Prescription Categories

Unit: Laws and Regulations

Problem Area: Legal Classifications of Medications

Lesson: Prescription Categories

Student Learning Objectives.

Instruction in this lesson should result in students achieving the following objectives:

1. **Differentiate between substance/drug categories.**
2. **Summarize the controlled substances schedules.**
3. **Summarize prescription fraud protections.**

Resources.

The following resources may be useful in teaching this lesson:

E-unit(s) corresponding to this lesson plan. CAERT, Inc. http://www.mycaert.com.

Ballington, Don A., and Robert J. Anderson. *Pharmacy Practice for Technicians,* 5th ed. Paradigm, 2014.

"Facts About Generic Drugs," *U.S. Food and Drug Administration: U.S. Department of Health and Human Services*. Accessed Feb. 5, 2016. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm.

Mizner, James J. *Mosby's Review for the Pharmacy Technician Certification Examination,* 3rd ed. Evolve, 2014.

"Pharmacist's Manual: An Informational Outline of the Controlled Substance Act," *U.S. Department of Justice: Drug Enforcement Administration, Office of Diversion Control*. Accessed Feb. 5, 2016. http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.

"Tamper-Resistant Prescription Form Requirements," *Centers for Disease Control and Prevention: Office for State, Tribal, Local, and Territorial Support*. Accessed Feb. 5, 2016. http://www.cdc.gov/phlp/docs/menu-prescriptionform.pdf.

"Tamper-Resistant Prescriptions," *CMS.gov.* Accessed Feb. 5, 2016. https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/FraudAbuseforProfs/TRP.html.

"What's the Difference Between Brand-Name and Generic Prescription Drugs?" *Scientific American*. Accessed Feb. 5, 2016. http://www.scientificamerican.com/article/whats-the-difference-betw-2004-12-13/.

Equipment, Tools, Supplies, and Facilities

- ✓ Overhead or PowerPoint projector
- ✓ Visual(s) from accompanying master(s)
- ✓ Copies of sample test, lab sheet(s), and/or other items designed for duplication
- ✓ Materials listed on duplicated items
- ✓ Computers with printers and Internet access
- ✓ Classroom resource and reference materials

Key Terms. The following terms are presented in this lesson (shown in bold italics):

- abuse
- addiction
- adulterated
- analgesic
- antidiarrheal
- antitussive
- bioequivalence
- brand name drug
- Centers for Medicare and Medicaid Services (CMS)
- controlled substance
- Drug Enforcement Administration (DEA)
- Food and Drug Administration (FDA)
- generic drug
- legend drug
- misbranded
- non-controlled substances
- non-legend drug
- over-the-counter (OTC)
- patent
- physical dependence
- prescription
- proprietary
- psychological dependence

- recoup
- Rx
- schedule
- Schedule 1
- Schedule 2
- Schedule 3
- Schedule 4
- Schedule 5
- tamper-resistant prescription

Interest Approach. Use an interest approach that will prepare the students for the lesson. Teachers often develop approaches for their unique class and student situations. A possible approach is included here.

> *Tell students that the Centers for Disease Control and Prevention classify prescription drug abuse as an epidemic. Research indicates that prescription drugs are the second-most abused category of drugs after marijuana. Then ask students to create a list of prescription drugs with which they are familiar. Have students write the list on the board. Review the list, and indicate that the group would come back to this list to place each drug in a category during the lesson. Finally, facilitate a discussion about reasons that teenagers might abuse prescription drugs.*

CONTENT SUMMARY AND TEACHING STRATEGIES

Objective 1: Differentiate between substance/drug categories.

Anticipated Problem: What is the difference between substance/drug categories?

I. Substance/drug categories

A. Controlled and non-controlled

1. Prescriptions

a. A ***prescription*** is a written formula for the preparation and administration of a medication or a remedy. Prescription medications are substances/drugs that require a written formula (prescription) as opposed to an over-the-counter medication that can be purchased by anyone at any pharmacy.

b. Protecting the health of the public is a primary concern of pharmacists and pharmacy technicians. Pharmacy employees must be aware of the state and federal laws and regulations regarding controlled substances.

2. Controlled substances/drugs
    a. A ***controlled substance*** is a material with a risk of abuse.
    b. ***Abuse*** is the wrongful or improper use of a controlled substance, resulting in physical and/or psychological dependence.
    c. ***Physical dependence*** is taking higher and higher doses of a medication to exert the desired pharmaceutical effect. If the drug is stopped, withdrawal symptoms (e.g., anxiety, insomnia, diarrhea, and vomiting) may occur. In some cases, physical dependence can lead to ***addiction***, which is the compulsive and uncontrolled use of a controlled substance/drug.
    d. ***Psychological dependence*** is taking a controlled substance on a regular basis as a crutch or because it produces a sense of enhanced wellbeing. Stopping the drug suddenly can lead to anxiety or other withdrawal symptoms.
3. ***Non-controlled substances*** are medications purchased without a prescription as well as medications prescribed to treat medical conditions (e.g., high blood pressure, diabetes, and bacterial infections). Prescriptions for non-controlled substances are not subject to all the limitations for controlled substance prescriptions.

B. Legend and non-legend drugs

1. One of the most important pieces of legislation in pharmaceutical history is the Food, Drug, and Cosmetic Act (FDCA) of 1938. The FDCA of 1938 led to the creation of the ***Food and Drug Administration (FDA)***, which is the federal agency responsible for protecting and promoting public health through the regulation and supervision of prescription and non-prescription drugs. The FDA requires that manufacturers of drugs prove that their products are safe for human use. The act also clearly defines regulations for preparations and the labeling of products. Two terms are closely associated with safe packaging:
    a. ***Adulterated*** is prepared, packed, or held under unsanitary conditions; prepared in containers composed of any poisonous substances; or containing unsafe additives.
    b. ***Misbranded*** is labeling that is false or misleading in any way; labeling that is not conspicuous and clear; and/or labeling that does not contain adequate directions for use or warnings.
2. An amendment to the FDCA of 1938 was enacted that required all products to have adequate directions for use, unless they contain the federal legend "Caution: Federal law prohibits dispensing without a prescription." This amendment established the distinction between legend and non-legend drugs.
    a. A ***legend drug*** is a medication that requires a prescription. A legend drug can be dispensed upon receipt of a prescription from a licensed health care provider. It is labeled with the legend "Rx" only. Legend or prescription drugs are available as controlled or non-controlled medications. ***Rx*** is the abbreviation for the term "prescription" and is a symbol for the Latin word "recipere" (meaning "to take"). The symbol is customarily part of a prescription's heading.

b. A ***non-legend drug*** is a medication that does not require a prescription. A non-legend drug is often referred to as ***over-the-counter (OTC)*** medication because it can be purchased without a prescription. The FDA must approve the sale of OTCs. To be approved, the drug must be verified as safe and effective when the patient follows the directions with regard to dose, frequency, and duration of therapy. It is important for OTC medications to have complete product labeling. Instructions must be written in terms easily understood by consumers, as there may be no contact with a pharmacist.

C. Brand name and generic

1. A ***brand name drug*** is a medicine discovered, developed, and marketed by a pharmaceutical company. For the company to market and sell its product, the company must first gain approval from the FDA. Then the company can file for a patent.
   a. A ***patent*** is an exclusive right granted by the government to an inventor to manufacture, use, or sell a drug for a certain number of years. This prohibits other companies from making copies and selling the drug. Once approved, the company can exclusively market and sell this brand name drug.
   b. The U.S. Patent Office registers the ***proprietary*** (protected brand name or trademark) name under which a manufacturer markets its product. A patent allows the company to sell its product exclusively to ***recoup*** (gain back) the money spent to develop the drug and generate a profit.
2. A ***generic drug*** is a product comparable to a brand drug (a "copy") in active ingredients, dosage form, strength, route of administration, quality, performance characteristics, and intended use (when inactive ingredients are already approved).
   a. Generic drugs must demonstrate ***bioequivalence***, which is the ability to perform in the same manner as the brand name product. Research has proven that brand name drugs do not work any better than generic drugs.
   b. On average, the cost of a generic drug is 80 to 85 percent lower than the brand name equivalent.
3. All drugs have two names: a generic name that is the drug's common scientific name and a brand name to make it stand out in the market. This is true for prescription and over-the-counter drugs. An example of a pain relief drug with two names is:
   a. Brand name: Tylenol
   b. Generic name: Acetaminophen

Teaching Strategy: *Many techniques can be used to help students master this objective. Use VM–A to review. Have small groups of students use the list of drugs created during the Interest Approach, and place them into each of the six categories: controlled, non-controlled, legend, non-legend, brand name, and generic. Have small groups post their categorization of the drugs. Then have each group visit the Quizlet*

Web site at http://www.quizlet.com and view the brand name drugs versus generic drug names or the prescription versus non-prescription drugs search engines to create a more substantial and a more refined listing.

Objective 2: Summarize the controlled substances schedules.

Anticipated Problem: What are the five schedules of controlled substances?

II. Controlled substance schedules: A ***schedule*** is a categorical list of controlled substances/drugs based on acceptable medical use and the drug's abuse or dependency potential. Controlled substances are drugs or other substances regulated under the Controlled Substances Act (CSA), which was designed to combat escalating drug abuse. Drugs, substances, and certain chemicals used to make drugs are classified into five distinct categories or schedules based on the drug's acceptable medical use and the drug's abuse or dependency potential. For example, Schedule 1 drugs are considered the most dangerous class of drugs, with a high potential for abuse and for severe psychological and/or physical dependence. As the drug schedule changes, so does the abuse potential. Schedule 5 drugs represent the least potential for abuse.

A. ***Schedule 1*** is drugs, substances, or chemicals with no currently accepted medical use and a high potential for abuse. Schedule 1 drugs are the most dangerous of all the drug schedules, with the potential for severe psychological or physical dependence. Schedule 1 drugs are not legally dispensed in the United States. Some examples are:

1. Heroin
2. LSD

B. ***Schedule 2*** is drugs, substances, or chemicals with a high potential for psychological or physical dependence, but with less potential than drugs listed in Schedule 1. Schedule 2 drugs differ from Schedule 1 drugs in that they have no currently accepted medical use in treatment or a currently accepted medical use with severe restrictions. Schedule 2 drugs are the most highly regulated drugs. Sudden increases in usage in a particular pharmacy or prescribed by a particular provider may cause the ***Drug Enforcement Administration (DEA)***—the federal agency responsible for enforcing laws and regulations governing narcotics and controlled substances—to investigate. Schedule 2 drugs have no refills. Some examples are:

1. Morphine
2. Cocaine
3. Oxycodone
4. Methamphetamine

C. ***Schedule 3*** is drugs, substances, or chemicals with a moderate potential for physical or psychological dependence. Schedule 3 drugs have a currently accepted medical use in treatment. Schedule 3 drugs may be refilled up to five

times within six months of the date they are written if the prescriber authorizes refills. Refill quantities cannot exceed the amount originally prescribed unless the pharmacist contacts the prescriber directly. Some examples are:

1. Anabolic steroids
2. Codeine
3. Hydrocodone
4. Some barbiturates

D. ***Schedule 4*** is drugs, substances, or chemicals with a low potential for abuse and a low risk of dependence. However, the risk of dependence is clearly present if these medications are used in high doses for long periods of time. Schedule 4 drugs have a currently accepted medical use in treatment. Schedule 4 drugs may be refilled up to five times within six months of the date they are written if the prescriber authorizes refills. Refill quantities cannot exceed the amount originally prescribed unless the pharmacist contacts the prescriber directly. Some examples are:

1. Xanax
2. Valium
3. Ambien
4. Tramadol

E. ***Schedule 5*** is drugs, substances, or chemicals with a lower potential for abuse than Schedule 4 drugs and consist of preparations containing limited quantities of certain narcotics. Some schedule 5 drugs may be sold without a prescription, depending on state law. This requires the purchaser to be over 18 years of age, to sign a log, and to show a valid driver's license. Schedule 5 drugs generally refer to antidiarrheal, antitussive, and analgesic medications.

1. ***Antidiarrheal*** is a medication (e.g., Lomotil) used to alleviate diarrhea.
2. ***Antitussive*** is a medication (e.g., Robitussin) used to prevent or treat a cough.
3. ***Analgesic*** is a medication (e.g., Lyrica) used to relieve pain.

Teaching Strategy: *Many techniques can be used to help students master this objective. Direct the class to the Quizlet Web site (http://www.quizlet.com). Enter the phrase "controlled substances" into the search engine. Instruct the students to practice with the controlled substance flashcards and learning games. When confident, students should complete the practice test. Have students print and turn in their test results. Use VM–B as a student handout.*

Objective 3: Summarize prescription fraud protections.

Anticipated Problem: What are some prescription fraud protections?

III. Prescription fraud protections

A. The United States is in the midst of an epidemic of prescription drug overdose deaths. States have the primary responsibility to regulate and enforce prescription drug practice. The pharmacist and the pharmacy technician must carefully assess the legitimacy (legality) of a prescription for all scheduled drugs. Legitimate prescription pads are stolen from physicians' offices, and prescriptions are written for fictitious patients. Forgeries may be written on stolen or preprinted facsimiles of prescriptions.

1. Some states have laws that require the use of tamper-proof prescription forms for all controlled substance prescriptions.
2. The ***Centers for Medicare and Medicaid Services (CMS)*** is an agency within the U.S. Department of Health and Human Services responsible for the administration of several key federal health programs. The CMS have developed guidelines to help prevent fraud by enacting The Medicaid Tamper-Resistant Prescription Law.

B. Tamper-proof prescriptions

1. A ***tamper-resistant prescription*** is a written formula printed in a fashion to ensure that it cannot be interfered with or changed. As of Oct. 1, 2008, to be considered tamper-resistant, a prescription pad must contain all three of the following features designed to prevent the:
   a. Unauthorized copying of a completed or blank prescription form
   b. Erasure or modification of information written on the prescription pad by the provider
   c. Use of counterfeit prescription forms
2. Schedule drug prescription tampering countermeasures
   a. Schedule 2 prescriptions can be handwritten or computer-generated and must be signed in ink by the provider, with no allowable refills. Schedule 2 prescriptions typically have a 30-day expiration from the date the provider writes the prescriptions. A partial filling is allowed if the remaining quantity is available to the patient within 72 hours. A new prescription must be issued if additional quantities are to be provided after 72 hours.
   b. Schedule 3, 4, and 5 prescriptions can be handwritten or computer-generated, but they must be signed in ink by the provider. A patient may receive up to five refills within six months of the date the prescription was written if authorized. Partial filling is permitted as long as refills are indicated on the original prescription.
   c. Schedule 3 and 4 medications are often valid for 6 months.
   d. Schedule 5 medications may be valid for up to 12 months.

Teaching Strategy: *Many techniques can be used to help students master this objective. Use VM–C. Create various scenarios of individuals using fraudulent methods to obtain controlled substances—perhaps from local or national news. Have students role-play the situations. Facilitate a discussion about how the pharmacy technician might respond to these methods. Assign LS–A. Then review the list of drugs that the students created at the beginning of the lesson. Have students compare the information on their brochures with the initial list of drugs.*

Review/Summary.

Use the student learning objectives to summarize the lesson. Have students explain the content associated with each objective. Student responses can be used in determining which objectives need to be reviewed or taught from a different angle. If a textbook is being used, questions at the ends of chapters may be included in the Review/Summary.

Application.

Use the included visual master(s) and lab sheet(s) to apply the information presented in the lesson.

Evaluation.

Evaluation should focus on student achievement of the objectives for the lesson. Various techniques can be used, such as student performance on the application activities. A sample written test is provided.

Answers to Sample Test:

Part One: Matching

1. c
2. g
3. e
4. b
5. a
6. d
7. h
8. f

Part Two: Completion

1. adulterated
2. controlled substance
3. FDA
4. psychological dependence
5. over-the-counter (OTC)
6. generic drug
7. physical dependence
8. recoup (gain back)

Part Three: True/False

1. F
2. F
3. T
4. F
5. T
6. F
7. T
8. T

Sample Test

Name _____

Prescription Categories

Part One: Matching

Instructions: **Match the term with the correct definition.**

a. addiction
b. brand name drug
c. bioequivalence
d. legend drug
e. misbranded
f. proprietary
g. Schedule 1
h. tamper-resistant prescription

_____1. The ability to perform in the same manner as the brand name product

_____2. Drugs, substances, or chemicals with no currently accepted medical use and a high potential for abuse

_____3. Labeling that is false or misleading in any way; labeling that is not conspicuous and clear; and/or labeling that does not contain adequate directions for use or warnings

_____4. A medicine discovered, developed, and marketed by a pharmaceutical company

_____5. The compulsive and uncontrolled use of a controlled substance/drug

_____6. A medication that requires a prescription

_____7. A written formula printed in a fashion to ensure that it cannot be interfered with or changed

_____8. A protected brand name or trademark

Part Two: Completion

Instructions: **Provide the word or words to complete the following statements.**

1. A substance prepared, packed, or held under unsanitary conditions; prepared in containers composed of any poisonous substance; or containing unsafe additives is _____.

2. A substance with a risk of abuse and physical or psychological dependence is a/an _____.
3. The federal agency responsible for protecting and promoting public health through the regulation and supervision of prescription and non-prescription drugs is the _____.
4. The diagnosis of a patient who takes a controlled drug on a regular basis, as a crutch or because it produces a sense of enhanced wellbeing, is _____.
5. Medications that can be purchased without a prescription are _____.
6. A product comparable to a brand drug in active ingredients, dosage form, strength, route of administration, quality, performance characteristics, and intended use when inactive ingredients are already approved is a/an _____.
7. The diagnosis of a patient taking higher and higher doses of a medication to exert the desired pharmaceutical effect is _____.
8. A patent allows the company to sell its product exclusively to _____ the money spent to develop the drug and generate a profit.

Part Three: True/False

Instructions: **Write *T* for true or *F* for false.**

_____1. Schedule 1 drugs are considered the least dangerous class.

_____2. Schedule 3 drugs have a high potential for physical and/or psychological dependence.

_____3. Schedule 2 drug prescriptions can be handwritten.

_____4. Schedule 1 drugs have five refills available.

_____5. The Centers for Medicare and Medicaid Services developed guidelines for preventing fraud when dispensing controlled substances.

_____6. Ambien is an example of a Schedule 5 controlled substance.

_____7. Abuse is the wrongful or improper use of a controlled substance resulting in physical and/or psychological dependence.

_____8. Rx is the abbreviation for the term “prescription.”

VM–A

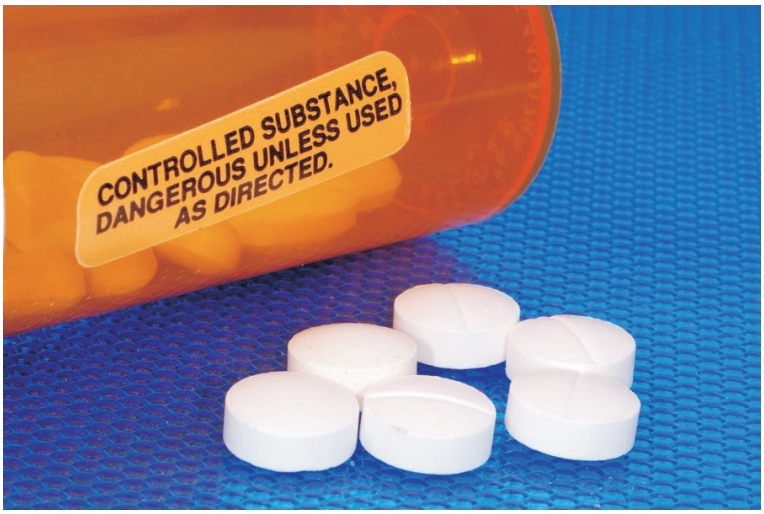
PRESCRIPTION DRUG CATEGORIES

Which of the following drug categories are identified on this morphine sulfate prescription?

- Controlled versus non-controlled
- Legend versus non-legend
- Brand versus generic

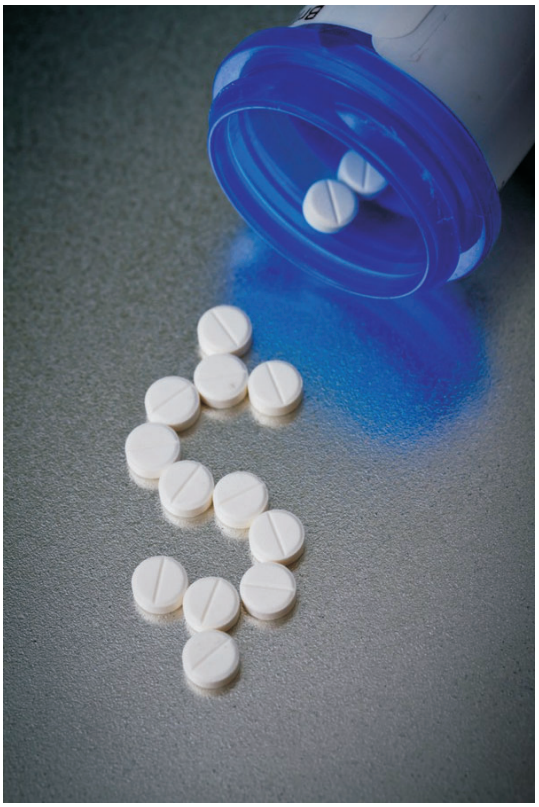
CONTROLLED SUBSTANCE SCHEDULES

- **Schedule 1:** Drugs, substances, or chemicals with no currently accepted medical use and a high potential for abuse, leading to severe psychological and/or physical dependence
  - *Examples:* Heroin and LSD
- **Schedule 2**: Drugs, substances, or chemicals with accepted medical use and with a high potential for abuse, leading to severe psychological and/or physical dependence
  - *Examples:* Morphine, cocaine, oxycodone, and methamphetamine



- **Schedule 3**: Drugs, substances, or chemicals with accepted medical use and with a moderate potential for abuse, leading to moderate psychological and/or physical dependence
  - *Examples:* Anabolic steroids, codeine, hydrocodone, and some barbiturates
- **Schedule 4**: Drugs, substances, or chemicals with accepted medical use and with a low potential for abuse, leading to limited psychological and/or physical dependence
  - *Examples:* Xanax, Valium, Ambien, and Tramadol
- **Schedule 5**: Drugs, substances, or chemicals with accepted medical use and an extremely low potential for abuse, leading to low psychological and/or physical dependence.
  - *Examples:* Robitussin, Lomotil, and Lyrica

PRESCRIPTION DRUG FRAUD CATEGORIES



- Forgery is copying a valid prescription or creating a prescription that looks like a real prescription a doctor might use and then filling it out, signing it, and submitting it to a pharmacy.
- Altering prescriptions is changing a genuine prescription a doctor filled out and signed by altering the type of drug, increasing the dosage or amount of pills per fill, adding or increasing the number of refills, writing other drugs on the prescription, or changing the name of the person on the prescription.
- Multiple doctors entails visiting several doctors or health care providers and having them all prescribe prescription drugs.
- Calling-in refills is taking someone's prescription bottle and calling the pharmacy impersonating that person to have a prescription refilled or impersonating a medical provider and calling in a false prescription.
- Stealing prescription forms typically occurs when someone visits a doctor's office, steals prescription pads, fills them out, and tries to fill them.

LS–A

Name _____

Controlled Substance Brochure

Purpose

The purpose of this activity is to differentiate between Schedule 1, 2, 3, 4, and 5 drug categories and rules and regulations.

Objectives

1. Research a schedule drug.
2. Collect information based on stated brochure criteria that properly identifies common generic and brand name controlled substances and their basic functions.
3. Create an informational brochure in hard copy or electronically. Proofread.
4. Prepare a two- to three-minute presentation about your research.
5. Present your brochure and the controlled substance information to the class.
6. Participate in a class discussion that compares the information about the controlled substance categories.
7. Distinguish between drugs of different classifications and their corresponding rules and regulations.

Materials

- lab sheet
- paper
- colored pencils or markers (or an electronic program)
- device with Internet access

Procedure

1. Work individually for this assignment.

2. Review the DEA's Controlled Substance schedule at http://www.dea.gov/druginfo/ds.shtml. Also, see the link at the bottom of the DEA page that shows an alphabetical listing of all Controlled Substances. Select a controlled substance for which you will create your brochure. [NOTE: Have your selection approved by your instructor. Your instructor will ensure that a variety of the schedule drug categories are selected.]

3. In the brochure, include the following information:

   a. Name of drug: brand and generic
   b. Classification (schedule)
   c. Dosage form and route of administration
   d. Drug strength availability
   e. Uses and indications of use
   f. Adverse drug reactions (side effects)
   g. Contraindications
   h. Drug-drug interactions
   i. Drug-food interactions
   j. Manufacturer(s)
   k. Refill information

4. Create the brochure in hard copy or electronically. Proofread.

5. Prepare a two- to three-minute presentation about your research. Present your brochure and the controlled substance drug information to the class.

6. Participate in a class discussion that compares and contrasts the information about the five controlled substance categories.

   a. Distinguish between drugs of different classifications and their corresponding rules and regulations.
   b. Make generalizations about Schedule 1, Schedule 2, Schedule 3, Schedule 4, and Schedule 5 drugs.

7. Turn in your brochure to your instructor.