensing cabinets and troubleshoot issues related to functioning and storage of medications in automated dispensing cabinets
c. Helping with clinical pharmacy services by collecting clinical data, tracking medication errors, or helping with clinical projects
d. All the above

35. Medications in the hospital must always be stored in the pharmacy and not on units or floors.
a. True
b. False

36. Benefits of automated dispensing devices include the following:
a. More accurate billing
b. Bar coding technology to reduce medication errors
c. Reporting discrepancies
d. All of the above

37. Which of the following forms of technology are primarily located in patient care areas that dispense medications to nurses for administration to their patients?
a. EXACTAMIX
b. Pyxis Medstation™, OmniCell®
c. Crash carts
d. Medication administration record (MAR)

38. Ambulatory care pharmacies include all of the following *except* _____.
a. Clinic pharmacies
b. Home care pharmacies
c. Independent pharmacies
d. Managed care pharmacies

39. The term *pharmaceutical care* refers to _____.
a. The proper storage of pharmaceutical products
b. The careful handling of private patient information
c. The role of the pharmacist as a manager of drug therapy
d. Patient counseling requirements for each prescription dispensed

40. Technician responsibilities include the following:
a. Ensuring patient privacy
b. Resolving third-party rejects
c. Counseling patients on their medications
d. Only a and b

41. A new patient brings a prescription to the pharmacy. What information should the technician obtain from the patient?
    a. The patient's date of birth
    b. Any allergies to medications
    c. Prescription insurance information
    d. All of the above should be obtained

42. Which of the following questions may a technician answer for a patient?
    a. What can I take for a cold?
    b. Where can I find the aspirin?
    c. What is the best thing for pain?
    d. Can I take this drug if I have high blood pressure?

43. During a point-of-sale (POS) transaction, important technician functions include the following:
    a. Verifying the patient's identity
    b. Answering a patient's questions about their prescription
    c. Meeting requirements for offering patient counseling by the pharmacist
    d. Only a and c

44. In addition to the prescription filling process, a technician may be responsible for all of the following except _____.
    a. Managing inventory
    b. Managing pharmacy records
    c. Providing disease state management services
    d. Preparing compounded drugs

45. To maintain patient privacy, a technician should not _____.
    a. Provide patients with the HIPAA policy in writing
    b. Discuss patient information in a private environment
    c. Place private information in an appropriate location for destruction
    d. Discuss patient information in a normal voice so it can be heard by others

46. Which of the following statements is true?
    a. Technicians play a critical role in allowing pharmacists to participate in medication therapy management.
    b. Technicians have less direct contact with patients in community and ambulatory care pharmacies than in other pharmacy practice settings.
    c. Accuracy is not an important responsibility for a pharmacy technician during the prescription filling process because all prescriptions must be checked for accuracy by a pharmacist.
    d. Technicians are not allowed to prepare compounded medications.

47. The directions on a prescription read: "*gtt ii both eyes BID,*" so what instructions should appear on the prescription label?
    a. Take two drops into your eyes twice a day.
    b. Put drops into both eyes twice a day.
    c. Instill two drops into each eye twice a day.
    d. Apply two drops into each eye twice a day.

48. A patient's medical record number changes with each admission or each clinic visit.
    a. True
    b. False

49. Which directions for use would be most appropriate for the following Cephalexin 500 mg capsules: SIG *"ii po now, then i QID X 10 days"*?
    a. Take two tablets now then one tablet four times a day for 10 days.
    b. Take two capsules by mouth now then one capsule four times a day for 10 days.
    c. Take two tablets by mouth now then one tablet four times a day for 10 days.
    d. Take two capsules now then one capsule three times a day for 10 days.

50. In addition to prescription medication and the refill history of prescriptions, a patient's profile should also include the following:
    a. Current disease state
    b. Any OTC medication, including herbal medication the patient takes
    c. The patient's healthcare providers
    d. All the above should be included

SELF-ASSESSMENT ANSWERS

1. b.
2. a.
3. d.
4. d.
5. b.
6. c.
7. e.
8. a.
9. c.
10. b.
11. a.
12. b.
13. d.
14. b.
15. a.
16. d.
17. a.
18. a.
19. b.
20. d.
21. b.
22. a.
23. a.
24. b.
25. c.
26. c and d are both correct
27. a.
28. b.
29. b.
30. b.

31. a.
32. d.
33. d.
34. d.
35. b.
36. d.
37. b.
38. b.
39. c.
40. d.
41. d.
42. b.
43. d.
44. c.
45. d.
46. a.
47. c.
48. b.
49. b.
50. d.

CHAPTER 9

PHARMACY INVENTORY MANAGEMENT



Learning Outcomes

After completing this chapter, you will be able to

- Describe the formulary system and its application in a purchasing and inventory system.
- Execute lending and borrowing pharmaceutical transactions between pharmacies.
- Apply the proper principles and processes when receiving and storing pharmaceuticals.
- Discuss the process for managing medication inventory.
- Identify products that require special handling.
- Complete the appropriate processes in the management of disposal of pharmaceutical products.
- Define medication reconciliation and medication therapy management.
- Describe the differences among various types of community and ambulatory practice care settings.
- Describe the technician's evolving role in community practice settings.
- Differentiate between questions technicians can answer and those reserved for a pharmacist.

Purchasing and inventory control processes impact the ability of the system to provide the *right* drug, to the *right* patient, in the *right* amount, in the *right* dosage form, by the *right* route of administration, and at the *right* time and frequency (known as the **5 rights**). Therefore, an effective purchasing and inventory control system requires the understanding and active participation of all pharmacy staff.

This chapter describes the basic principles of pharmaceutical supply chain management. It applies to all types of pharmacy settings including decentralized, centralized, home infusion, and ambulatory care pharmacy operations.

Pharmacy technicians are often principally involved in procuring medication and related supplies for the pharmacy. Many hospitals must maintain compliance with the regulatory standards of the Centers for Medicare & Medicaid Services (CMS) and also strive to maintain accreditation by organizations such

as The Joint Commission (TJC). Regulatory standards on medication management are intended to guide operational procedures and promote consistently safe practices related to the procurement, storage, prescribing, dispensing, administration, and monitoring of pharmaceuticals. Pharmacy technicians are such an important part of preparation and dispensing of medications; their knowledge and performance in adhering to established standards are critical to the success of the pharmacy department.

PURCHASING AND INVENTORY CONTROL SYSTEM

Some pharmacies employ a few specialized individuals charged with managing the purchasing and inventory process of pharmaceuticals. Others employ numerous individuals in the role. The state-of-the-art practice involves the use of automated technology to manage the processes of purchasing and receiving pharmaceuticals from drug wholesalers. This technology uses sophisticated software algorithms often involving robotic devices, barcode scanning, and computer integration. These systems are highly automated, yet they require a human interface to oversee and manage the process. Other practices simply use technology, including product barcodes and hand-held computer devices that enable electronic data transmission in this process of procurement, purchase order generation, and electronic receiving of medication and related supplies. Using computer technology for these purposes has many apparent benefits including up-to-the-minute product availability information, comprehensive reporting capabilities, accuracy, tighter inventory control, and operational efficiency. It also enables compliance with various pharmaceutical purchasing contracts intended to facilitate best pricing and control drug expenditures.

NATIONAL DRUG CODE

All commercial pharmaceutical manufacturers are required to register pharmaceuticals with the U.S. Food and Drug Administration (FDA). This FDA Drug Registration and Listing System (DRLS) is a database that utilizes a unique identification number, called the National Drug Code (or NDC number), to uniquely identify drug products that are intended for human consumption or use.

The **NDC number** appears on the manufacturer's label and follows a 10-digit format: either 4-4-2 (four digits-four digits-two digits), 5-3-2, or 5-4-1.

- The first set of digits identifies the specific drug manufacturer or labeler of the product and is assigned by the FDA.
- The next segment of digits is the product code, denoting the formulation, dosage form, and strength.
- The final segment identifies package type and size.

The NDC number is particularly useful in precisely identifying drug products in the processes of dispensing, placing orders, and addressing drug recalls.

FORMULARY SYSTEM

The **formulary** is the cornerstone of the purchasing and inventory control system. The **Pharmacy and Therapeutics (P&T) Committee** develops and maintains the formulary. This group generally comprises medical and allied health staff such as physicians, pharmacists, nurses, and administrators. These professionals collaborate to ensure that the safest, most effective, and economical medications are included on the formulary.

The products on the hospital formulary dictate what the hospital pharmacy should purchase and keep in inventory. Third-party prescription drug benefit providers will also establish plan-specific formularies for their ambulatory patients. Ambulatory (retail) pharmacy staff frequently encounter insurance plan-specific drug formularies in serving their patients and adjust their inventory accordingly. Most retail pharmacies do not rigidly restrict items in their inventory because, in this setting, inventories are largely dependent on the dynamic needs of their patient population and their patients' respective insurance plans. Therefore, the concept of formulary management differs greatly depending on the practice setting (e.g., that of the hospital compared with that of the retail pharmacy).

Formats and Updates

The hospital formulary is generally available in print or online formats. The formulary is produced exclusively for all health practitioners involved in prescribing, dispensing, and monitoring medications; this tool is formatted generally to inform users of preferred product availability, the appropriate therapeutic uses, and recommended dosing and monitoring of medications. Some formulary systems include comprehensive drug monographs, which serve as a primary drug information resource to practitioners within the system of care. Most formularies are organized alphabetically by therapeutic class and the generic drug's name, which is typically cross-referenced with the respective trade names of products. In many cases, the drug storage areas in the pharmacy are arranged alphabetically by either the generic or trade name of the drug. Therefore, the formulary can help the pharmacy personnel determine if a product is stocked in the pharmacy and where it would be shelved.

Drugs are added and deleted from the formulary on a regular basis with the frequency varying among organizations. Formulary publications should remain current (ideally, with information updated in real-time). Loose-leaf formularies and those maintained online can be updated continuously in a timelier manner, whereas bound formulary handbooks rely on supplementary updates or publication of serial editions.

Important information available in the formulary includes:

- dosage form
- strength
- concentration
- package size(s)
- common side effects
- administration instructions

Some institutions also indicate the actual or relative cost of a given item to guide the prescribing of the most cost-effective alternatives.

Nonformulary Protocol

In keeping with the standards and controls created by an organized formulary system, most hospitals employ a formal procedure to manage appropriate drug use. The use of products that are not on the official hospital formulary is considered **nonformulary** drug use.

The pharmacy's nonformulary procedure may or may not restrict the use of various dosage forms of any particular drug, so pharmacy technicians need to understand the policy in place at their specific institutions.

PHARMACEUTICAL PURCHASING GROUPS

Most health-system pharmacies are members of a **group purchasing organization (GPO)**. The GPO contracts with manufacturers to purchase pharmaceuticals at discounted prices, typically in return for a guaranteed minimum purchase volume on behalf of the members of the group. Hospitals, independent community pharmacies, and other retail chain pharmacies generally become members of a GPO to leverage buying power and take advantage of the lower prices that manufacturers offer to the GPOs (in some cases, corporations are independently large enough to form their own "group").

Purchasing contracts can involve sole-source or multisource products. Sole-source *branded* products are available from only one manufacturer, whereas multisource *generic* products are available from numerous manufacturers.

GPOs negotiate purchasing contracts that are mutually favorable to members of the group and to manufacturers. In addition to lower prices, pharmacies also benefit because this reduces the time staff spends establishing and managing purchasing contracts with product vendors.

DIRECT PURCHASING

Direct purchasing from a manufacturer involves the execution of a *purchase order (PO)* from the pharmacy to the manufacturer of the drug. A **purchase order** is a document, executed by a purchaser and forwarded to a supplier that is considered a legal offer to buy products or services. It usually indicates descriptive information such as the item description, package size, desired quantity, and listed price.

For most pharmacies, the disadvantages of direct ordering outweigh the advantages. As a result, most pharmacies primarily purchase through a drug wholesaler. The **wholesaler** (also known as *distributor*) usually operates a large-scale warehouse in various geographic regions. They exist to help bring pharmaceutical products closer to the market, better meeting its dynamic demands. Some drugs can only be purchased directly from manufacturers and generally require unique control or storage conditions and may be very costly, relative to others. Consequently, most pharmacies use a combination of direct purchases from manufacturers and drug wholesalers.

DRUG WHOLESALER AND PRIME VENDOR PURCHASING

Purchasing from a drug wholesaler permits the acquisition of drug products from different manufacturers through a single vendor. When a health-system pharmacy agrees to purchase most (e.g., 90–95%) of its pharmaceuticals from a single wholesale company, a prime vendor arrangement is established, and, customarily, a contract between the pharmacy and the drug wholesaler is developed.

These wholesaler services make the establishment of a prime vendor contract appealing and result in the following advantages:

- more timely ordering and delivery
- less time spent creating purchase orders
- fewer inventory carrying costs
- less documentation, analytics, and reporting capabilities
- computer-generated lists of pharmaceuticals purchased
- Overall simplification of the credit and return process

Borrowing Pharmaceuticals

No matter how effective a purchasing system is at times, the pharmacy must borrow drugs from other pharmacies. Most pharmacies have policies and procedures addressing this situation. *Note*: Several state and federal laws limit the extent to which a pharmacy may serve in the same capacity as a licensed drug wholesaler.

RECEIVING AND STORING PHARMACEUTICALS

Receiving Process

Some pharmacies follow a policy that dictates the person who receives pharmaceuticals cannot be the person who orders them. This process is especially important for controlled substances because it effectively establishes a check in the system to minimize potential drug-diversion opportunities.

Receiving personnel play a critical role in protecting the pharmacy from financial responsibility for the following:

- Products damaged in shipment
- Products not ordered
- Products not received

Any obvious damage or other discrepancies with the shipment, such as a breach in the cold storage environment or delivery of an incorrect or outdated product, should be noted on the shipping manifest; if warranted, that part of the shipment should be refused. Ideally, identifying gross shipment damage or incorrect box-counts should be performed in the presence of the delivery person and should be well documented when signing for the order. Identifying other problems after delivery personnel have left the premises such as mistaken picks, product dating, or internally damaged goods, must be resolved according to the vendor's policies. Most vendors have specific procedures to follow in reporting and resolving such discrepancies. The technician can also identify packages that are received containing broken tablets, defective seals, etc., so that the wholesaler/shipper can be alerted to weaknesses in the delivery system. Quality issues can often be identified first by the technicians working the receiving area.

The next step of the receiving process entails checking the newly delivered products against the receiving copy of the purchase order.

Controlled substances require additional processing on receipt. Traditionally, regulations specific to Schedule II controlled substances require Drug Enforcement Administration (DEA) Form 222 to be completed on receipt of these products and filed separately with a copy of the invoice and packing slip accompanying each shipment. The DEA also allows for controlled substances to be procured without the supporting paper Form 222. Secure electronic technology known as the *Controlled Substances Ordering System (CSOS)* allows for order transmission of controlled substance orders without use of Form 222 as long as the purchaser enrolls with the DEA to acquire a digital CSOS certificate.

CSOS is associated with the following benefits: freedom of ordering as it includes Schedules II–V without the line item limit encountered on the paper Form 222; faster transactions facilitate just-in-time ordering and inventory management; ordering errors are reduced, promoting accuracy; and transaction costs are lower based on ordering efficiency, reduction in rework, and reduced paperwork associated with controlled substances.

Barcode-assisted medication administration (BCMA) is technology that is meant to improve the safety of medication administration at the bedside and improve medication administration documentation in the patient's electronic health record (EHR). If a hospital uses a BCMA system, it is critical that each barcode be scanned at the time that each product is received. This ensures that the product barcode is in the BCMA system so that it can scan correctly when it gets to the bedside.

Storing Process

Once the product has been received properly, it must be stored properly. Products already in stock that have expired should be removed and appropriately segregated. Products that will expire in the near future should be highlighted and placed in the front of the shelf or bin. This is a common practice known as **stock rotation**. The newly acquired products will generally have longer shelf lives and should be placed behind packages that will expire before them.

PRODUCT HANDLING CONSIDERATIONS

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

Because pharmacy technicians handle so many products each day, they are in an ideal position to identify packaging and storage issues that could lead to errors.

Three main issues of product similarity are as follows:

1. *Look-alike/sound-alike (LASA) products*—Stocking products of similar color, shape, and size could result in error if someone fails to read the label carefully.
2. *Misleading labels*—Sometimes the company name or logo is emphasized on the label instead of the drug name, concentration, or strength.
3. *Product storage*—Storing products that are similar in appearance adjacent to one another can result in error if someone fails to read the storage area but rather thoughtfully organized.

POP QUIZ!

NDC numbers are always transmitted in what format?

Products Requiring Special Handling

Controlled Substances

Controlled substances have specific ordering, receiving, storage, dispensing, inventory, record-keeping, return, waste, and disposal requirements established under the law. Technicians work with pharmacists to manage inventory and order, dispense, store, and secure controlled substances.

The pharmacy technician should know two principles regarding controlled substances:

1. Ordering and receiving Schedule II controlled substances requires special order forms and additional time (1–3 days) unless utilizing CSOS, which may be faster.
2. These Schedule II controlled substances are inventoried and tracked continuously via a perpetual inventory process, whereby each dose or packaged unit is accounted for at all times.

Schedule III, IV, and V controlled substances are generally obtained in a manner identical to that for other noncontrolled substances. Some pharmacies may require all controlled substances inventories to be shelved separately from other legend drugs, whereas others may store them together.

Investigational Drugs

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

1. In a formal protocol approved by the institution.
2. For a single patient on a one-time basis that has been authorized by the manufacturer and the FDA.

In both cases, the physician may be responsible for the ordering, and the pharmacy staff handles the inventory management of the investigational drug.

Compounded Products

Compounded pharmaceuticals are another type of product handled by pharmacy personnel. Unlike drugs ordered from an outside source, compounded products are extemporaneously prepared in the pharmacy as indicated by scientific compounding formulas and processes.

Repackaged Pharmaceuticals

Although manufacturers supply many drugs in a prepackaged unit dose form, the pharmacy staff is responsible for packaging some products. These items are generally unit-dose tablets and capsules, unit-dose oral liquids, and some bulk packages of oral solids and liquids.

Nonformulary Items

Nonformulary items also require special handling. Nonformulary medications generally are stored separately from formulary products and have separate inventory mechanisms. *Manual tracking mechanisms* and *computer system queries of active nonformulary orders* are the two most common techniques used to monitor and order these products.

Medication Samples

Storage and use of medication samples in institutions are controversial and require special handling procedures. Traditional inventory management and handling practices do not work well with medication samples for two reasons. *First*, medication samples are not typically ordered by the pharmacy; they are generally provided free. *Second*, the pharmacy does not usually dispense samples.

Hazardous Drugs

The reader is referred to Chapter <800> of the United States Pharmacopeia for more a comprehensive review of **hazardous drugs (HDs)**. Despite numerous medical publications and known risks, prior to the recent publication of USP Chapter <800> there was no enforceable standard to mitigate the risks resulting from HD exposure in the healthcare setting. The intent of USP Chapter <800> is to protect all workers, patients, and the general public who may enter facilities where HDs are prepared for administration. This includes but is not limited to pharmacists, pharmacy technicians, nurses, physicians, and other practitioners such as physician assistants, home care workers, and veterinarians.

HDs are categorized into one of three types: *antineoplastic, non-antineoplastic,* and *reproductive risk* only. Risk assessment, an important part of compliance with Chapter <800>, incorporates the type of HD, its dosage form, the relative risk of human exposure, as well as packaging and dosage form manipulation requirements.

Compounded Products

Unlike drugs ordered from an outside source, compounded products are extemporaneously prepared

in the pharmacy as indicated by scientific compounding formulas. These products may include oral liquids, topical preparations, solid dosage forms, and sterile products.

Radiopharmaceuticals

Radiopharmaceutical agents are typically used in diagnostic imaging as contrast media and can include oral and injectable products. Other radiopharmaceutical products are used therapeutically to treat diseases of the thyroid gland and forms of cancer. Technically, these drugs are radioactive and potentially hazardous to humans and the environment because they emit low-to-moderate levels of radiation.

Resource Conservation and Recovery Act (RCRA) Regulations

The U.S. Environmental Protection Agency (EPA) and in many cases, the state's hazardous waste regulatory agency enforces hazardous waste laws. In the context of handling and disposal, numerous pharmaceutical products are considered to be hazardous wastes. The practical considerations necessary to be compliant with state and federal waste regulations exceed the scope of this chapter. However, a cursory knowledge that these laws exist and required practical considerations (e.g., inventory procurement, receiving, dispensing, waste-stream management processes) is important. Full compliance with these regulations is essential to avoid state and federal sanctions.

MAINTAINING AND MANAGING INVENTORY

An **inventory management system** is an organized approach designed to maintain just the right number of pharmaceutical products in the pharmacy at all times. A key goal of inventory management is to maximize inventory turns, meaning simply that products should be used and not remain on the shelf aging. Although drugs left on the shelf could be considered financial assets, their useful shelf-life wanes with each passing day and excessive inventory is an unproductive asset, tying up money and resources that can be used in running other elements of the pharmacy operation or business as a whole. Inventory turns, defined in accounting terms, are the fraction of a year that an average item remains in inventory.

Inventory turnover is one way of measuring the productivity of a pharmacy's inventory use and the use of invested capital. By relative comparison, higher inventory turnover is a sign of quality (i.e., efficiency) because inventory is constantly at work and generating revenue, which translates to value. Low inventory turnover is a sign that product (capital) is sitting unused on the shelf and is a signal of a lesser quality operation (i.e., inefficiency). *Financial liquidity* is a favorable term largely established by the amount of cash a business has in bank accounts. Liabilities such as payroll expenses, notes due to suppliers, taxes, and interest payments depend on a firm's financial liquidity.

A variety of inventory management systems are used in pharmacy practice, ranging from simple to complex including *the order book, the minimum/maximum (par) level and just-in-time systems, the Pareto (ABC) analysis, and the economic order quantity (EOQ).* Each of these systems attempt to maximize inventory turnover while at the same time minimize inventory carrying costs (or holding costs). Carrying costs are defined as all costs associated with inventory investment plus storage costs, which might include interest, insurance, taxes, and storage expenses, among others.

Order Book

Many pharmacies use an order book system, also called a *want list* or *want book*. The order book is the simplest form of inventory control. When used as the sole method of inventory control, it is likely to lead to over- and under-ordering of inventory. The order book is a simple order list—much like a home grocery shopping list.

Although this approach is simple, it provides the least amount of organized control of inventory because it is highly dependent on the active staff participation. Individuals must note how much drug inventory remains on the shelf, remember how much is typically used over a specified time period, forecast a need for that drug, and place a request on the order book. The order book system is usually not the sole method of

inventory management and is often used in conjunction with one of the other systems mentioned previously.

Par-Level Systems

Par-level inventory systems are slightly more sophisticated than the order book. The **par-level inventory system** relies on a predetermined order quantity and an order point. Par-level systems, also known as *minimum/maximum systems*, are based on the principle that individual inventory drug use falls within a predictable range. The term *par-level* means within a standard range. If that range can be identified, then minimum and maximum order quantities can be set. In more sophisticated models where just-in time inventory quantity is maintained, a computerized database may be employed to manage a par-level system as opposed to shelf stickers and manual accounting.

Just-in-time inventory management is a philosophy that simply means products are ordered and delivered at just the right time—when they are needed for patient care—with a goal of minimizing wasted steps, labor, and cost. When the inventory is reduced to or below the reorder point, designated pharmacy personnel initiate a purchase order or electronically transmit a purchase order to a drug wholesaler. In the case of automation, the robot may initiate the purchase order. The amount of drug ordered should be of a sufficient quantity to bring the amount to a level within the min-max range but should generally not exceed the maximum level established. This par-level system frequently requires pharmacy staff to routinely scan inventory levels, often using a hand-held barcode scanning device, and then place orders accordingly.

In the fully computerized inventory system, each dispensing transaction is subtracted from the perpetual inventory log that is maintained electronically; conversely, all products received are added to the inventory log. When the quantity of a pharmaceutical product in stock reaches a predetermined par-level point, a purchase order is automatically generated to order more of the product. The system does not depend on any one employee to monitor the inventory or to reorder pharmaceuticals. The technology is available to have a computerized inventory in most pharmacies but interfacing a computerized inventory system with existing pharmacy computer systems designed for dispensing and patient management is often difficult. Even the most sophisticated electronic or automated systems require careful human oversight and management.

Economic Models

Economic models of inventory control attempt to use economic and statistical methods to predict the need for drugs over time. One time-tested model is the **Pareto/ABC analysis**. The Pareto/ABC analysis is based on the 80/20 principles or law of the vital few. This theory states that approximately 80% of most problems can be attributed to roughly 20% of their potential causes. Applied to inventory control, the Pareto principle highlights the fact that a relatively small number of drugs account for a disproportionate amount of drug usage (and often times cost) in a health system. Thus, a Pareto ABC analysis essentially groups inventory products by aggregate value and volume of use into three groupings (A, B, and C).

The **economic order quantity (EOQ) model** of inventory control is another method that attempts to minimize inventory holding costs and ordering costs. The EOQ approach (also known as the *minimum cost quantity approach*) decides inventory order quantities through the use of an accounting formula that calculates the point where the combination of order costs and inventory holding costs is minimized.

Automated or Computerized Systems

A sophisticated system for inventory management is an automated or computerized system that supports a just-in-time product inventory. Pharmaceuticals are neither overstocked nor understocked. The pharmacy's productivity "pulls" the inventory required into the system at just the right time. In pharmacy, this business philosophy integrates responsible financial management of pharmaceutical purchasing with the clinical aspects of patient care. The effectiveness of a just-in-time inventory management system is highly dependent on the reliability of the supply chain before product reaches the pharmacy.

The use of automated dispensing devices in inpatient hospital nursing units, clinics, operating rooms, and emergency departments has facilitated the use

of computers for inventory management. These devices are essentially repositories, or pharmaceutical vending machines, for medications that will be dispensed directly from a patient care area. A variety of manufacturers of automated dispensing devices are in the market today. The Pyxis Medstation and Omnicell suppliers are examples of products available to institutions today. These machines generally are networked via a dedicated computer file server within the facility, and they allow both unit dose and bulk pharmaceuticals to be stocked securely on a given patient care unit location. The machines are capable of tracking perpetual inventory at the product level. They also limit access to only authorized personnel, record the identities of those who access inventory, and record how much of a specific drug was removed for a given patient. A useful feature in many of these systems allows pharmacy personnel to automatically generate a fill-list of what needs to be replenished on the basis of a par-level system.

Regardless of the inventory system used, pharmacy technicians are vital contributors to its success. The pharmacy technician may frequently identify changes in use or prescription patterns of pharmaceuticals.

POP QUIZ!

Define **par-level.**

PHARMACEUTICAL WASTE MANAGEMENT

As a result of increasing concern, the EPA and state health departments are expected to enforce proper pharmaceutical disposal practices more rigorously. Adherence with regulations and pharmaceutical waste-stream management protocols is expensive and operationally challenging, to say the least. However, it is a socially responsible imperative to curb this environmental threat.

COUNTERFEIT PHARMACEUTICALS

There is a growing global concern related to the fraudulent mislabeling and distribution of counterfeit drugs. These products are dangerous because they may not meet standards of quality or potency and are therefore ineffective in treating the disease for which they are intended and can cause harm. These products can range from those containing incorrect ingredients, subpotency, and sometimes toxic ingredients, even though the package or dosage form appears to be legitimate. Obviously, these products are illegal and pose serious threats to the patient and caregiver.

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

DRUG QUALITY AND SECURITY ACT

In 2013, then President Obama signed into legislation the *Drug Quality and Security Act (DQSA)* to be phased in over a 10-year period. Title I of the Act is in respect to compounded drugs and historically important because the DQSA was introduced in response to the tragic New England Compounding Center (NECC) fungal meningitis outbreak associated with contaminated, preservative-free corticosteroid injections compounded and distributed by this Massachusetts-licensed pharmacy operation.

Title II of the DQSA relates specifically to the security of the drug supply chain. It is expected that over time, the DQSA interoperable electronic system will enable reliable verification of a given drug product's legitimacy at the package level, enhance the notification and detection capabilities associated with illegitimate (counterfeit) drug products, and facilitate more efficient drug product recalls. Title II will require drug product manufacturers, wholesale distributors, re-packagers, and dispensers to utilize product-specific identifiers that must be placed on each drug package in the form of 2-dimensional barcodes. These barcodes are expected to contain product identifiers such as the NDC, lot number, as well as other information that will enable precise tracking and tracing for each product's chronological history as it moves through various stages of handling in the entire pharmaceutical supply chain.

COMPOUNDING MANUFACTURERS

Title I of the DQSA is known as the *Compounding Quality Act*, and it clarifies certain conditions whereby certain compounded drug products are exempted from particular aspects of the Food, Drug and Cosmetics Act. Additionally, it created provisions for a compounder to become an *outsourcing facility*. Such facilities qualify for certain exemptions from FDA approval requirements, including the end-product labeling requirement concerning directions for use. However, it does not exempt outsourcing facilities from the requirement to follow FDA-prescribed current Good Manufacturing Practice regulations, which are also expected of any pharmaceutical manufacturer.

PROCURING SPECIALTY PHARMACEUTICALS

Although an industry-wide definition for the term **specialty pharmaceutical** is not readily apparent, the practice of handling these products has steadily become more commonplace. Historically these products were limited to a relatively small array of injectable products but now include oral products.

Characteristics of specialty pharmaceuticals include use in the treatment of complex, chronic, serious, or life-threatening conditions; relatively high treatment cost, restricted distribution channels; nuanced storage, handling, and/or administration requirements; as well as the need for close therapeutic monitoring. It is important that all pharmacists and technicians have a foundational understanding of *specialty pharmacy practice* as the purchasing and inventory control of specialty pharmaceuticals is likely to continue to be restrictive.

SECTION 340B OF THE PUBLIC HEALTH SERVICE ACT

Because of the strong implications related to pharmaceutical purchasing and inventory management for covered entities, section 340B of the Public Health Service Act (340B) is worth a mention in this chapter. In this context, *covered entities* is a term that includes organizations qualifying as disproportionate share hospitals or as Health Resources and Services Administration (HRSA) federal grantees under the Social Security Act.

The intent of the 340B Program is to permit covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services." The program requires drug manufacturers to discount medication provided to outpatients. In turn, this increases the financial stability of the covered entities and their ability to continue to serve vulnerable patient populations and reduces the financial burden on taxpayers.

PROPER DISPOSAL AND RETURN OF PHARMACEUTICALS

Expired Pharmaceuticals

The most common reason drugs are returned to the manufacturer is because they are expired. The process for returning drugs in the original manufacturer packaging is relatively simple and not particularly time-consuming when done routinely. Returning expired

products to the manufacturer or wholesaler prevents the inadvertent use of these products while enabling the department to receive either full or partial credit for them.

Pharmaceuticals compounded or repackaged by the pharmacy department cannot be returned and must be disposed of after they have expired. The pharmacy technician's disposal of expired compounded or repackaged pharmaceuticals should be completed under the pharmacist's supervision.

Other products requiring disposal rather than return are chemicals used in the pharmacy laboratory.

Expired controlled substances are disposed of uniquely. These products may not be returned to the manufacturer or wholesaler for credit. They must be destroyed in accordance with the applicable state or federal regulations, and the destruction must be documented to the satisfaction of the DEA. The DEA provides a specific form—Registrant's Inventory of Drugs Surrendered (Form 41)—for recording the disposal of expired controlled substances.

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

Pharmaceuticals that need to be returned because of an ordering error require authorization from the original supplier and the appropriate forms. The *Prescription Drug Marketing Act* mandates that pharmacies authorize and retain records of returned pharmaceuticals to prevent potential diversion of pharmaceuticals.

SELF-ASSESSMENT QUESTIONS

1. The formulary contains important information to assist the pharmacy technician in all of the following areas except:
   a. Identification of trade names of products
   b. Identification of product concentration
   c. Identification of package size
   d. Identification of expiration dates

2. According to provisions of USP Chapter <800>, workers who come in contact with hazardous drugs (HDs) must receive appropriate HD training and be assessed for competency regularly. According to Chapter <800>, specific HD categories include:
   a. Antineoplastic drugs
   b. Non-antineoplastic drugs
   c. Drugs with reproductive risk only
   d. a, b, and c
   e. Veterinary drugs
   f. Radiopharmaceuticals

3. Effective pharmaceutical supply chain management systems are essential to fulfilling many aims or measures that improve the quality of healthcare. These aims include all of the following except:
   a. Safety
   b. Efficiency
   c. Effectiveness
   d. Timeliness
   e. Resiliency

4. The products on the hospital formulary dictate which drugs may be dispensed to patients according to third-party prescription drug benefit plans.
   a. True
   b. False

5. When documenting the receipt of pharmaceuticals for which the purchase order or manufacturer's invoice cannot be located, which of the following should be recorded?
   a. Product name and amount
   b. Product name, strength, and amount
   c. Date of receipt, product name, and amount
   d. Date of receipt, name of receiver, product name, strength, dosage form, and amount

6. GPOs (group purchasing organizations) benefit health-system pharmacy operations because they negotiate favorable purchasing agreement terms with drug product manufacturers.
   a. True
   b. False

7. Which of the following is not an important consideration in processing a manufacturer's recall notice?
   a. Checking the refrigerator temperature logs
   b. Timely response in checking the inventory and removing affected products
   c. Documenting the inspection and any action required
   d. Receiving proper credit from the manufacturer

8. The first set of numbers in an NDC number signify
   a. package size
   b. specific product
   c. manufacturer
   d. schedule of the controlled substance

9. Provisions of the Drug Quality and Security Act (DQSA) govern all of the following except:
   a. Credentialing of technicians involved in the safe handling and storage of pharmaceuticals
   b. Compounding of medication
   c. Drug supply chain quality standards (e.g., systems for drug product tracing, detection of counterfeit drugs in the supply chain, drug recalls)
   d. Licensing details of drug wholesale distributors and other logistics providers

10. Which types of pharmaceuticals are found in increasing amounts in waterways and drinking water?
    a. Injectables
    b. Contrast media
    c. Antimicrobials
    d. Over-the-counter products

11. Expired C-II drugs
    a. Should be returned to the distributor for credit.
    b. Must be destroyed in accordance with the applicable state or federal regulations, and the destruction must be documented to the satisfaction of the DEA.
    c. Must be returned to the manufacturer in accordance with the DEA regulations.
    d. Are destroyed in accordance with good manufacturing policies.

12. The Drug Quality and Security Act _____.
    a. Was introduced in response to the tragic NECC fungal meningitis outbreak associated with contaminated, preservative-free corticosteroid injections compounded and distributed by this Massachusetts-licensed pharmacy operation.
    b. Requires drug manufacturers to discount medication provided to outpatients.
    c. Is an organized approach designed to maintain just the right number of pharmaceutical products in the pharmacy at all times.
    d. States that approximately 80% of most problems can be attributed to roughly 20% of their potential causes.

13. Prime vendor contracts are appealing and result in a number of advantages; name three of them.

14. _____ develops and maintains the formulary.
    a. Director of Pharmacy and the CEO of the institution
    b. Director of Pharmacy
    c. GPO
    d. P& T Committee

15. The GPO _____.
    a. Contracts with manufacturers to purchase pharmaceuticals at discounted prices.
    b. Develops and maintains the formulary.
    c. Contracts with third-party carriers.
    d. Destroys outdated drug products.

SELF-ASSESSMENT ANSWERS

1. d.
2. d.
3. e.
4. b.
5. d.
6. a.
7. a.
8. c.
9. a.
10. c.
11. b.
12. a.
13. These wholesaler services make the establishment of a prime vendor contract appealing and result in the following advantages:
    - More timely ordering and delivery
    - Less time spent creating purchase orders
    - Fewer inventory carrying costs
    - Less documentation, analytics, and reporting capabilities
    - Computer-generated lists of pharmaceuticals purchased
    - Overall simplification of the credit and return process
14. d.
15. a.

CHAPTER 10

BILLING/ REIMBURSEMENT AND INFORMATION SYSTEMS



Learning Outcomes

After completing this chapter, you will be able to

- Explain the basic principles of pharmacy billing and reimbursement.
- Define common pricing benchmarks.
- List various payers of pharmaceuticals and pharmacy services.
- Describe the differences in reimbursement processes dependent on payers and patient care settings.
- Describe the categories of information that are needed to submit a third-party claim for a prescription or medication order.
- Use knowledge of third-party insurance billing procedures to identify a reason for a rejected claim.
- Describe the use of current technology in the healthcare environment to ensure the safety and accuracy of medication dispensing.
- Explain how medical information systems are used in pharmacy practice activities.
- Explain the type of data pharmacy information systems collect, transmit, and store.
- Explain the impact on quality of decision making of valid, reliable, and consistent data entered into medical information systems.
- Describe proficiency with word processing, spreadsheets, and databases.
- Describe skills in using the Internet, e-mail, and electronic medication information databases.
- Explain currently emerging technologies that may impact the practice of pharmacy.
- Describe the ability to use technologies including barcoding and automated dispensing technology, and unit-dose packaging and reporting.

In many practice settings, pharmacy technicians serve as the patient's first point of contact with the pharmacy billing system. With the adoption of computers within pharmacies, pharmacists and technicians often started accepting new roles to support the hardware and the software that were quickly changing the way pharmacy was practiced. The need for pharmacy technicians with basic skills in medication-use system technology is a prerequisite to enter practice in hospitals and health systems. There are opportunities for both pharmacists

and pharmacy technicians to specialize in informatics and medication-use technology positions. With the complexities of pharmacy practice in today's healthcare setting, it is important to consider further training in informatics and computer science to support these systems.

Pharmacy technicians require skills in pharmacy-related computer applications for documenting the dispensing of prescriptions or medication orders and knowledge in databases, pharmacy computer applications, and documentation management. They also need to demonstrate the use of a dispensing system that could include the documentation and maintenance of the electronic medical (or health) record (EHR), patient adherence, risk factors, alcohol and drug use, drug allergies, and side effects. It is essential to know how to maintain user access, update drug databases, troubleshoot interfaces, and prepare reports such as inventory, drug usage, overrides, and diversion reports.

PHARMACY ACCOUNTING BASICS

The outflow of cash is considered *expenses*. Before the revenue can be generated, the products (i.e., drugs) must be purchased by the pharmacy. The amount the pharmacy pays to a vendor to buy the drugs for stock is called the *acquisition cost*. In pharmacy terms, the *margin* is typically the difference between the selling price of a drug to the patient and the acquisition cost of the drug.

Margin = amount paid by the patient – acquisition cost of drugs

In addition to drug purchases, there are overhead costs associated with providing pharmaceutical products to patients. *Overhead costs* often include various expenses such as rent and utilities, personnel costs (i.e., salaries for pharmacists and technicians), equipment (computers, fax machines, printers), and supplies (labels, vials, etc.).

Net Profit = total revenue – total expenses (i.e., cost of drugs and other expenses)

PHARMACY REIMBURSEMENT BASICS

Prospective payment typically includes all costs associated with treating a particular condition, including medications. With prospective payment systems, pharmacies are challenged to deliver drugs at or below the predetermined rate to ensure that drug costs are covered.

In community pharmacy practice, the most common type of payment method is retrospective, or **fee for service**. In the **retrospective payment model**, drugs are dispensed and later reimbursed, according to a predetermined formula that is specified in a contract between the pharmacy and the **third-party payer**, such as the insurance company or pharmacy benefit manager.

The reimbursement rate for third-party prescriptions is based on a formula consisting of various parts: ingredient cost, dispensing fee, and patient copayments. The *ingredient cost* is the amount paid to the pharmacy for the cost of the drug product, the **dispensing fee** is the amount paid for items related to dispensing the prescription, and the **copayment** (also known as *copay*) is the cost-sharing amount that the patient or customer pays.

Third-party reimbursement = (ingredient cost + dispensing fee) – copayment

Historically, the **average wholesale price (AWP)** has been the most commonly used benchmark for billing drugs that are reimbursed in the community pharmacy setting. The AWP for a drug is meant to represent the average price wholesalers sell medications, and the AWP is readily available from several sources. **Wholesale acquisition cost (WAC),** a second benchmark used, is set by each manufacturer. It represents the **list price** at which the manufacturer sells the drug to the wholesaler.

New benchmarks used for drug pricing within the past decade include **average sales price (ASP)** and **average manufacturer price (AMP)**. ASP is based on manufacturer-reported selling price data and includes

volume discounts and price concessions that are offered to all classes of trade.

AMP is the average price wholesalers pay to manufacturers for drugs dispensed through retail pharmacies and includes discounts and other price concessions provided by manufacturers.

Typically, the reimbursement formula for a generic product is different than that for a brand product. Sole-source or brand name drugs are usually reimbursed based on AWP or WAC, whereas generic or multi-source drugs are reimbursed based on a **maximum allowable cost (MAC)** schedule, which is usually based on the cost of the cheapest available generic equivalent.

PAYMENT FOR DRUGS AND DISPENSING SERVICES

Consumers (Self-Pay)

Although many patients have some form of prescription drug coverage, a significant number are still uninsured or underinsured. The amount that is paid by a cash-paying customer is often referred to as the *usual and customary price* or the *cash price*. Many third-party contracts will indicate that the amount to be paid for a prescription is based on a reimbursement formula (as explained above) or the usual and customary price. The lower of the two prices is the amount usually paid.

Many drug companies offer certain free drugs through **patient assistance programs (PAPs)** to low-income patients who lack prescription drug coverage and meet certain criteria. Some companies also offer bulk replacement or **institutional patient assistance programs (IPAPs)**. In the IPAP model, medications are provided to an institution rather than to the individual patient. The *340B drug-pricing program* is another option that can be utilized to assist patients who lack adequate prescription drug coverage. There are several types of facilities that qualify as *covered entities* for 340B pricing including federal qualified health centers (FQHC), disproportionate share hospitals (DSH), and state-owned AIDS drug assistance programs. The Office of Pharmacy Affairs, which is located within Health Resources and Services Administration, administers the 340B drug discount program.

POP QUIZ!

What is the Average Sales Price based on?

Private Insurance

The most common purchasers of private insurance are employers, labor unions, trust funds, and professional associations. *Managed care* is a type of private health insurance or healthcare organization that is based on networks of providers such as pharmacies, doctors, and hospitals.

Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) are organizations that administer pharmacy benefits for private or public third-party payers, also known as **plan sponsors**. These organizations may include managed care organizations, self-insured employers, insurance companies, labor unions, Medicaid and Medicare prescription drug plans, the Federal Employees Health Benefits Program, and other federal, state, and local government entities. Some of the major PBMs are CVS Health, Express Scripts, Humana, OptumRx, and Prime Therapeutics.

The **formulary** is the cornerstone of any PBM activities. It is a specific list of drugs covered within a given pharmacy benefit. The formulary usually includes both brand and generic drugs in most therapeutic categories. Brand name drugs can be either preferred (designated by the PBM as the first-choice drugs) or non-preferred.

The PBM can utilize administrative tools within the context of the formulary to optimize the clinical and economic performance of the pharmacy benefit. Some of the more common administrative tools are prior authorization, step therapy, and quantity limits.

- Prior authorization requires the prescriber to receive preapproval from the PBM in order for the drug to be covered by the benefit.
- Step therapy requires use of a recognized first-line drug before a more complex or expensive second-line drug is used.
- Quantity limits set upper limits of the amount of a drug that will be covered by the benefit, or the total days of therapy.

For PBMs, administering the pharmacy benefit is a constant balancing act of managing costs and providing quality service and value to their sponsors and beneficiaries. Many PBMs try to achieve this balance by offering mail service for prescriptions, whereby beneficiaries can get up to a 90-day supply of medication through the mail for a reduced copayment.

Another way that PBMs try to better serve their customers and manage costs is to offer specialty services for beneficiaries who require high-cost drugs, such as the newer biotechnology drugs that patients inject themselves. Overall, PBMs provide a complex and valuable service for the healthcare system and assist plan sponsors in administering the pharmacy benefit to millions of beneficiaries.

POP QUIZ!

Define PBM.

Processing Private Third-Party Prescriptions

Patients with a prescription drug benefit should have a *prescription identification (ID) card*. The information on the prescription ID card is necessary in order to submit a claim to the PBM.

The card identifies the PBM (or drug benefit provider). It shows a telephone number for the PBM customer service department. The employer may be identified, followed by the Member Name and Member ID Number. If the beneficiary is different from the plan member, such as a spouse or dependent child, the Participant's Name may be listed. Finally, the BIN # is the bank identification number, which is also needed to submit the claim.

Once the technician enters information in the pharmacy computer from the prescription ID card and the prescription, the PBM either accepts or rejects the claim. If the claim is rejected, the PBM responds with a message, commonly known as a *rejection code*. These rejection codes are standard across all prescription benefit plans and may include:

- Missing or Invalid Patient ID
- Prior authorization required
- Pharmacy not contracted with plan on date of service
- Refill too soon
- Missing or invalid quantity prescribed

Public Payers

Medicare is the largest public payer, accounting for 69% of these prescription costs, followed by Medicaid at 24%, and other public payers such as the Department of Veterans Affairs, the Department of Defense, and the Children's Health Insurance Program at 7%.

Medicare

Medicare is the federal health program for the elderly, disabled, and people with end-stage renal disease (ESRD) or amyotrophic lateral sclerosis (ALS), otherwise known as Lou Gehrig's disease. There are four parts to Medicare:

- Part A (hospital insurance)
- Part B (medical insurance)
- Part C (Medicare Advantage plans)
- Part D (prescription drug coverage)

Medicare Part A

Medicare Part A helps cover inpatient care (hospitals, skilled nursing facilities, hospice care, and some home healthcare). Medicare Part A coverage involves a deductible and a benefit period of 60 days. A **deductible** is an out-of-pocket amount that must be paid before insurance coverage begins. Part A claims are processed by a fiscal intermediary, and the diagnosis-related group (DRG) is the basis for reimbursement.

Medicare Part B

Medicare Part B is optional medical insurance for outpatient physician and hospital services, clinical laboratory services, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Part B coverage involves paying a monthly premium, an annual deductible, and coinsurance.

Medicare Part C

Medicare Part C, also known as a *Medicare Advantage Plan*, combines Part A and B coverage. Under this plan,

benefits are provided by Medicare-approved private insurance companies. These private fee-for-service and managed care plans often include prescription drug benefits, called *Medicare Advantage Prescription Drug* plans or MAPDs; as such, Part C beneficiaries should not enroll in a Part D prescription drug plan.

Medicare Part D

Medicare Part D is a federal prescription drug program that is paid for by the Centers for Medicare & Medicaid Services (CMS) and by individual premiums. It was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Medicare Part D offers a voluntary insurance benefit for outpatient prescription drugs.

Medicare prescription drug plans are administered by private PBMs or other Medicare-approved companies. Each plan varies in terms of cost and drugs covered.

Medicaid

Medicaid is a medical and long-term care program that is jointly funded by the federal and state governments. All states, the District of Columbia, and all U.S. Territories participate in the Medicaid program. *Medicaid covers three main groups of low-income Americans:* parents and children, the elderly, and the disabled. State spending on Medicaid is matched by the federal government up to a point. The federal government has developed broad guidelines for the Medicaid program that states must follow to receive *matching funds*; however, the specific requirements are determined by each state. As a result, there is a wide variation in Medicaid coverage from state to state. Income guidelines are based on federal poverty limits (FPLs), which are updated annually.

States must cover a minimum set of Medicaid benefits for eligible patients. All states provide coverage for prescription drugs that are prescribed by a licensed physician and dispensed by a licensed pharmacist. Additionally, the medication must be recorded on a written prescription; as of April 1, 2008, all Medicaid prescriptions must be electronically prescribed or written/printed on "tamper resistant" paper. Finally, the need for the medication must be supported in the patient's medical record.

Other Public Payers

In addition to Medicare and Medicaid, the government pays for health benefit programs for the Department of Veterans Affairs (VA), Department of Defense, and the Indian Health Service (IHS). All veterans of active military service are potentially eligible for health benefits from the VA. Eligibility is not just for veterans who served in active combat. Beneficiaries do not pay premiums for VA health benefits, but they usually pay copays depending on their income. Typical copays are $15 for a medical visit and $8 for a 30-day supply of medication.

TRICARE is the health benefit program from the Department of Defense. Active military personnel, retirees, and their families are eligible for TRICARE. The TRICARE retail and mail-order prescription benefit is administered by Express Scripts. The prescription benefit is based on a national TRICARE formulary. Like the VA, TRICARE prescription coverage is considered creditable with Medicare Part D.

The IHS provides a comprehensive federal healthcare delivery system to American Indian and Alaska Native tribes and their descendants.

CLAIMS PROCESSING

There are various payers of pharmacy benefits, and each payer has different policies, procedures, coverage rules, and formulas. Although private insurers pay a large portion of drug costs, Medicare and Medicaid have a significant influence on how drugs are paid. The next section discusses reimbursement strategies and billing information required to receive payment.

POP QUIZ!

What does Medicare Part B pay for?

Billing for Drugs and Dispensing Services

Healthcare insurers process billions of claims each year. To process and pay claims in a consistent manner, standardized billing methods are essential.

Inpatient Hospital and Skilled Nursing Facility Setting

In an inpatient setting, per diem and prospective payment rates are the primary methods of payment. Generally, separate payments are not made for drugs provided during a covered stay. The drug costs are included in the DRGs, which are used to determine the bundled payments made to the hospital by insurers. DRGs were introduced in the early 1980s as part of a **prospective payment system (PPS)** to classify hospital cases based primarily on type of patient, diagnoses, procedures, complications, comorbidities, and resources used.

Outpatient Hospitals, Clinics, and Physician Offices

In an outpatient hospital, clinic, or physician office setting, physician-administered drugs may either be included as part of the procedure or paid separately. Many drugs given in this setting are considered fee-for-service or separately billable (if the drug exceeds the Medicare packaging threshold). Typically, the fee-for-service formula is based on AWP; however, Medicare payment rates are based on the ASP. Under Medicare Part B, hospital outpatient services are reimbursed using the *outpatient PPS (OPPS)*, which is a predetermined payment system for covered drugs and services. Each drug charge requires the appropriate **Healthcare Common Procedure Coding System (HCPCS)** code, and the quantity should be billed in service unit increments. *Service units* are predetermined billing increments that may be unrelated to the package size. Key data elements necessary for claim submission include the following:

- Beneficiary name and Health Insurance Claim Number (HICN)
- Date of service
- HCPCS codes
- Current Procedural Terminology (CPT) codes
- *International Classification of Diseases*, 10th Revision (ICD-10) codes (also known as Diagnosis codes)
- Clinical Modifiers
- National Drug Code (NDC)
- Units of Service (quantity expressed in service units or billing increments)
- Place of service

Community Pharmacy Setting

Community pharmacies submit the majority of pharmacy claims that are reimbursed by a third-party payer. When working in the outpatient care setting, it is essential to understand how drugs are billed and paid. The prescription drug claims adjudication process involves the following steps:

- Submitting appropriate information
- Determining eligibility, coverage, and payment
- Communicating reimbursement
- Settling the claim

PRESCRIPTION PROCESSING

To submit an electronic online claim, key billing elements include the following:

- Prescription Processor (Insurance Company or contracted PBM information on the ID card)
  - BIN (bank identification number)
  - PCN (processor control number)
- Pharmacy Provider Information (specific to each pharmacy)
  - NPI (national provider identification)
  - NCPDP or NABP (formerly NPIC = National Pharmacy Identification Code)
- Eligibility (specific to each patient)
  - Member Name and Identification Number (unique identifier)
  - Group Number (insurers have several groups or plans)
  - Relationship (Plan Member, Spouse, Dependent)
- Prescription Information
  - Date of Prescription (date when prescription was written and each fill)

- NDC (which identifies the manufacturer, drug, strength, dosage form, and package size)
- Directions for Use
- Quantity Dispensed
- Days Supply
- Refills (number of refills authorized)
- Dispense as Written (DAW) or Product Substitution
- Physician Signature (electronic signature, if permitted), NPI number and DEA number, when required

In addition to processing claims, the present online system provides information such as eligibility information, specific coverage, prompts for prior approval, and copayment amounts. The system sends common claim edits and messages, such as "refill too soon" and "exceeds quantity limits or days supply," and may communicate denials when an item is not covered. Information necessary to file a claim is available on the prescription drug ID card and includes the following:

- Cardholder ID
- Group Number
- Dependent Coverage (relationship codes)
  - 1 = Cardholder or Eligible Primary Person or Subscriber
  - 2 = Spouse of Cardholder
  - 3 = Dependent Child
  - 4 = Other (e.g., Disabled Dependent, Dependent Adult, Dependent Parent, Domestic Partner)
- BIN and PCN Numbers

Pharmacies are often subject to audits, which can result in situations in which pharmacies are required to pay back third-party payers. The following are several criteria that can have an impact on reimbursement and are scrutinized during a pharmacy audit:

- Patient Name and Unique Identifier
- Date of Prescription
- Drug name, strength, package size, and NDC
- Instructions or Directions
- Quantity
- Days Supply
- Number of Refills
- DAW Codes

Common reasons for repayment following an audit include the following:

- Incorrect information
- Dates, drugs, strengths, or directions
- Incorrect days supply (quantity ordered and directions should match)
- Overbilled quantity (an amount that exceeds the quantity written)
- Incomplete information
- No quantity indicated
- "Use as directed" instructions (this is unacceptable: the directions must allow for a calculated days supply)

BASIC COMPUTER SKILLS

Pharmacy technicians working in today's pharmacies must have basic computer skills. These requirements are essential no matter what the practice setting is. Some employers require new employees to pass computer proficiencies as part of the hiring process.

They may use these computer applications to generate labels, create monitoring forms, prepare purchase requisitions, prepare letters for prior authorization, or other communications. Most communications within hospitals and pharmacy departments typically rely on e-mail. Pharmacy personnel need to manage e-mail communications and develop a professional response when replying to others. Some pharmacy technicians will require additional skills in some of these applications if they are in advanced roles.

KEY TERMINOLOGY

Pharmacy informatics is the scientific field that focuses on medication-related data and knowledge within the continuum of healthcare systems—including its acquisition, storage, analysis, use, and dissemination—in the

delivery of optimal medication-related patient care and health outcomes. Pharmacists involved in informatics have various titles such as medication integration architect, clinical informaticist, or pharmacist informaticist. Pharmacy technicians involved in informatics may possess a title such as pharmacy analyst, informatics support specialist, or pharmacy technician informaticist (PTI). Pharmacies utilize interfaces for patient information such as admission/discharge/transfer (ADT) interfaces, orders interfaces to dispensing technologies (e.g., automated dispensing cabinets [ADCs], carousels, robots), and billing interfaces.

Integration is the seamless interaction of various applications from a single vendor that forms a larger and more complex system.

Technologies used in pharmacies are designed to support the medication-use process to improve safety and efficiency. Pharmacy department's staff often supports many technologies.

Computerized Order Entry

Computerized physician order entry (CPOE) is essentially the use of a computer to write patient-specific orders electronically. The "**P**" can stand for prescriber, physician, or provider depending on the health system's definition. The federal government's definition of CPOE is:

> CPOE entails the provider's use of computer assistance to directly enter medication orders from a computer or mobile device. The order is also documented or captured in a digital, structured, and computable format for use in improving safety and organization.

From a pharmacy perspective, medication orders are entered into the patient's EHR and are routed to the pharmacy for verification. The pharmacist will evaluate the order based on the available patient-specific information within the EHR. After the pharmacist verifies that the order is the right drug, route, dose, indication, and other patient-specific variables, the order is then assigned a product for dispensing. The use of an integrated system allows for easy retrieval of information for the pharmacist to verify the order.

An additional benefit of having a CPOE system is combining the system with a *clinical decision support (CDS)* system. The Office of the National Coordinator for Health Information Technology defines CDS as "a process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery." Since pharmacies began computerization, they have used alerts to notify a prescriber or a pharmacist that there is a problem with a medication order. The common drug-allergy and drug-drug interaction type of alerts are most recognizable by pharmacists and pharmacy technicians. The use of alerts often causes a phenomenon described as *alert fatigue*. Providers can become desensitized to the alert and ignore it when it may have clinical relevance for the patient for whom it was triggered.

Barcode-Assisted Medication Administration

Barcode-assisted medication administration (BCMA) ensures the *five rights* during medication administration: right patient, drug, dose, route, and time. Pharmacy departments must work closely with nursing staff and other disciplines that administer medications. The need to have barcodes on all products used in a healthcare setting is the pharmacy department's responsibility.

The barcode on the medication product will contain either the NDC, universal product code (UPC), or an institutional assigned identifier. The goal for most successful BCMA programs is to have a barcode on the medication dispensed for patient use. The type of barcode used can be linear or 2-dimensional. For most patient-specific parenteral infusions, the barcode will likely incorporate a dispense identification number or similar identifier. This patient- and dose-specific identifier will allow for a positive scan at the point of care. With the implementation of the *U.S. Food and Drug Administration's Drug Supply Chain Security Act (DSCSA)*, pharmacy departments will be required to assess their BCMA systems. Manufacturers will be required to have a 2-dimensional barcode on their products that includes the NDC, serial number, lot number, and expiration date. These requirements allow for the

tracing, verification, and identification of the medication product. Vaccines and blood products have already incorporated much of the requirements into their labeling/packaging.

Automated Dispensing Cabinets

ADCs are widely used in hospitals to support medication use. These devices allow for prompt, real-time availability of medications for the use at the point of care. The addition of unit-dose medications and some bulk medications allows for timely treatment of patients. The use of ADCs may improve controlled substances accountability, increase productivity, improve charge capture and documentation accuracy, and reduce nursing and pharmacy labor costs (**Table 10-1**).

Pharmacy technicians are the key pharmacy staff interacting with ADCs on a daily basis. Many institutions allow the pharmacy technician to replenish the ADC when a set par level is reached. Depending on the state laws, the pharmacist may still require a visual check of the medications prior to leaving the pharmacy.

Intravenous Workflow Software

The use of intravenous (IV) workflow software is mostly performed by highly trained pharmacy technicians in the pharmacy's clean room. The computer prompts the pharmacy technician to follow a preparation script that is tailored based on the compounded sterile preparation (CSP) that is required. The system requires a combination of barcode scanning and may or may not require photographic or gravimetric verification. Because these applications drive pharmacy operations, the pharmacy informatics team needs to work with pharmacy technicians and pharmacists responsible for CSP preparation.

Robotics

The adoption of robotics in hospital pharmacy is relatively low due to their cost and size. The implementation of robotics is typically in a large academic medical center or large community hospital setting. Pharmacy robots consist of three types: dispensing, delivery, and IV/chemotherapy.

Specialized Applications

Many hospitals will have specialized software and/or technology to meet operational requirements. Software that supports specialty pharmacy practice may be used. Software that may be implemented in specialty practice areas may consist of investigational drug service management, pharmacist intervention/stewardship documentation and tracking, chemotherapy ordering, parenteral nutrition ordering, or extemporaneously compounding management.

POP QUIZ!

What is CPOE and what are the benefits of this?

TABLE 10-1. Goals and Objectives of Automated Dispensing Cabinets

Information necessary for appropriate medication management and patient care is accurate, accessible, and timely.
Appropriate medications are readily available and accessible to meet patient needs within safety and security controls.
Vulnerabilities to medication errors are minimized, and those that remain are identified, documented, and mediated.
Staff members involved in the medication-use process are safety conscious, accurate, and productive.
Patients are satisfied with the quality and delivery of care.
Medication distribution services are facilitated across the continuum of practice settings in the healthcare system.
Resource management is improved by linking supply ordering channels to the medication distribution system.
Billing accuracy is improved by allowing charges and credits to post when medications are dispensed from or returned to the automated dispensing device.

Source: Originally published in American Society of Health-System Pharmacists. ASHP guidelines on the safe use of automated dispensing devices. *Am J Health-Syst Pharm.* 2010; 67:483-90. Copyright © 2010 by the American Society of Health-System Pharmacists, Inc. All rights reserved.

RETAIL PRACTICE

Electronic Prescribing

Electronic prescribing (eRx) is a well-established means of transmitting prescriptions to retail pharmacy settings. SureScripts is a national network that connects clinicians, EHRs, hospitals, PBMs, pharmacies, and technology vendors. The use of e-Rx has advantages, but not all implementations have all the features enabled. Some benefits of (e-Prescribing or eRx) may include:

- Fast, efficient way to write/reorder and transmit prescriptions
- Use of preset fields so all the required information for prescriptions are entered and automatically stored in the patient's record
- Increased overall patient satisfaction because the prescriptions can be automatically transmitted to patient's pharmacy
- Guided dose algorithms to assist providers
- Querying a patient's formulary benefit to ensure the patient's health plan covers the selected drug to assist in reducing costs

e-Rx works based on standards that transmit and receive messages or prescriptions to pharmacies. The *National Council for Prescription Drug Programs (NCPDP)* is a standards development organization (SDO). The standard allows for exchange of information between prescribers, pharmacies, intermediaries, and payers. Transaction and data requests that are part of the standard include:

- New prescription request
- Change of new prescription
- Cancel of prescription
- Refill/renewals request/response or resupply in long-term care
- Fill status notification
- Medication history exchange
- Drug administration exchange in long-term care
- Prescriber-reported samples for more robust medication history
- Query functions for new prescriptions

Errors can still occur with e-Rx, but they have been minimized with a decrease in transcription. Pharmacists and technicians play an important role in preventing e-prescription errors through the detection of errors and the verification of prescribers' intent. SureScripts offers certification of e-Rx applications. The criteria can be found in **Table 10-2**.

Electronic prescribing of controlled substances (EPCS) is supported by NCPDP's SCRIPT Standard, but the Drug Enforcement Administration (DEA) also has additional requirements. The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances. To use EPCS, a provider must utilize two-factor authentication (*two of the following:* something you know, something you have, something you are) that protects the practitioner from misuse of his or her credential by insiders as well as protecting him or her from external threats because the practitioner can retain control of a biometric or hard token. An increasing number of states are requiring EPCS to minimize diverting controlled substances. This will require both providers and pharmacies to enable this functionality within their EHR and pharmacy management system (PMS). Pharmacies and providers are required to search their state's *prescription drug monitoring program (PDMP)* prior to prescribing a controlled substance or prior to filling a prescription for a controlled substance. The PDMP may serve several purposes such as:

- Supporting access to legitimate medical use of controlled substances
- Identifying and deterring or preventing drug abuse and diversion
- Facilitating and encouraging the identification, intervention with, and treatment of persons addicted to prescription drugs
- Informing public health initiatives through outlining of use and abuse trends
- Educating individuals about PDMPs and the use, abuse, and diversion of and addiction to prescription drugs

TABLE 10-2. e-Rx Application Requirements for SureScripts Certification

New Rx: Route new prescriptions to community pharmacies and mail-order pharmacies.
Rx Renewal: Route prescription renewal requests and responses between prescribers and pharmacies (retail and mail-order).
Prescription Benefit: Allow prescribers to choose medications that are on formulary and covered by the patient's drug benefit.
Medication History: Access information on a patient's current and past prescriptions and inform physicians and pharmacists about potential medication issues.
Census: Notify pharmacy of patient status changes such as when a patient is admitted to a facility, leaves the facility, or has changes to patient information (room number, insurance, etc.).
Resupply: Allows facilities, such as those for long-term and post-acute care, to request additional quantity of a patient's medication from the pharmacy.
CancelRx: Cancel prescriptions that have been sent to community pharmacies.
RxChange: Allow pharmacies to send messages electronically to a prescriber and request authorization to make a change to a prescription.
Electronic Prescribing of Controlled Substances: Prescribes controlled substances for a streamlined workflow.
CompletEPA: Access a real-time electronic prior authorization solution integrated into the EHR workflow.

EHR = electronic health record; e-RX = electronic prescription

Note: See **https://surescripts.com/network-connections/prescriber-software/** for more information.

Pharmacy Management Systems

PMSs operate similar to hospital-based PIS with the exception that a PMS manages the filling of prescriptions and a pharmacy information system (PIS) facilitates the filling of medication orders. A PMS relies on NCPDP standards for processing prescriptions. The incorporation of medication therapy management (MTM) tools should be part of the PMS or interfaced with the PMS to facilitate documentation and billing. With proper training, technicians can assist pharmacists in the tasks that do not require the professional judgment of a pharmacist, freeing pharmacists to focus on clinical activities and enabling an MTM program to be more sustainable.

Integrating Patient Data

Many patients have become accustomed to monitoring their own health and are comfortable sharing data they collect with their care providers. The use of patient portals to request prescription refills and appointments has increased over the past decade. Pharmacy technicians have been successful in teaching patients to use glucose monitoring devices and blood pressure monitors. Community pharmacists today are striving to integrate patient care with a pharmacy's traditional goods and services. Pharmacy technicians are recognized as an important resource in helping pharmacists provide better patient care.

Telepharmacy

Telepharmacy is the delivery of pharmaceutical care via telecommunications to patients in locations where they may not have direct contact with a pharmacist. It is an instance of the wider phenomenon of telemedicine, as implemented in the field of pharmacy. The use of telepharmacy and remote order verification has been established in some rural areas of the United States when approved by the Board of Pharmacy.

POP QUIZ!

What does the acronym PDMP mean?

DOWNTIME PLANNING

As many hospitals and pharmacies become more dependent on technology for operations, it is important to have a downtime plan for various contingencies. There are planned and unplanned downtimes that will affect pharmacy operations very differently. *Planned downtime situations* occur when an institution requires taking a major upgrade to their EHR, upgrade hardware and infrastructure, and time changes (Daylight Savings to Standard). *Unplanned downtime events* occur due to natural disasters, human error, or failed hardware to name a few examples. Medication labeling and dispensing will still occur during a downtime, so the pharmacy requires a plan to generate electronically or manually hand-write labels. Each institution needs to evaluate all of their institutional technologies and applications to determine a mitigation plan to proceed with near normal operations. Institutions need to have policies that guide providers on what events require back-documentation into the patient's EHR. Billing and financial data require an evaluation after the event to ameliorate any lost charges. Retail pharmacies will also require a plan for downtime situations to manage manual prescription filling.

SPECIALIZED ROLES IN INFORMATICS

The need for pharmacy technicians in advanced informatics roles is needed to support the complex needs of technology enhanced medication-use process. Pharmacy technicians involved in informatics need to possess a variety of skills to be successful (**Table 10-3**). The PTI will need to exhibit his or her skills in the following areas: automation and technology, systems management, management of projects, end-user training and education, policy and governance, customer service, charge integrity, and reporting.

SUMMARY

Healthcare reimbursement is constantly evolving. On March 23, 2010, the Patient Protection and Affordable Care Act of 2010 was enacted. This legislation expands healthcare coverage to people who were previously uninsured or underinsured. As a result, pharmacy billing and reimbursement will continue to change. More people have become eligible for Medicaid. More prescriptions will be filled, and commonly used payment benchmarks for prescriptions will change. The Medicare Part D coverage gap will close by 2020. Further revisions in healthcare payment may occur, and pharmacists and technicians should stay abreast of these changes. Pharmacy technicians play an important role by ensuring that prescriptions contain the appropriate information for proper reimbursement. The challenge for pharmacy technicians is to stay informed of the changes in billing and reimbursement and understand how these changes impact the pharmacy and the patients they serve.

The complexities of technology within our hospital and retail pharmacies can be difficult for many pharmacy personnel. Understanding expectations of the technology and when to solicit expert assistance is imperative to ensure that care is provided to patients in a safe, efficient, and effective manner. There are many more technologies that are used in pharmacies that are not discussed here. Whenever faced with a new device or software application, it is important to seek out the subject matter experts to help educate and demonstrate the appropriate use. Informatics pharmacists and technicians are available to assist in making the best outcomes of the technology that you use in your daily work.

TABLE 10-3. Informatics Knowledge, Skills, and Abilities for Pharmacy Technicians

1. Understanding of information technology systems: ■ Interfaces ■ Computer management techniques ■ Problem resolution ■ Database maintenance
2. Pharmacy, medication, and medical terminologies: ■ Medication-use workflow processes ■ Drug procurement ■ Pharmacy inventory ■ Medication ordering ■ Order management ■ Dispensing ■ Drug preparation ■ Distribution ■ Billing systems
3. Knowledge of the clinical environment: ■ Practices, procedures, policies, strengths, and weaknesses to effectively use data to track and manage patient care. ■ Emerging and state-of-the-art technology, regulations, programs, and processes related to health informatics. ■ Ability to formulate administrative and clinical policies and directives, instruct practitioners on the change and application of new policies and directives, and provide leadership on informatics committees or teams.
4. Knowledge of automation and software systems that affect clinical practice and technologies that may benefit healthcare delivery processes.
5. Ability to troubleshoot functionality issues, develop solutions, and ensure quality management of clinical operations.
6. Comprehensive knowledge of the data life cycle including data design, collection, and management to input, retrieve, analyze, summarize, and present information effectively.
7. Extensive required knowledge base: ■ Usability ■ Data standards ■ Data validation ■ Understanding of content relationships ■ Interoperability among systems
8. Understanding common network standards and network architectures and the functions and purposes of common hardware components and configurations.
9. Understanding the design of safe technology and automation systems.
10. Database skills to successfully create patient and medication information data sets and successfully construct reports.
11. Ability to skillfully communicate both orally and in a variety of written media for a variety of audiences, from information technology and clinical experts to end-users.
12. Ability to guide the evolution of automation technology and processes using creative and well-developed interpersonal skills to achieve effective communication with end-users and management.

Source: Originally published in ASHP statement on the pharmacy technician's role in pharmacy informatics. *Am J Health-Syst Pharm.* 2014;71(3):247-50. Copyright © 2014 by the American Society of Health-System Pharmacists, Inc. All rights reserved.

SELF-ASSESSMENT QUESTIONS

1. Roberta Jones is a 67-year-old single female with no known disabilities. Her annual income is $18,000. Her income does not make her eligible for Medicaid. Roberta has Medicare Parts A and B but no prescription drug coverage. She pays cash for prescriptions. Roberta has a prescription for Eliquis, but she is unable to pay for it. A generic form of Eliquis is not currently available. What are Roberta's options for obtaining her prescription?
   a. Roberta should apply for Medicaid.
   b. Roberta should buy only as much Eliquis as she can afford today.
   c. Roberta should apply for Medicare Part D.
   d. Roberta should not have her Eliquis prescription filled.

2. Payment from third-party payers for prescription medications is based on the following formula:

   Third-party reimbursement = (ingredient cost + dispensing fee) – copayment

   How is "ingredient cost" determined?
   a. By using the acquisition cost on the pharmacy invoice.
   b. By using the formulas included in the Budget Deficit Reduction Act (DRA).
   c. By using a pricing benchmark such as MAC or WAC.
   d. By calculating how much the pharmacy needs to cover their costs.

3. _____ is the largest public payer of prescription drug benefits.
   a. Medicaid
   b. Medicare
   c. CVS Health
   d. Department of Defense

4. Mr. Simon has been coming into your pharmacy for years and paying cash for his prescriptions. He recently turned 65 years old and has Medicare Part A. Is Mr. Simon eligible for Medicare Part D?
   a. Yes
   b. No

5. Dual eligibles:
   a. Are individuals who qualify for both Medicaid and Medicare.
   b. Are individuals who enroll in two types of managed care plans.
   c. Have creditable insurance to Medicare Part D.
   d. Pay double copays for brand name prescriptions.

6. The Low-Income Subsidy (LIS) is:
   a. A fixed amount the individual pays out of pocket at the beginning of the year before the Part D plan begins to pay.
   b. Extra help to pay for the Medicare drug plan.
   c. A period of reduced coverage once the initial coverage limit is reached.
   d. A manufacturer coupon program.

7. Lily Jackson comes into your pharmacy with a prescription for metformin 500-mg tablets, Sig: take one tablet twice daily, Quantity #100. When you enter the information into the pharmacy system, you get a message saying "Maximum days supply = 30." You should:
   a. Dispense 100 tablets as a 30 day supply.
   b. Dispense 60 tablets, submit the claim as a 30 day supply, and document the change in quantity on the face of the prescription.
   c. Not dispense the prescription. Ask Mrs. Jackson to obtain a new prescription for 60 tablets.
   d. Dispense 100 tablets and submit the claim as a 50 day supply.

8. Stanley Johnson is enrolled in a Medicare Part D plan. He does not qualify for Extra Help. Every month, he has four prescriptions filled and usually, he pays copayments of $120 for the four prescriptions. This month, the pharmacy system shows that Mr. Johnson's copayments for his prescriptions total $600. What should/do you tell Mr. Johnson?
   a. He is most likely in the donut hole (coverage gap) of his Medicare Part D plan and must pay the ($600) "out-of-pocket cost" until he reaches Catastrophic Coverage.
   b. He should ask his physician to obtain prior approvals for the prescriptions.
   c. He should switch to another Medicare Part D plan immediately.
   d. There is an error in the pharmacy system and he only owes $120.

9. A Medicare beneficiary comes into your pharmacy with a new prescription. She enrolled in a Medicare Part D plan 3 months ago but does not have her prescription ID card. Your pharmacy system does not show any Part D information for her. What should you do?
   a. Call the major Part D plans and ask if she is a member.
   b. Check the Medicare website (www.medicare.gov) to determine the name of her plan.
   c. Perform an E1 transaction on the pharmacy system to determine her Part D eligibility information.
   d. Tell her to go home and look for her card.

10. Mrs. Hernandez is a widow with Medicare Part A and B who receives healthcare and prescription insurance from her husband's former employer. She received a letter from the employer stating that the prescription drug coverage she has is creditable to Medicare Part D. This letter indicates that Mrs. Hernandez could/should:
   a. Apply for Medicaid.
   b. Drop her current coverage since she is a widow.
   c. Enroll in Medicare Part D.
   d. Remain with her current prescription coverage.

11. A customer comes into your pharmacy with a prescription ID card for a new Medicare Part D plan. She has a prescription for Tylenol #3 tablets # 360, Sig: take one or two tablets every 6 hours as needed for chronic pain. She has been taking the Tylenol #3 for many years. When you enter the information in the pharmacy system, you get a message saying "MME limit exceeded." What should you do?
   a. Advise the customer to have the physician prescribe a non-opioid pain medication.
   b. Advise the customer to switch Medicare Part D plans immediately.
   c. Fill the prescription anyway and charge the normal copayment.
   d. Contact the Part D plan because a quantity override may be available and/or may be required.

12. Mrs. Patel comes into your pharmacy with a new prescription for Aricept and a prescription ID card for a Medicare Part D plan. You enter the information into the pharmacy system and get a message that states, "prior authorization required." You tell Mrs. Patel that:
   a. She should switch to a different Medicare Part D plan.
   b. She may be entitled to a 30-day supply of medication while her physician completes the paperwork for a prior authorization.
   c. She needs to pay cash for the prescription.
   d. She should try to get the prescription filled in 30 days.

13. Mr. Fisher presents a prescription for Novolog 100 units/mL #3 vials with Sig: As directed per sliding scale. Is this an acceptable prescription to bill to an insurance company?
   a. Yes, all necessary information is included.
   b. No, the quantity is too high.

c. No, the instructions are too vague.
d. No, Novolog should not be used for sliding scale insulin treatment.

14. Ms. Smith presents a prescription for itraconazole 100-mg oral capsules with directions: Take 2 capsules by mouth twice daily for 1 week. The prescribing physician signed the prescription, indicating "may substitute." The pharmacy does not have the generic product in stock and only has the brand name product (Sporanox 100-mg capsules). Which of the following should the pharmacy technician do?
    a. Call another pharmacy to borrow a bottle of itraconazole 100-mg, 28 capsules.
    b. Offer to fill the prescription with the brand name product. Dispense 28 capsules of Sporanox and process the claim with DAW code 4.
    c. Give the prescription back to Ms. Smith and state that the pharmacy cannot fill the prescription.
    d. Tell Ms. Smith that her prescription will be filled. Dispense 28 capsules of Sporanox and process the claim as itraconazole.

15. AMP is the average price paid by the
    a. Wholesaler
    b. Pharmacy
    c. Manufacturer
    d. Self-pay patient

16. The plan whereby a drug company offers certain free drugs to low-income patients who lack prescription drug coverage is
    a. Indemnity insurance
    b. Medicare Part D
    c. Patient assistance program
    d. WAC

17. PBMs are organizations that administer pharmacy benefits for
    a. Private insurance companies
    b. Third-party insurance providers
    c. Federal government
    d. Private or third-party payers

18. Medicare is
    a. A medical and long-term care program funded by federal and state governments
    b. The federal health program for the elderly, disabled, and others with ESRD and ALS
    c. The federal health program for low-income Americans

19. Medicare Part D plans all subscribe to the same formulary with the same costs and benefits to all subscribers.
    a. True
    b. False

20. ICD-10 codes used in claim submissions are used to designate
    a. Beneficiaries
    b. Drug name, strength, and manufacturer
    c. Place of service
    d. Diagnosis

21. The use of barcoding technology reduces the errors filling ADCs by 100%.
    a. True
    b. False

22. The use of EHR systems have been adopted by greater than 90% of hospitals in the United States due to which federal program:
    a. U.S. Food and Drug Administration (FDA)
    b. Meaningful use
    c. Drug Supply Chain Security Act (DSCSA)
    d. Prescription Drug Monitoring Programs (PDMPs)

23. The use of clinical decision support alerts provide guidance to providers to make the right choice, but when they alert too frequently they cause a phenomenon described as:

a. Alert fatigue
b. Disruptive innovation
c. Abhorrent workflow
d. Work-arounds

24. The use of CPOE and e-Rx minimizes which step of the medication-use process?
a. Administration
b. Dispensing
c. Monitoring
d. Transcription

25. What identifier is usually incorporated into the barcode of a medication that the nurse will administer with a BCMA system?
a. National Drug Code (NDC)
b. RxNorm CUI
c. Lot number
d. Expiration Date

26. Electronic prescribing of controlled substances is routinely used in all 50 states.
a. True
b. False

27. The use of IV workflow software products incorporate the following technologies except for:
a. Photography
b. Barcode scanning
c. Gravimetrics
d. Telemetry

28. _____ helps ensure that correct medications are placed into the right pocket/drawer of an ADC.
a. Nurse witness
b. Barcode scanning on refill
c. Organizing the drawers alphabetically
d. Using color to load high-risk medications

29. Pharmacy technicians can use _____ to prepare medications without a pharmacist directly present.
a. Barcode-assisted medication administration
b. ePrescribing
c. Robotics
d. Telepharmacy

30. All pharmacies should develop a _____ plan to ensure that pharmacy operations continue.
a. Budget
b. Downtime
c. Capital
d. Marketing

31. Name three common reasons for a claim to be rejected by a PBM.

32. A PDMP
a. Identifies and deters drug abuse and drug diversion
b. Sets the standards for e-prescribing
c. Standardized Medicare Part D cards
d. Administers pharmacy benefits for third-party payers

33. Adjudication
a. Is the cost-sharing amount that the insured individual pays; the amount is a percentage of a charge for a service.
b. Is the predetermined amount that insured individuals pay at the time of service.
c. Refers to the determination of the insurer's payment after the member's insurance benefits are applied to a prescription claim.
d. Is the fixed amount that must be paid each year by the individual before the insurance starts to pay.

34. Prior authorization
a. Is the amount to be paid for drugs predetermined based on the treatment condition.
b. Requires a prescriber to receive preapproval from the PBM in order for the drug to be covered by the benefit.

c. Sets upper limits of an amount of a drug that is covered by a prescription plan.

d. Requires the use of a recognized first-line drug before a more complex drug is used.

35. Overhead costs of doing business include all EXCEPT

a. Utilities

b. Salaries

c. Drug acquisition costs

d. Supplies

SELF-ASSESSMENT ANSWERS

1. c.
2. c.
3. b.
4. a.
5. a.
6. b.
7. b.
8. a.
9. c.
10. d.
11. d.
12. b.
13. c.
14. b.
15. a.
16. c.
17. d.
18. b.
19. b.
20. d.
21. b. Errors can still occur.
22. b.
23. a.
24. d.
25. a.
26. b.
27. d.
28 b.
29. d.
30. b.

31. (1) Missing or invalid Patient ID, (2) prior authorization required, (3) pharmacy not contracted with plan on date of service, (4) refill too soon, and (5) missing or invalid quantity prescribed.

32. a.

33. c.

34. b.

35. c.

APPENDIX A

PRACTICE EXAM 1 + ANSWERS



PRACTICE EXAM 1

Choose the best answer for each of the following.

1. Prior authorization requires the:
   a. Insurance company to receive a new prescription order from the provider.
   b. Member pharmacy to get approval from the prescriber to dispense a nonformulary drug.
   c. Physician to seek approval from the insurance company to prescribe a specific medication.
   d. Patient to get approval from the insurance company to fill a prescription order for a specific medication.

2. Which dosage form is considered enteral?
   a. PO tablet
   b. Suppository
   c. IM injection
   d. IVPB antibiotic

3. According to the CSA, which drug listed below is a C-II substance?
   a. Diazepam
   b. Tylenol® elixir with codeine
   c. Vicodin®
   d. Atomoxetine

4. If a patient takes 112 mcg of levothyroxine daily for 3 months, how many grams have they ingested?
   a. 10.08
   b. 0.01

c. 1.08
d. 100.8

5. Which auxiliary label should be affixed to a prescription vial containing metronidazole?
   a. *"Do not drink alcohol."*
   b. *"Take with food."*
   c. *"Do not take within 4 hours of dairy products."*
   d. *"Caution; may be habit-forming."*

6. Ritalin® is to methylphenidate as Vyvanse® is to:
   a. Dextroamphetamine
   b. Lisdexamfetamine
   c. Dexlanosoprazole
   d. Lenalidomide

7. The NDC number is used to identify drug products. Which set of digits identifies the specific drug?
   a. The third set
   b. The middle set
   c. The first set
   d. Need all three to identify the drug

8. What is the function of the DEA? It is to:
   a. Enforce the FDA amendments.
   b. Enforce the CSA.
   c. Resolve OSHA complaints.
   d. Accredit pharmacy programs.

9. XXIV is equal to:
   a. 26
   b. 25
   c. 24
   d. 23

10. A patient receives 90 tablets of a drug and is ordered to take 3 tablets every morning and 2 tablets every evening. How many days' supply does the patient have?
    a. 18
    b. 30
    c. 60
    d. 45

11. Laminar flow hoods should be cleaned:
    a. Not be cleaned—HEPA filter takes care of everything
    b. Top to bottom and back to front
    c. Bottom to top and back to front
    d. Front to back and top to bottom

12. A patient receives a prescription for an ophthalmic suspension. Which auxiliary label should be affixed to the container?
    a. *"Use in EARS."*
    b. *"Use in EARS" and Shake Well.*
    c. *"Use in EYES."*
    d. *"Use in EYES" and Shake Well.*

13. What is the maximum number of refills allowed for Lyrica®?
    a. 6 times in 5 months
    b. May be refilled 11 times in 12 months
    c. 5 times in 6 months
    d. 1 time only

14. What instrument is used for trituration?
    a. Spatula and ointment slab
    b. Hot plate and stir rod
    c. Electronic balance and conical
    d. Mortar and pestle

15. According to federal law, prescriptions for C-II substances are to be kept on file in the pharmacy for:
    a. 1 year
    b. 2 years
    c. 5 years
    d. 10 years

16. What piece of information is not required on a medication order?
    a. Patient name

b. Prescriber information
c. Drug name and strength
d. Insurance information

17. Information that is generally *not* found in a patient's profile in an outpatient pharmacy includes which of the following?
    a. Preferences regarding child-resistant packaging
    b. Date of birth
    c. Preferred hospital
    d. Prescription and refill history
    e. Allergies

18. According to USP <797>, personnel must wash fingers, hands, wrists, and arms up to the elbow for:
    a. 30 seconds
    b. 1 minute
    c. 2 minutes
    d. 3 minutes

19. Which FDA recall is the most severe?
    a. Class I
    b. Class II
    c. Class III
    d. Class IV

20. Which drug listed below is the same therapeutic class as Diovan®?
    a. Cymbalta®
    b. Lotensin®
    c. Coreg®
    d. Benicar®

21. The generic name for Lipitor® is:
    a. Simvastatin
    b. Atorvastatin
    c. Pravastatin
    d. Rosuvastatin

22. Escitalopram is used for:
    a. Noninsulin-dependent diabetes mellitus
    b. Hypertension
    c. Depression
    d. Cholesterol

23. Aleve is to naproxen as Mobic® is to:
    a. Celecoxib
    b. Citalopram
    c. Ibuprofen
    d. Meloxicam

24. The common ending for prostaglandin analog drugs is:
    a. *"mab"*
    b. *"statin"*
    c. *"prost"*
    d. *"olol"*

25. Vicodin® is a narcotic analgesic containing:
    a. Hydrocodone and acetaminophen
    b. Hydrocodone and aspirin
    c. Oxycodone and acetaminophen
    d. Oxycodone and aspirin

26. Which statement below is false?
    a. All suspensions must be shaken.
    b. Otic products may be used opthalmically.
    c. Elixirs contain alcohol.
    d. Solutions contain drug that is completely dissolved.

27. Medicare part ____ covers prescription drugs.
    a. A
    b. B
    c. C
    d. D

28. Pyrogens are:
    a. Unwanted particulate matter present in parenteral products.

b. Remnants of bacteria that may cause a fever.
c. Beakers used on a hot plate for compounding.
d. Substances that cause an allergic reaction.

29. A *"buffer"* room, as defined by USP <797>, is a:
a. Room where the primary engineering controls are sterile as aseptic compounding takes place there.
b. Segregated compounding area with a positive pressure and an ISO of 7 or 8.
c. Room reserved for non-aseptic activity.
d. Room reserved for hand hygiene.

30. Betamethasone 0.1% cream is dispensed in a 4-oz tube (120 g). How much betamethasone is in the tube?
a. 12 g
b. 12 mg
c. 0.12 g
d. 12 g

31. A prescription asks for 60 g of lidocaine® 4% (w/w) ointment. How much lidocaine powder must be weighed for this product?
a. 24 mg
b. 2.4 g
c. 240 mg
d. 240 g

32. An alcohol solution is labeled 10% v/v. How much alcohol is in 200 mL of this solution?
a. 20 mL
b. 2 mL
c. 200 mL
d. 10 mL

33. Using 2.25-g sodium chloride tablets, how many would be needed to prepare 500 mL of a 0.45% sodium chloride solution?
a. 1 tablet
b. 10 tablets
c. ½ tablet
d. 5 tablets

34. The _____ develops the formulary for an institutional pharmacy.
a. Policy and Procedure Committee
b. Pharmaceutics Committee
c. Pharmacy and Therapeutics Committee
d. Quality Control Committee

35. Express the following in reduced form: 3/4 + 7/8
a. 13/8
b. 2
c. 1 3/8
d. 1.5
e. 1 5/8

36. A child is to be treated with 50 milligrams (mg) of a particular drug per kilograms (kg) of body weight. If the child weighs 38 lbs., what is the dose of the drug that should be administered? (Round to the nearest 5 mg.)
a. 430 mg
b. 865 mg
c. 1200 mg
d. 1655 mg
e. 1900 mg

37. Using the information from the previous question, how much would be needed to provide the correct dose if the drug concentration is 100 mg per milliliter (mL)?
a. 4.3 mL
b. 8.65 mL
c. 12 mL
d. 16.55 mL
e. 19 mL

38. What is *quality control*?
a. A final check to ensure safety and quality of the preparation.
b. Something done only by the pharmacist.
c. Something accomplished by comparing the finished product with pictures of what it should look like.

d. All of the above.
e. None of the above.

39. Which of the following is *false* concerning the drug-receiving process in a pharmacy?
    a. It is not necessary to verify the number of boxes delivered.
    b. Each item should be carefully checked to make sure it is the correct drug and correct strength.
    c. Expiration dating should be checked so that short-dated products can be returned.
    d. Controlled substances require additional record-keeping steps.
    e. The person who checked-in the order should sign the invoice or packing slip.

40. A patient is supposed to take 375 mg of an antibiotic 3 times daily for 10 days. The pharmacy dispenses 250 mg per 5 mL suspension. How much must the patient take per dose?
    a. 3.75 mL
    b. 5 mL
    c. 7.5 mL
    d. 8.75 mL
    e. 10 mL

41. Using the information from the previous question, how much should the pharmacy dispense for the full 10-day supply?
    a. 100 mL
    b. 150 mL
    c. 200 mL
    d. 225 mL
    e. 300 mL

42. Which statement below is FALSE?
    a. A LAFW should not be turned off.
    b. If a LAFW is turned off, it should run for a minimum of 30 minutes before use.
    c. If a LAFW is turned off, it should run for a minimum of 60 minutes before use.
    d. A LAFW should be tested every 6 months by qualified personnel.

43. High-risk sterile compounds made from nonsterile ingredients:
    a. Have a beyond-use date of 48 hours at room temperature.
    b. Have a beyond-use date of 30 hours at room temperature.
    c. Have a beyond-use date of 24 hours at room temperature.
    d. Must be used immediately.

44. Base components of a TPN include:
    a. Multivitamins and dextrose
    b. Electrolytes, dextrose, and amino acids
    c. Dextrose, lipids, and electrolytes
    d. Dextrose, amino acids, water, and sometimes fat

45. Hazardous drugs have three categories. Category 3 includes:
    a. Antineoplastic drugs
    b. Non-antineoplastic drugs
    c. Medication that interferes with reproduction
    d. All REMS drugs

46. Compounding an extemporaneous formulating master formulation record is:
    a. An individual record that is followed each time the preparation is compounded.
    b. Completed each time the preparation is made.
    c. Contains the prescription number and duplicate labels.
    d. Contains the beyond-use date for each particular compound.

47. Geometric dilution is the process of:
    a. Reducing particle size in a mortar pestle.
    b. Reducing particle size into a paste.
    c. Uniformly mixing ingredients with a wide discrepancy of amounts.
    d. Adding electrolytes to a TPN.

48. Which dosage indication listed below would help reduce the chance of a medication error?
    a. 5.0 mg
    b. 2 µ
    c. 0.5 mg
    d. .5 g

49. ISMP has listed several classes of drugs as *high-alert* medications. Which drug listed below would NOT be a high-alert medication?
    a. Heparin
    b. Potassium chloride injection
    c. Methotrexate
    d. Sildenafil

50. To ensure that a verbal order is processed correctly, the recipient of the order should:
    a. Repeat back, then write the order down.
    b. Repeat back, enter the order into the computer, then write it down.
    c. Write it down, then enter it into the computer.
    d. Write it down, then repeat back.

51. The purpose of TALL man lettering is to:
    a. Identify medications associated with serious adverse reactions.
    b. Distinguish between two drugs with similar-looking or -sounding names.
    c. Highlight the generic name of a drug.
    d. Identify the drug class.

52. A PBM sets quantity limits to optimize economic performance; this is defined as:
    a. Only utilizing formulary drugs.
    b. Setting maximum days of therapy amounts.
    c. Requiring 30 days of first-line drugs to be used first.
    d. Requiring mail-order pharmacies to be used for patients to get 3 months of a drug.

53. A 1-oz. tube of OTC hydrocortisone (0.5%) cream contains:
    a. 15 mg of hydrocortisone
    b. 150 mg of hydrocortisone
    c. 0.15 mg of hydrocortisone
    d. 30 mg of hydrocortisone

54. The four steps of pharmacokinetics are:
    a. Absorption, distribution, metabolism, and excretion
    b. Absorption, distribution, migration, and enzyme action
    c. Absolution, dissolution, metabolism, and excretion
    d. Absorption, dissolution, metabolism, and excretion

55. The Methamphetamine Act of 2005 allows customers to purchase:
    a. 9 g of pseudoephedrine per day
    b. 3.6 g of pseudoephedrine per day
    c. Only 60-mg tablets of pseudoephedrine
    d. Only 30-mg tablets of pseudoephedrine

56. A company seeking to manufacture a generic drug must apply to the:
    a. FDA for a NDA
    b. FDA for a ANDA
    c. DEA for a NDA
    d. DEA for a ANDA

57. _____ defined a *legend drug*.
    a. Durham Humphrey Amendment
    b. Kefauver Harris Amendment
    c. Sherley Amendment
    d. Hatch-Waxman Amendment

58. Sandy Sue has a prescription for *YAZ*. She should receive a patient package insert:
    a. Upon request
    b. With her original prescription fill
    c. Every time her prescription is filled
    d. Only if the doctor ordered it

59. HIPAA:
    a. Allows for disclosure of PHI for patient care.
    b. Allows for disclosure of PHI upon a patient's death.
    c. Allows for disclosure of PHI to a spouse.
    d. Never allows for disclosure of PHI.

60. Laminar flow workbenches need to be certified:
    a. Every 2 years
    b. Every 6 months
    c. Every 3 months
    d. Monthly

61. The first set of numbers in an NDC number identifies the _____ of the drug.
    a. Manufacturer
    b. Dosage formulation
    c. Strength
    d. Package size

62. Prime vendor contracts have several advantages including timely ordering and delivery, overall simplification of credits and returns, and:
    a. Product availability from a single manufacturer
    b. No POs, but additional documentation
    c. Advantages associated with ordering
    d. Fewer inventory carrying costs and product availability from different manufacturers

63. Stock rotation is the process of:
    a. Placing newly received products behind all other products on the shelf.
    b. Returning outdated products.
    c. Filling the ADC with products as they are received.
    d. Inventory recycling.

64. When referring to a *"par level,"* this means:
    a. The maximum allowable # of doses allowed on the shelf.
    b. The minimum allowable # of doses allowed on the shelf.
    c. *Just-in-time* inventory control.
    d. Within a standard range (minimums and maximums).

65. Which group listed below grants technicians the "right" to practice either by registration or licensure?
    a. PTCB
    b. NABP
    c. ECEPT
    d. State Boards of Pharmacy

66. A prescription order reads *"1 tab QID, AC and at bedtime."* What instructions should be on the prescription label?
    a. Take 1 tablet 4 times a day before meals and at bedtime.
    b. Take 1 tablet 4 times a day, after meals and at bedtime.
    c. Take 1 tablet before meals 4 times a day and 1 tablet at bedtime.
    d. Take 1 tablet 3 times a day before meals.

67. A patient is to take 1 teaspoonful of suspension TID. How many days will a 4-oz. bottle last?
    a. 8 days
    b. 12 days
    c. 4 days
    d. 10 days

68. Which drug listed below is NOT an SSRI?
    a. Trazodone
    b. Escitalopram
    c. Celexa®
    d. Paroxetine

69. Which pair of drugs listed below are anticonvulsants?
    a. Gabapentin and pregabalin

b. Escitalopram and topiramate
c. Bupropion and lamotrigine
d. Diazepam and alprazolam

70. The online processing of an insurance claim to determine payment is called a(n):
a. Deductible
b. Co-pay
c. Adjudication
d. Co-insurance

71. Which of the following is an ARB (angiotensin II receptor blocker)?
a. Valsartan
b. Famotidine
c. Diltiazem
d. Lisinopril

72. Which of the following dosage forms bypass the digestive tract?
a. Elixir
b. Ointment
c. Oral capsule
d. Suspension

73. Which category of drugs has the characteristic ending "–olol"?
a. Loop diuretics
b. ACE inhibitors
c. Angiotensin II receptor blockers
d. Beta-blockers
e. None of the above

74. Which question should be referred to a pharmacist?
a. "Who manufactures Lovenox®?"
b. "How much codeine is in one Tylenol #3® tablet?"
c. "What is the difference in price between brand name Valium® 10-mg tablets and the generic version?"
d. "If I am allergic to penicillin, is it safe for me to take erythromycin?"

75. If you are asked to prepare an IV fluid with 2 g of magnesium sulfate using a solution with 500 mg of magnesium sulfate per mL, how many mL do you need?
a. 1.25 mL
b. 2 mL
c. 3.5 mL
d. 4 mL
e. 5 mL

76. Which question should be referred to a pharmacist?
a. "What is the brand name of Zoloft®?"
b. "Should amoxicillin suspension be kept in the refrigerator?"
c. "What is the usual dose of ciprofloxacin?"
d. "How many milliliters are in a teaspoonful?"
e. "Is Zertec® available over the counter?"

77. If you have to make 100 mL of a 10% w/v solution from water and a 90% w/v solution, how much of the 90% solution do you need to use?
a. 9 mL
b. 10 mL
c. 11 mL
d. 12 mL
e. None of the above

78. If a drug is ordered "one pc & at bedtime" and 40 capsules are dispensed, what is the estimated days' supply?
a. 10
b. 12
c. 15
d. 40

79. How many grams of hydrocortisone would be required to make 1 lb. of a 5% ointment?
a. 2.27 g

b. 3 g
c. 5 g
d. 22.7 g
e. 90.8 g

80. Convert 180 lb to kg.
a. 81.8 kg
b. 100 kg
c. 120 kg
d. 396 kg

81. You receive a prescription for erythromycin suspension 400 mg/5 mL. Dispense 100 mL.
The Sig: reads _____ tsp QID until all the medication is taken. If the dose of erythromycin is given as 40 mg/kg/day and your patient weighs 44 lbs., what should the amount in the signa be?
a. 2 teaspoonsful
b. 1 teaspoonful
c. ½ teaspoonful
d. 800 mg

82. The prescription reads hydrocortisone ointment 20 g 0.5%. Sig: Apply to eye. How many grams of 2% ophthalmic hydrocortisone ointment and how many grams of ophthalmic diluent should be used in compounding the prescription?
a. 15 g of hydrocortisone; 5 g of diluent
b. 5 g of hydrocortisone; 15 g diluent
c. 1 g of hydrocortisone; 19 g of diluent
d. 19 g of hydrocortisone; 1 g diluent

83. A prescription for prednisone reads: "Take 5 tablets BID for 5 days, then take 5 tablets daily for 5 days, then take 4 tablets BID for 5 days; then take 4 tablets daily for 5 days, then take 3 tablets daily for 5 days, then take 2 tablets daily for 5 days, then day 1 tablet daily for 10 days. How many tablets should be dispensed?
a. 140 tablets
b. 160 tablets
c. 170 tablets
d. 180 tablets

84. A patient takes levothyrodine 0.25 mg daily. How many micrograms should the patient take over 2 weeks' time?
a. 3.5 mcg
b. 250 mcg
c. 1750 mcg
d. 3500 mcg

85. A prescription is delivered to the pharmacy for cefuroxime 250 mg/5 mL. The patient is ordered to receive 200 mg per dose twice a day for 7 days. How many milliliters will be dispensed, and how many milliliters will the patient take per dose?
a. 84 mL; 12 mL
b. 56 mL; 4 mL
c. 28 mL; 4 mL
d. 8 mL; 4 mL

86. Convert 126 lbs. to kg.
a. 60 kg
b. 300 kg
c. 57.3 kg
d. 277.2 kg

87. You are asked to prepare a 10% solution using 10 g of a powder that occupies 14 mL. How much diluent will you add?
a. 100 mL
b. 86 mL
c. 14 mL
d. 90 mL

88. If you add 8.8 mL of diluent to a 2-g vial with a concentration of 200 mg/mL, what would the final percent solution be?
a. 10%
b. 20%
c. 2%
d. 5%

89. You are asked to prepare 30 mL of a 200-mcg/mL folic acid solution. The stock solution is 5 mg/mL. How much folic acid and how much diluent do you need?
    a. 0.4-mL folic acid; 29.6-mL diluent
    b. 1.2-mL folic acid; 28.8-mL diluent
    c. 2-mL folic acid, 28-mL diluent
    d. 6-mL folic acid; 24-mL diluent

90. A patient has an order for cephalexin oral suspension 250 mg/5 mL; SIG 500 mg QID for 1 day, then 250 mg QID for a total of 10 days. How many milliliters will the patient need to complete the course of therapy?
    a. 150 mL
    b. 200 mL
    c. 220 mL
    d. 240 mL

91. How many milligrams of drug are in 1 oz. of a 2.5% solution?
    a. 0.75 mg
    b. 1.5 mg
    c. 750 mg
    d. 1500 mg

92. A liter of IV fluid is ordered to be infused over 6 hours with a 20 drop set. What is the flow rate in drops per minute?
    a. 56 gtt/min
    b. 50 gtt/min
    c. 17 gtt/min
    d. 5 gtt/min

93. Penicillin has been prescribed for a child at 5000 units/kg PO q 6h. The child weighs 75 lbs. Penicillin is available in a suspension with a concentration of 100,000 units/mL. How much should be dispensed for a 10-day course of therapy?
    a. 17 mL
    b. 6.8 mL
    c. 68 mL
    d. 125 mL

94. An IV solution has a concentration of 123 mg/250 mL. It is to be administered at the rate of 200 mcg/min. What is the flow rate in mL/hr?
    a. 19.5 mL/hr
    b. 20 mL/hr
    c. 12 mL hr
    d. 24 mL/hr

95. The term weight in volume (w/v) refers to the number of:
    a. Milligrams of drug per 100 mL of final solution
    b. Milligrams of drug per liter of final solution
    c. Grams per 100 mL of final solution
    d. Grams per liter of final solution

96. How many grams of coal tar should be added to 1 lb. of zinc oxide paste to prepare an ointment containing 5% coal tar?
    a. 0.8 g
    b. 22.8 g
    c. 23.9 g
    d. 38.9 g

97. How many milliliters of water must you add to 500 mL of a 10% stock solution of sodium chloride to make a batch of normal saline?
    a. 5555 mL
    b. 5055 mL
    c. 11,111 mL
    d. 10,611 mL

98. Dexamethasone is available in a 20-mg/mL concentration in a 20-mL vial. You are ordered to make a 5-mg/mL dilution of dexamethasone. How much diluent will you add?
    a. 80 mL
    b. 60 mL
    c. 20 mL
    d. 10 mL

99. A patient has an order for prednisone 5-mg tablets: 30 mg tonight, 10 mg PO BID days x 2 days, 10 mg daily for 2 days, then 5-mg tablets for 2 days, then stop. How many tablets should you dispense?
    a. 5 tablets
    b. 10 tablets
    c. 20 tablets
    d. 25 tablets

100. If a patient is ordered to inject 22 units of U-100 insulin each morning, how many days will a 10-mL vial last?
    a. 5 days
    b. 31 days
    c. 35 days
    d. 45 days

101. USP <800> covers:
    a. All sterile compounding
    b. All nonsterile compounding
    c. Compounding of hazardous drugs
    d. Community pharmacy manufacturing

102. A patient needs 500 mg of an antibiotic BID for 2 weeks. How many 500-mg tablets do you dispense?
    a. 30
    b. 20
    c. 14
    d. 28

103. Aseptic technique is the process of manipulating sterile products to prevent :
    a. Introduction of inactive ingredients
    b. Unnecessary handling
    c. Introduction of pathogens
    d. Unnecessary cost

104. A medication is ordered Q 4h, and the first dose is given at 6 AM. When will the next 2 doses be given?
    a. 1200, 1800
    b. 10,00, 1400
    c. 0800, 1200
    d. 0900, 1300

105. You are compounding a pediatric suspension using 25-mg tablets. The order is for a 1 mg/5mL concentration. The patient is to take 1½ teaspoonfuls PO BID and ordered to have a 30-day supply. How many tablets will you have to crush to get the correct amount of drug?
    a. 4 tablets
    b. 3 tablets
    c. 2 tablets
    d. 1 tablet

106. What is the brand name for duloxetine?
    a. Colerys®
    b. Cymbalta®
    c. Strattera®
    d. Allegra®

107. Abilify® is a(n):
    a. Antidiabetic
    b. Antidepressant
    c. Antibiotic
    d. Antipsychotic

108. A category of drug on the ISMP high-alert medication list is:
    a. Antithrombitic
    b. Corticosteroid
    c. ARBs
    d. Antihistamines

109. Augmentin® belongs to which antibiotic family?
    a. Tetracyclines
    b. Penicillins
    c. Macrolides
    d. Fluroquinalones

110. The pharmacy received a notice for a Class II recall for fentanyl patches. What is the first step the pharmacy technician should take?

a. Isolate all the recalled lot numbers.

b. File the notice.

c. Prepare a list of patients to contact.

d. Return all the fentanyl in stock to the manufacturer.

ANSWERS FOR PRACTICE EXAM 1

1. c
2. a
3. c
4. b
5. a
6. b
7. b
8. b
9. c
10. a
11. c
12. d
13. c
14. d
15. b
16. d
17. c
18. a
19. a
20. d
21. b
22. c
23. d
24. c
25. a
26. b
27. d
28. b
29. a
30. c
31. b
32. a
33. a
34. c
35. e
36. b
37. b
38. a
39. a
40. c
41. d
42. c
43. c
44. d
45. c
46. a
47. c
48. c
49. d
50. d
51. b
52. b
53. b
54. a
55. b
56. b
57. a
58. c
59. a
60. b
61. a
62. d
63. a
64. d
65. d
66. a
67. a
68. a
69. a
70. c
71. a
72. b
73. d
74. d
75. d
76. c
77. c
78. a
79. d
80. a
81. c
82. b
83. c
84. d
85. b
86. c
87. b
88. b
89. b
90. d
91. c
92. a
93. c
94. d
95. c
96. c
97. b
98. b
99. c
100. d
101. c
102. d
103. c
104. a
105. a
106. b
107. d
108. a
109. b
110. a

APPENDIX B

PRACTICE EXAM 2 + ANSWERS



PRACTICE EXAM 2

Choose the best answer for each of the following.

1. Choose the false statement.
   a. Counterfeit pharmaceuticals may contain incorrect ingredients.
   b. Counterfeit pharmaceuticals may not have a reliable amount of drug (sub potent).
   c. Counterfeit pharmaceuticals may be ineffective in treatment of disease.
   d. Counterfeit pharmaceuticals are often reliable substitutes for backordered drugs.

2. When controlled substances are disposed of, the DEA regulates that:
   a. They are handled by the manufacturer upon return from the pharmacy.
   b. A Form 41 is completed for documentation.
   c. They are disposed of along with other outdated drugs, completing a Form 222 for the DEA for documentation.
   d. They are disposed of by DEA-approved pharmacies only.

3. When a prescriber places an order into the hospital's computer system, this is referred to as:
   a. CSOS
   b. eMAR
   c. COPE
   d. PHI

4. In order to prepare sterile compounds, the pharmacy technician gowns and washes hands in the:
   a. LAFW
   b. Ante area

c. Buffer area
d. Inpatient pharmacy

5. According to federal law, prescriptions for methylphenidate must be kept on file for ____ year(s).
   a. 7
   b. 5
   c. 2
   d. 1

6. Overhead in a pharmacy:
   a. Is the costs of all drugs.
   b. Is the PBM reimbursements.
   c. Includes rent and utilities.
   d. Includes rent and utilities as well as salaries and equipment.

7. Medicare part _____ is the medical insurance.
   a. A
   b. B
   c. C
   d. D

8. Medicare part D:
   a. Covers drugs and automatically includes part C.
   b. Is a voluntary plan covering outpatient prescriptions.
   c. Covers clinic and outpatient visits.
   d. Is required.

9. Medicaid:
   a. Is the federal health program covering the elderly.
   b. Covers hospital healthcare.
   c. Is the federally funded program for low-income Americans.
   d. Is the federal- and state-funded program for low-income Americans.

10. _____ is the health benefit program for the Department of Defense.
    a. Corum
    b. Amicore
    c. Tricare
    d. Medicare

11. A prescription for a controlled substance must contain the prescriber's:
    a. Home address
    b. Birth date
    c. DEA number
    d. BIN number

12. A prescription is written for a 2.5-mg tablet; the SIG states "iii weekly." How many would be dispensed for a 1-month supply?
    a. 30 tablets
    b. 90 tablets
    c. 60 tablets
    d. 12 tablets

13. What agency regulates the registration and licensure of pharmacy technicians?
    a. State Boards of Pharmacy
    b. National Boards of Pharmacy
    c. American Association of Pharmacy Technicians
    d. Pharmacy Technician Certification Board

14. A patient has a prescription insurance policy that covers 80% of the cost; the patient pays the remaining 20%. This is an example of:
    a. Coinsurance
    b. Copayment
    c. A deductible
    d. Medicare part B

15. A secured cabinet for dispensing and tracking medication use in an institutional setting is:

a. An ADC
b. A CPOE
c. An eMAR
d. An e CSA

16. How many Tylenol® #3 tablets would be dispensed if the physician ordered XXIV?
a. 25
b. 26
c. 24
d. 30

17. On-line adjudication is the process of:
a. Submitting data to the PDMP
b. Verification of a DEA
c. Submitting prescriptions for payment
d. Verification of a wholesale order

18. A PBM works for the:
a. Patient
b. Provider
c. Pharmacy
d. Insurance company

19. Epinephrine is a 1:10,000 dilution. How many milligrams of epinephrine would the patient get if he or she received 1 mL?
a. 0.001 mg
b. 0.01 mg
c. 0.1 mg
d. 1 mg

20. You are required to make 2 liters of a 0.25% sodium chloride solution using SWFI and normal saline. How many milliliters of normal saline do you need?
a. 450 mL
b. 555.5 mL
c. 1444.5 mL
d. 750 mL

21. Schedule II narcotics traditionally could only be ordered with a DEA Form 222; now, they can be electronically ordered via:
a. PBM
b. CPOE
c. CSOS
d. From your wholesaler with the rest of your order

22. Prescription order for amoxicillin suspension 1 tsp BID for 10 days is presented in the pharmacy. What volume should be dispensed?
a. 75 mL
b. 100 mL
c. 150 mL
d. 200 mL

23. Ventolin HFA should be administered by which route?
a. SL
b. PO
c. PR
d. IM

24. Which drug listed below is an ACE inhibitor?
a. Cardizem®
b. Benicar®
c. Altace®
d. Cozaar®

25. Which drug listed below is the same therapeutic classification as telmisartan?
a. Avapro®
b. Altace®
c. Trandolapril
d. Atenolol®

26. A patient is to receive D_5W using a 60 gtt/mL set at a rate of 25 mL/hr. What is the rate in gtt/min?
a. 15 gtt/min
b. 25 gtt/min
c. 50 gtt/min
d. 250 gtt/min

27. If a patient receives 7.5% dextrose at a rate of 100 mL/hr, how many grams of dextrose will the patient receive over 24 hours?
    a. 7.5 g
    b. 750 g
    c. 18 g
    d. 180 g

28. A patient has an order for 15 mg of citalopram daily. The patient has requested the liquid dosage formulation, which is available in a 10-mg/5-mL concentration. What volume will the patient take per dose?
    a. 15 mg
    b. 5 mL
    c. 7.5 mL
    d. 75 mL

29. All benzodiazepines are :
    a. Schedule III drugs
    b. Schedule IV drugs
    c. Schedule V drugs
    d. Not scheduled but need an alcohol warning

30. Class II antiarrhythmic drugs are:
    a. Calcium-channel blockers
    b. High-alert drugs
    c. Amiodarone and lidocaine
    d. Beta-blockers

31. Which drug below is NOT a cephalosporin?
    a. Biaxin®
    b. Ceclor®
    c. Maxipime
    d. Rocephin

32. Which drug is an antiplatelet drug?
    a. Ticlid®
    b. Warfarin
    c. Xarelto
    d. Levenox

33. Which drug is an anticonvulsant?
    a. Cymbalta®
    b. Effexor®
    c. Risperidone
    d. Gabapentin

34. Which drug is NOT an SSRI?
    a. Venlafaxine
    b. Paroxetine
    c. Trazodone
    d. Citalopram

35. A patient using terbinafine is most likely treating:
    a. Diarrhea
    b. A topical fungal infection
    c. Herpes
    d. A topical bacterial infection

36. A prostaglandin used to treat glaucoma is:
    a. Lanoprost®
    b. Trusopt®
    c. Pilocarpine®
    d. Timoptic®

37. A patient taking 40 mg of Crestor daily is most likely treating:
    a. Type II diabetes mellitus
    b. HIV-AIDS
    c. High cholesterol
    d. Depression

38. The common ending for beta-blockers is:
    a. *"pril"*
    b. *"sartan"*
    c. *"epam"*
    d. *"olol"*

39. Serotonin (5-HT) receptor agonists (triptans) are used to treat:
    a. Depression
    b. Migraine HA

c. Anxiety
d. ADHD

40. An e-prescription decreases the potential for:
a. Rejection
b. Lawsuits
c. Forgeries
d. Noncompliance

41. Which of the following steps in processing a prescription in a community pharmacy is the pharmacy technician allowed to do?
a. Over-ride warnings.
b. Create the label and affix it to the filled container.
c. Perform the final check.
d. Counsel the patient.

42. Verification of insurance information when a patient drops off a prescription:
a. Eliminates patient wait time.
b. Eliminates customer's co-insurance.
c. Eliminates needlessly filling the prescription and transmitting to an expired insurance company.
d. Reduces need to verify with physician.

43. Which of the following medications is considered a high-alert drug?
a. Insulin
b. Eszopiclone
c. Adderall®
d. Amlodipine

44. What information is required on a prescription label?
a. Provider DEA
b. Patient address
c. Drug manufacturer
d. Prescription serial number

45. A barcode on pharmaceutical products is encrypted with:
a. The chemical name of the drug
b. The brand name of the drug
c. MSD information
d. NDC number

46. How much medication will be dispensed during a typical cart fill in an institutional pharmacy?
a. 24 hours
b. 36 hours
c. 5 days
d. 1 dose

47. Which drug would include a warning about grapefruit juice?
a. Ramipril
b. Propranolol
c. Pravastatin
d. Ranitidine

48. Which medication must a Type I diabetes mellitus patient be prescribed?
a. Glyburide
b. Liraglutidine
c. Glipizide
d. Insulin

49. Many drugs have more than one use. Neurontin was originally approved as an anticonvulsant and is now commonly prescribed for:
a. Depression
b. Migraine HA
c. Pain management
d. Hypertension

50. How much of a 20% stock solution would be needed to make 480 mL of a 10% dilution?
a. 48 mL
b. 240 mL
c. 120 mL
d. 100 mL

51. Which antibiotic has to be dispensed with a medication guide because of the risk of tendon rupture?
    a. Augmentin
    b. Tetracycline
    c. Cephalexin
    d. Levofloxacin

52. Which drug is indicated for insomnia?
    a. Esomeprazole
    b. Eszopiclone
    c. Ecitalopram
    d. Diazepam

53. In what proportion would a 50% cream be mixed with a 10% cream to make a 20% cream?
    a. 3:1
    b. 1:3
    c. 3:4
    d. 1:4

54. Which is NOT part of a continuous quality improvement process?
    a. Terminate employees responsible for medication errors.
    b. Analyze variables causing errors.
    c. Review procedures and educate staff.
    d. Implement plans to improve processes and measure results.

55. A medication order is normally processed in:
    a. A community pharmacy
    b. A chain pharmacy
    c. An acute care hospital
    d. A mail-order pharmacy

56. How many refills can a prescriber legally order for fentanyl patches?
    a. 0
    b. 1
    c. 5
    d. 11 in 12 months

57. What agency defines good compounding practices?
    a. FDA
    b. State Boards of Pharmacy
    c. USP
    d. DEA

58. Universal precautions help protect patients and healthcare professionals from what common blood-borne pathogen?
    a. Common cold
    b. Tuberculosis
    c. Hepatitis B
    d. Pneumonia

59. The middle set of numbers in the NDC indicate the:
    a. Manufacturer
    b. Drug
    c. Package size
    d. Type of packaging

60. Convert 0.05% to a ratio.
    a. 0.05:1000
    b. 1:0.005
    c. 1:200
    d. 1:2000

61. Convert 1:10,000 to a percent.
    a. 1%
    b. 0.1%
    c. 0.01%
    d. 0.001%

62. A patient needs 50 mg of lidocaine. The stock is 2% w/v. How many milliliters will the patient need?
    a. 2.5 mL
    b. 25 mL
    c. 0.25 mL
    d. 1 mL

63. Your pharmacy has a computer system that maintains a perpetual inventory with minimum and maximum stock levels for all the inventory. Once an order is received, what is the next step the technician should take to maintain the integrity of future orders?
    a. Rotate stock.
    b. Update all prices.
    c. Enter the quantity received.
    d. Enter quantity of all backordered drugs.

64. Your hospital pharmacy's formulary fills orders for any proton pump inhibitor with pantoprazole. Which drug would be substituted based on this policy?
    a. Ranitidine
    b. Pravastatin
    c. Pioglitazone
    d. Esomeprazole

65. The anesthesiologist has requested a 3% cocaine solution. How much cocaine will you need to prepare 30 mL?
    a. 3 g
    b. 0.9 mg
    c. 900 mg
    d. 300 mg

66. A 20-kg child is prescribed amoxicillin at 50 mg/kg/day in 4 divided doses for 10 days. Amoxicillin is available in a 250-mg/5-mL concentration. What is the volume for each dose, and how much should be dispensed?
    a. 200 mg; 200 mL
    b. 5 mL; 100 mL
    c. 200 mg; 100 mL
    d. 5 mL; 200 mL

67. A patient has a prescription order for Cleocin® 75 mg/mL; SIG: 450 mg PO QID x 5 days. What volume should the patient take per dose?
    a. 450 mg
    b. 5 mL
    c. 10 mL
    d. 6 mL

68. If a patient takes ¾ tsp of an antibiotic TID. How long will 150 mL last if the patient takes it all?
    a. 13 days
    b. 10 days
    c. 7 days
    d. 15 days

69. 2.5 L of TPN solution is ordered to run over 24 hours. What is the rate in mL/hr?
    a. 100 mL/hr
    b. 104 mL/hr
    c. 25 mL/hr
    d. 250 mL/hr

70. Directions on a vial of medication state "add 12.5 mL of diluent to make a 500-mg/mL dilution with a volume of 15 mL." How much drug is in the vial?
    a. 100 mg
    b. 7500 mg
    c. 6250 mg
    d. 1 g

71. An inhaler contains 200-metered doses. If the patient is to use 2 puffs QID, how many days will the inhaler last?
    a. 20 days
    b. 25 days
    c. 30 days
    d. 50 days

72. A patient has a prescription for Mobic®. Which drug on the patient's profile should be stopped to prevent drug duplication?
    a. Celexa®
    b. Diovan® HCT
    c. Ibuprofen
    d. Amliodipine

73. Which inhaler listed below would be considered a "maintenance" inhaler?
    a. ProAir® HFA
    b. Ventolin
    c. Flovent®
    d. Xopenex® HFA

74. How often does the DEA require an inventory to be completed for all controlled substances?
    a. Biennially
    b. Annually
    c. Every 6 months
    d. Every 5 years

75. _____ provides specific guidelines for nonsterile compounding.
    a. FDA
    b. <797>
    c. <823>
    d. <795>

76. _____ provides specific guidelines for sterile compounding.
    a. FDA
    b. <797>
    c. <823>
    d. <795>

77. Patients taking thalidomide must register with ___ to protect patient safety.
    a. ISMP
    b. FDA
    c. STEPS
    d. IPLEDGE

78. For which medication listed below might the insurance company limit the number of tablets dispensed per 30 days because it is not recommended for daily use?
    a. Valsartan
    b. Zolmitriptan
    c. Rosuvastatin
    d. Glyburide

79. What is the proper way to write alprazolam *five tenths milligram* to prevent a medication error?
    a. 5 mg
    b. .5 mg
    c. 0.5 mg
    d. 0.005 mg

80. What is legally required on all prescriptions?
    a. Refill information
    b. Indication for use
    c. Date written
    d. Manufacturer

81. The maximum inventory for a drug used in the treatment of cancer is 20 vials of 400 mg with a minimum level of 10 vials. You need all but 2 vials today. The drug is available in packages of 10 vials of 400 mg and 10 vials of 150 mg. How many vials should be ordered?
    a. 8 vials of 400 mg
    b. 10 vials of 400 mg
    c. 20 vials of 400 mg
    d. 10 vials of 150 mg

82. The drug Zofran® is used to:
    a. Prevent nausea and vomiting.
    b. Prevent organ transplant reject.
    c. Treat rheumatoid arthritis.
    d. Prevent deep vein thrombosis.

83. The _____ is used to look up approved drugs and bioequivalent generics.
    a. *Blue Book*
    b. *Red Book*
    c. *Orange Book*
    d. *PDR*

84. If you have to mix a KCl infusion with 35 mEq of KCl using a vial of KCl with 40 mEq/20 mL, how much do you need to add?
    a. 3.5 mL
    b. 12.5 mL

c. 17.5 mL
d. 20 mL

85. Which DEA number would be valid for Dr. Maxine Smith?
a. AM 4561937
b. AS 4561937
c. BM 4561936
d. BS 4561933

86. If a patient is taking an antitussive, he or she is treating:
a. An allergy
b. A productive cough
c. A dry non-productive cough
d. Congestion

87. Why would patients take pantoprazole?
a. They have GERD.
b. They suffer from depression.
c. They have high cholesterol.
d. They have insomnia.

88. Calculate the flow rate for 1 liter of IV fluid to run over 12 hours using a set calibrated to deliver 10 gt/mL.
a. 7 gtt/min
b. 13 gtt/min
c. 14 gtt/min
d. 833 gtt/min

89. 75 mg of a drug is ordered in 250 mL of fluid to infuse at 2 mcg/kg/min for a patient weighing 150 lb. Calculate the flow rate in mL/hr.
a. 2 mL/hr
b. 20 mL/hr
c. 27 mL/hr
d. 200 mL/hr

90. If a patient takes furosemide daily, he or she may need to:
a. Increase their chloride intake.
b. Eat more foods rich in calcium.
c. Increase their potassium intake by eating foods high in potassium or take potassium supplements.
d. All of the above.

91. If you add 15 g of coal tar to one pound of 5% coal tar, what is the percent strength of the final product?
a. 3.8%
b. 5%
c. 8%
d. 126%

92. If a medication is ordered at 5 mg/kg/day for a 65-lb. patient, how many grams will the patient receive if he or she receives the medication for 10 days?
a. 1,477 g
b. 1.477 g
c. 14.77 g
d. 0.1478 g

93. Ciprofloxacin is a _____ antibiotic.
a. Penicillin
b. Cephalosporin
c. Fluoroquinolone
d. Macrolide

94. If an order states that a medication is to be given at 1800 hours, this would be:
a. 4 PM
b. 5 PM
c. 6 PM
d. 8 PM

95. Which is the BEST option for a prescription label for: "A*moxicillin 400/5 Sig: 600 mg po BID X 10 days*"?
a. Take 600 mg by mouth twice a day for 10 days.
b. Take 7.5 mL by mouth twice a day for 10 days.

c. Take 1 teaspoonful twice a day for 10 days.
d. Take 1½ teaspoonful by mouth daily for 10 days.

96. You are asked to make 2 oz. of a solution containing 15 mg/5 mL. Your stock is a concentration of 5 mg/mL. How much drug and how much diluent do you need?
a. 36 mL of drug; 24 mL of diluent
b. 24 mL of drug; 36 mL of diluent
c. 90 mL of drug; 40 mL of diluent
d. 40 mL of drug; 90 mL of diluent

97. Which drug is not a calcium-channel blocker?
a. Amlodipine
b. Diltiazem
c. Verapamil
d. Isosorbide

98. A patient requests a refill for her *little pink water pills.* Which drug from her profile would you choose?
a. Levothyroxine 200 mg
b. Diazepam 2 mg
c. Propranolol 10 mg
d. Hydrochlothiazide 25 mg

99. Which drug would be considered a high-alert/high-risk medication that requires special attention when dispensed and administered to prevent serious adverse events?
a. Diazepam
b. Buspirone
c. Heparin
d. Isoniazid

100. Which medication should be dispensed it its original brown glass container?
a. Digoxin 0.125-mg tablets
b. Plavix® 75-mg tablets
c. Colchicine 0.6-mg tablets
d. Nitroglycerine 0.4-mg tablets

101. When must the pharmacy notify patients about a drug recall?
a. For Class I recalls
b. For Class II recalls
c. For Class III recalls
d. Never; the drug manufacturer must notify patients

102. An insurance card has a BIN number and a PCN number. These numbers provide information for:
a. The clinic; they contain the patient's EHR information
b. Demographic information
c. Filling the medication
d. On line adjudication

103. A fill list is used by a technician:
a. To process orders to the wholesaler.
b. To process the daily cart fill.
c. To compound sterile products.
d. To refill crash carts or trays.

104. When should a patient profile be updated on a community pharmacy?
a. Annually; on the patient's birthday.
b. EHR eliminates the need to update the profile.
c. Every time the patient gets a prescription filled.
d. Only when the pharmacy updates their software.

105. All chemicals in the pharmacy must have documentation that details the characteristics of the chemicals and outlines procedures for accidental human exposure. What is this documentation called?
a. PPI
b. Policy and Procedure Manual
c. MSDS or SDS
d. OSHA Manual

106. What auxiliary label(s) should be affixed to a prescription vial containing amoxicillin suspension?
   a. "Shake Well."
   b. "Finish All Medication."
   c. "Take with Food."
   d. "May cause DROWSINESS."
   e. A and B only.
   f. A, B, and C.

107. The Methamphetamine Act of 2005 restricts sales of:
   a. Dextromethorphan
   b. Pseudoephedrine
   c. "Morning after" contraceptives
   d. Cold preparations to children under 2

108. A patient brings in a new prescription for Paxil.® Which drug on the patient's profile should he or she stop taking because it would duplicate the new therapy?
   a. Prozac®
   b. Pantoprazole
   c. Flomax®
   d. Valsartan

109. Which drug below is a beta-blocker?
   a. Inderal®
   b. Amlodipine
   c. Prazosin
   d. Benazepril

110. You only have 10 g of HC powder available in the pharmacy, and you have an order for 5% HC ointment. How much can you make?
   a. 0.5 g
   b. 50 g
   c. 200 g
   d. 20 g

ANSWERS FOR PRACTICE EXAM 2

1. d
2. b
3. c
4. b
5. c
6. d
7. b
8. b
9. d
10. c
11. c
12. d
13. a
14. a
15. a
16. c
17. c
18. d
19. c
20. b
21. c
22. b
23. b
24. c
25. a
26. b
27. d
28. c
29. b
30. d
31. a
32. a
33. d
34. c
35. b
36. a
37. c
38. d
39. b
40. c
41. b
42. c
43. a
44. d
45. d
46. a
47. c
48. d
49. c
50. b
51. d
52. b
53. b
54. a
55. c
56. a
57. c
58. c
59. b
60. d
61. c
62. a
63. c
64. d
65. c
66. d
67. d
68. a
69. b
70. b
71. b
72. c
73. c
74. a
75. d
76. b
77. c
78. b
79. c
80. c
81. b
82. a
83. c
84. c
85. b
86. c
87. a
88. c
89. c
90. c
91. c
92. b
93. c
94. c
95. b
96. a
97. d
98. d
99. c
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