12TH EDITION

ABRAMS' CLINICAL DRUG THERAPY

Rationales for Nursing Practice

Geralyn Frandsen
Sandra Smith Pennington

Wolters Kluwer

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Rationales for Nursing Practice

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Twelfth Edition

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9 8 7 6 5 4 3 2 1

Printed in China

Cataloging-in-Publication Data available on request from the Publisher
ISBN: 978-1-9751-3613-0

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I dedicate this edition to my husband and nursing colleague, Gary. I also dedicate this edition to the Maryville University nursing faculty, alumni, and students. Each one of you inspires me!

Geralyn Frandsen

To my family, my constant source of strength, inspiration, and gratitude.

Sandy Pennington

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Foreword

The 12th edition of *Abrams' Clinical Drug Therapy: Rationales for Nursing Practice* comes at a critical juncture in health care worldwide. Even as health care was in transition due to changes in delivery, access, and economics, the global pandemic related to COVID-19 shook traditional processes for everyone. News headlines around the world hailed nurses for their steadfastness and diligence in providing frontline care, frequently in dire circumstances. This unprecedented showcase of the work nurses do every day, pandemic or not, demonstrates the deep knowledge and skills that characterize professional nursing practice and the professional values and attitudes that drive nurses. Every day nurses are the primary administrators for medications. Quality safe medication administration, though, became a centerpiece of managing the COVID-19 outbreaks and highlighted the imperative of evidence-based nursing practice. The principles and practices in this book are a roadmap to guide nurses across health care settings to ensure a patient-centered approach to quality safe care for all populations and settings.

Now as never before, the challenges for quality safe medication administration hinge on nurses' knowledge, skills, and attitudes. Daily, nurses call on the basic pharmacologic knowledge honed in academic programs and refined in practice to address challenges in medication management across all environments, and particularly when following strict infection control guidelines.

To guide quality safe care practices, nurses have turned to the Quality and Safety Education for Nurses (QSEN) project, launched in 2006 as an evidence-based framework of six competencies: patient-centered care, teamwork and collaboration, evidence-based practice, safety, quality improvement, and informatics (Cronenwett et al., 2007, 2009). These six competencies are integrated into national curriculum standards for nursing so that all nurses are accountable for integrating safety and quality responsibilities into their daily work. Many schools of nursing apply the

QSEN framework to guide their curriculum and course objectives. Each has a role in safe clinical drug therapy.

In the midst of COVID-19, nurses' stories from the frontlines of care revealed the role of these six competencies as nurses valiantly applied the knowledge, skills, and attitudes to keep their patients safe. But was this really any different from the holistic care nurses provide every day, except for the fact that it was now illuminated because of the exponential explosion of demand for intense care brought on by the influx of critically ill patients in nearly every country?

As noted in this evidence-based 12th edition, nurses are the primary administrators of medications in most settings. Every day, nurses administer pharmacologic interventions. Every day, they apply the six QSEN competencies by considering patient-centered preferences and situations, collaborating across interprofessional teams, applying evidence-based standards for each medication and within the patient's context, participating in continuous quality improvement, applying safety science concepts, and using informatics to plan and manage the pharmacology needs of their patients.

Medication administration is multifaceted, complex, team-based, patient-centered, and carries the possibility of multiple failures. One in nine emergency department admissions is related to an adverse drug event, 3.2 billion medication orders are prescribed each year, and 160 medication errors occur each year in primary care (AHRQ, 2018). These shocking statistics remind us that nurses may in fact be a last line of defense in safe medication administration.

Nurses are accountable for current knowledge of a particular patient's medication regimen. To achieve reliability, nurses must follow practices that ensure the right medication is administered in the right dose, by the right route, at the right time, and to the right patient, every time. Safety culture, a subset of the overall organizational culture, demands awareness of the potential for error, willingness to report errors and near misses, and action to correct system failures. Safety culture includes "just culture." In just culture, all personnel are responsible for reporting near misses and breakdowns in care but share accountability across the system to trace broken processes, analyze the action pathway for administering a

medication, and implement improvement processes to prevent the same type of event from happening again.

This text serves as a reliable reference for safe medication administration. A key feature of *Abrams' Clinical Drug Therapy: Rationales for Nursing Practice* is the incorporation of disease characteristics with clinical drug knowledge in demonstrating a comprehensive approach to safe medication administration. Nurses are provided a step-by-step guide for medication safety through pharmacologic knowledge, evidence-based standards for administration, awareness of organizational challenge, instructions for careful medication administration, and knowledge of how to complete documentation. Learners at all levels are able to apply the learning actions included in this text to ensure reliability and safety by following the QSEN competencies.

- Patient-centered care means treating all patients and families with respect and honor. By including patients and families as partners in care, they become safety allies. Engaging patients and their family members in making decisions about the treatment plan encourages active engagement as team members so they help with choices about their care that are more likely to have the desired therapeutic effects.
- Teamwork and collaboration may include nurses, physicians, a nurse practitioner, a physician assistant, pharmacist, social worker, dietitian, physical therapist, occupational therapist, and speech–language pathologist. To help coordinate the complexities of safe medication administration, teamwork behaviors include flexible leadership, standardized communication, mutual support, and constant environmental scans.
- Evidence-based practice requires an enquiring mind to constantly seek the best available information in pharmacotherapeutics, which appears in the QSEN Alerts throughout the text. Safe medication administration uses evidence-based practice standards to ensure that appropriate precautions are taken to assess for adverse effects.
- Quality improvement processes measure care outcomes to compare with benchmark data to determine areas to improve. Teams apply quality improvement tools to raise performance.
- Safety is the constant awareness of the inherent risks in medication administration and how that risk can be miti gated through

collaboration among physicians, pharmacists, nurses, and the patient and family.
- Informatics is the thread in all the competencies for managing care, documentation, and decision support tools.

Reflection before action (planning), reflection in action (pausing to problem solve), and reflection on action (debriefing) are processes for nurses to ask questions to examine their actions for constant improvement and growth. With a spirit of enquiry, nurses develop a habit of the mind for constant questioning as they follow clinical drug therapy in their practice. In using this text, central questions guide practice development.

- What are the roles and responsibilities for each team member in the complex steps in medication administration? How do I maintain awareness of the scope of responsibility for each discipline involved, particularly when patients have multiple providers?
- How do I ensure medication safety during transitions in care when I hand over my patient to another provider?
- Where do I find the information I need about this medication for safe administration?
- What communication skills will help me understand my patient's preferences and values related to medications?

Reflecting on questions like these develop a quality and safety mindset so that by following the guidance in this book, nurses will ensure that the next national medication safety measures will reflect improvement. The year 2020 will be remembered for the global COVID-19 pandemic but also the designation by WHO as the Year of the Nurse and Midwife. It is also the year the first *State of the World's Nursing* was released (WHO, 2020). It has and continues to be the year of the nurse; stories of the impact of nurses stand out in all media outlets. As the largest health care profession, nurses have a profound impact in universal access and in safety. Medication safety is a key area where nurses can truly make a difference for every patient, every time, every day.

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Preface

Abrams' Clinical Drug Therapy: Rationales for Nursing Practice has a long tradition of guiding students and instructors through the practice of safe and effective medication administration. The 12th edition includes Quality and Safety Education for Nurses (QSEN) content in each chapter. Each chapter also includes information about the pathophysiology of disease and associated drug therapy for prevention and treatment of disease.

GOALS AND RESPONSIBILITIES OF NURSING CARE RELATED TO DRUG THERAPY

Varied goals and responsibilities inherent in safe medication administration are identified in each chapter. The following information will guide you in developing your own goals and responsibilities inherent to safe and effective nursing practice.

- Preventing the need for drug therapy, when possible, by promoting health and preventing conditions that require drug therapy.
- Using nonpharmacologic interventions alone or in conjunction with drug therapy. When used with drugs, such interventions may promote lower drug dosage, less frequent administration, and fewer adverse effects.
- Administering drugs accurately and taking into consideration patient characteristics such as age, weight, and hepatic and renal function, which can influence drug response.
- Preventing or minimizing adverse effects by knowing the major adverse effects associated with particular drugs. It is important to assess patients with impaired hepatic and renal function closely for

adverse effects. The early recognition of adverse effects allows for the implementation of interventions to minimize their severity. All drugs cause adverse effects, and nurses must maintain a high index of suspicion that the development of new signs and symptoms may be drug induced.

- The effect produced if medications are combined with other medications, herbs, or foods.
- Teaching patients and families about the effects of medications. The nurse must instruct patients and families about the role and importance of their medications in treating particular illnesses, accurate administration of medications, nonpharmacologic treatments to use with or instead of pharmacologic treatments, and when to contact their health care provider.

ORGANIZATIONAL FRAMEWORK

The 10 sections of the textbook provide the reader with basic information about drug therapy as well as the administration of medications for the prevention and treatment of disease. The first section introduces the safeguards in place to promote drug safety, the Institute of Medicine Core Competencies, and medication administration. It also describes the nursing process and explains the application of the nursing process in the care of patients receiving drug therapy. The use of concept maps addresses priority considerations and nursing actions related to drug therapy. The second section addresses the effect medications have throughout the life span. The text introduces the effects of drugs on infants, children, older adults, pregnant and lactating women, and drugs affecting male and female health. The remaining sections provide information on drug therapy related to systems, infections, and disease processes.

Each chapter opens with a case study, and its use throughout the chapter helps the reader integrate information about a particular disease and its drug therapy so he or she can apply it. The chapters also have NCLEX-style questions distributed throughout to test knowledge of the content and its application to patient care. This approach will help the reader prepare for class examinations as well as the NCLEX itself.

The chapters that focus on drug treatment for specific diseases use the prototype approach, allowing the reader to see the similarity in medications within each broad drug classification. Introduction and Overview sections provide the basis for understanding the drug therapy that prevents or treats the disease. The presentation of disease pathophysiology helps the reader understand the effect of a particular medication on the prevention and treatment of disease. Drug therapy sections summarize the medications, identifying the pharmacokinetics, action, use, adverse effects, contraindications, and nursing implications—including administration, assessment, and patient teaching. Many chapters discuss the effect of herbal supplements on prescribed medications. This information has become crucial for the maintenance of patient safety. Boxes containing patient teaching guidelines for a drug or class of drugs highlight crucial information the nurse should teach the patient and family. Each chapter also includes a clinical reasoning case study to assist in the application of drug therapy in the care of patient.

RECURRING FEATURES

This updated edition includes new and revised features to enhance learning.

Chapter-Opening Features

- **Learning Objectives** summarize what the student should learn while reading the chapter and answering both the Clinical Application Case Study Questions and NCLEX Success questions, described below.
- A **Clinical Application Case Study** opens each chapter with a patient-focused clinical scenario. Throughout the chapter, the reader is asked **critical thinking questions** to apply chapter content, emphasizing a patient-centered and interdisciplinary approach to pharmacology.
- **Key Terms** with definitions help the reader understand the chapter's content.

Special Features

- Each chapter introduces the disease process and the pertinent **pathophysiology**. This allows students to make connections between the pathophysiology and pharmacologic management of a disease.
- **QSEN Alerts**, presented in the context of the chapter discussion, alert the reader to important QSEN considerations and emphasize safety as a primary objective in patient care.
- **Black Box Warnings** highlight serious or life-threatening adverse effects identified by the FDA as being associated with a drug.
- **Drugs at a Glance Tables**—which include **Canadian drug names**—summarize the routes and dosage ranges (for adults and for children), as well as the pregnancy category, for each drug in the class. The prototype drug is indicated with an icon. Medications developed after 2015 reflect the new FDA Pregnancy Category guidelines.
- **Drug Interactions** and **Herb and Dietary Interactions** boxes highlight the risk of interactions as well as increased or decreased drug effects when drugs are combined with other medications, food, or herbal supplements.
- **Patient Teaching Guidelines** list specific information for the education of the patient and family.
- **NCLEX Success** sections interspersed throughout the chapter ask the student to answer NCLEX-style questions that pertain to the learning objectives and the information just presented. This feature helps students check and apply their knowledge as they read and assists them to prepare for patient care and for the NCLEX. The questions align to the terminology used on the NCLEX. The NCLEX Success questions exclusively use generic names for medications, which is consistent with the RN licensure examination.
- **Nursing Process Concept Maps** provide a succinct overview of drug therapy in terms of assessment, planning/goals, nursing interventions, and evaluation. Located at the end of each chapter, the nursing process concept maps provide the guidelines for drug therapy specifically related to nursing care. (Nursing diagnoses do not appear in these concept maps because nursing diagnoses are not tested on the NCLEX.)

- **Clinical Reasoning Case Studies** focus on the action of the medication prescribed and the associated assessment of medication outcomes.
- **Unfolding Patient Stories**, written by the National League for Nursing, are an engaging way to begin meaningful conversations in the classroom. These vignettes, which appear in relevant chapters, feature patients from Wolters Kluwer's *vSim for Nursing | Pharmacology* (co-developed with Laerdal Medical) and DocuCare products; however, each Unfolding Patient Story in the book stands alone, not requiring purchase of these products.
- **Concept Mastery Alerts** clarify common misconceptions as identified by Lippincott's Adaptive Learning Powered by prepU
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Chapter-Ending Features

- **Key Concepts** summarize the most salient content that appears in each chapter.
- **References and Resources** provide sources on which content is based and direction for further reading.

A COMPREHENSIVE PACKAGE FOR TEACHING AND LEARNING

To further facilitate teaching and learning, a carefully designed ancillary package has been developed to assist faculty and students.

Resources for Instructors

Tools to assist with teaching this text are available upon its adoption on thePoint® at http://thePoint.lww.com/Abrams12e.

- An **e-Book** gives you access to the book's full text and images online.
- The **Test Generator** lets you put together exclusive new tests from a bank containing more than 1,000 questions to help assess students'

understanding of the material. Test questions are mapped to chapter learning objectives and page numbers.

- An extensive collection of materials is provided for each book chapter:
  - **Pre-Lecture Quizzes** (and answers) are quick, knowledge-based assessments that allow you to check students' reading comprehension.
  - **PowerPoint Presentations** provide an easy way for you to integrate the textbook with your students' classroom experience, either via slide shows or handouts. Multiple-choice and true/false questions are integrated into the presentations to promote class participation and allow you to use i-clicker technology.
  - **Guided Lecture Notes** walk you through the chapters, objective by objective, and provide you with corresponding PowerPoint slide numbers.
  - **Discussion Topics** (and suggested answers) can be used as conversation starters or in online discussion boards.
  - **Assignments** (and suggested answers) include group, written, clinical, and Web assignments.
  - **Case Studies** with related questions (and suggested answers) give students an opportunity to apply their knowledge to a client case similar to one they might encounter in practice.
- An **Image Bank** lets you use the photographs and illustrations from this textbook in your PowerPoint slides or as you see fit in your course.
- Sample **Syllabi** provide guidance for structuring your nursing pharmacology course.
- A **QSEN Competency Map** identifies content and special features in the book related to competencies identified by the QSEN Institute.
- A **BSN Essentials Competency Map** identifies book content related to the BSN Essentials.
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  - Appendix E: Serum Drug Concentrations
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implement CoursePoint+ with ease.

Acknowledgments

The expertise of our contributors and reviewers is a great example of how the power of collaboration improves outcomes, and we thank them. We also wish to thank the team at Wolters Kluwer who provided their expertise to this edition.`

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SECTION 1
The Conceptual Framework of Pharmacology

CHAPTER 1

The Foundation of Pharmacology: Quality and Safety

LEARNING OBJECTIVES

After studying this chapter, you should be able to:

1. Define a prototype drug.
2. Distinguish between generic and trade names of drugs.
3. Describe the main categories of controlled substances in relation to therapeutic use, potential for abuse, and regulatory requirements.
4. Identify the multiple safeguards that are in place to promote drug safety in packaging, drug laws, and approval processes.
5. Recognize initiatives designated to enhance safe drug administration.
6. Develop personal techniques for learning about drugs and using drug knowledge in patient care.
7. Identify authoritative sources of drug information.

CLINICAL APPLICATION CASE STUDY

Joan Clark, a senior nursing student, is preparing for the NCLEX-RN examination. As she reviews material, she examines safeguards in place to protect the public from injury due to medication administration.

KEY TERMS

Biotechnology: process that may involve manipulating deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) and recombining genes into hybrid molecules that can be inserted into living organisms (often Escherichia coli bacteria) and repeatedly reproduced

Brand (trade) name: manufacturer's chosen name for a drug, which is protected by a patent

Controlled substances: drugs that are categorized by federal law according to therapeutic usefulness and potential for abuse; also known as scheduled drugs

Drug classifications: groups of medications that are classified according to their effects on particular body systems, their therapeutic uses, and their chemical characteristics

Generic name: chemical or official name of the drug that is independent of the manufacturer and often indicates the drug group

Over-the-counter (OTC) drugs: medications available for purchase without a prescription

Pharmacoeconomics: costs of drug therapy, including costs of purchasing, dispensing, storage, administration, and laboratory and other tests used to monitor patient responses; also considers losses due to expiration

Pharmacogenomics (also known as pharmacogenetics): study of how a person's genetic heritage leads to variable responses to drugs; more generally refers to genetic polymorphisms that occur in a patient population, such as an ethnic group, as opposed to an individual person

Pharmacotherapy: use of drugs to prevent, diagnose, or treat signs, symptoms, and disease processes

Placebo: inert substance containing no medication and given to reinforce a person's expectation to improve

Prescription drugs: medications that are ordered in writing by a licensed health care provider

Prototype: often the first drug of a particular drug class to be developed; usually the standard against which newer, similar drugs are compared

INTRODUCTION

Pharmacology is the study of drugs (chemicals) that alter the functions of living organisms. **Pharmacotherapy** , also known as drug therapy, is the use of drugs to prevent, diagnose, or treat signs, symptoms, and diseases. When prevention or cure is not a reasonable goal, relief of symptoms can greatly improve a patient's quality of life and ability to perform activities of daily living. Contemporary nursing guidelines require that nurses keep safety issues in mind when involved in the practice of pharmacotherapy.

Drugs given for therapeutic purposes are also called medications. These substances may be given for their local or systemic effects. Drugs with local effects, such as sunscreen lotions and local anesthetics, act mainly at the site of application. Those with systemic effects are taken into the body, circulated through the bloodstream to their sites of action in various body tissues, and eventually eliminated from the body. Most drugs are given for their systemic effects. Drugs may also be given for acute disorders, such as pain or infection, or to relieve signs and symptoms of long-term disease processes, such as hypertension or diabetes.

DRUG SOURCES

Historically, drugs came from plants, animals, and minerals. Now, most drugs are synthetic compounds manufactured in laboratories. Chemists, for example, often create useful new drugs by altering the chemical structure of existing drugs. Such techniques and other technologic advances have enabled the production of new drugs as well as synthetic versions of many drugs originally derived from plants and animals. Synthetic drugs are more

standardized in their chemical characteristics, more consistent in their effects, and less likely to produce allergic reactions. Semisynthetic drugs (e.g., many antibiotics) are naturally occurring substances that have been chemically modified.

Biotechnology is also an important source of drugs. This process may involve manipulating deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) and recombining genes into hybrid molecules that can be inserted into living organisms (*Escherichia coli* bacteria are often used), which can be repeatedly reproduced. Each hybrid molecule produces a genetically identical molecule, called a clone. Cloning makes it possible to identify the DNA sequence in a gene and to produce the protein product encoded by a gene, such as insulin. Cloning also allows production of adequate amounts of the drug for therapeutic or research purposes. Biotechnology drugs constitute an increasing percentage of drugs now undergoing development, and this trend is expected to continue into the foreseeable future.

DRUG CLASSIFICATIONS AND PROTOTYPES

Drugs are classified according to their effects on particular body systems, their therapeutic uses, and their chemical characteristics. For example, morphine can be classified as a central nervous system depressant and a narcotic or opioid analgesic. The names of therapeutic classifications usually reflect the conditions for which the drugs are used (e.g., antidepressants, antihypertensives). However, the names of many drug groups reflect their chemical characteristics rather than their therapeutic uses (e.g., adrenergics, benzodiazepines). Many drugs fit into multiple groups because they have wide-ranging effects on the human body.

An individual drug that represents groups of drugs is called a **prototype** . The prototype, often the first drug of a particular drug class to be developed, is usually the standard with which newer drugs in the class are compared. For example, morphine is the prototype of the opioid analgesics, and penicillin is the prototype of the beta-lactam antibacterial drugs.

Drug classifications and prototypes are quite well established, and most new drugs can be assigned to a group and compared with a recognized

prototype. However, some groups lack a universally accepted prototype, and some prototypes are replaced over time by newer, more commonly used drugs. In this text, information about the prototype is provided for each drug class.

DRUG NAMES

Individual drugs may have several different names, but the two that are most commonly used are the generic (official) name and the brand (trade) name. The **generic name** (e.g., amoxicillin) is related to the chemical or official name and is independent of the manufacturer. The generic name often indicates the drug group (e.g., drugs with generic names ending in "cillin" are penicillins). In the United States, the United States Adopted Names Council assigns the generic name. The **brand (trade) name** is designated and patented by the manufacturer. For example, amoxicillin is manufactured by several pharmaceutical companies, some of which assign a specific trade name (e.g., Amoxil, Larotid) and several of which use only the generic name. In drug literature, trade names are capitalized, and generic names are presented in lowercase unless in a list or at the beginning of a sentence. Drugs may be prescribed and dispensed by generic or trade name. Generic equivalents are available for the majority of drugs and can be substituted for trade-named drugs unless the prescriber requests the trade-named medication by writing "do not substitute" on the prescription. Generic drugs are required to be therapeutically equivalent and are less expensive than trade-named drugs.

QSEN Alert: Safety

Using different drug names (i.e., generic or trade names) increases confusion and the risk of misuse. If the drug name on the package does not

match the one on the **prescription drug** label, an individual may take too much medication or not take it at all.

NCLEX Success

1. The nurse is caring for a woman who has strong beliefs about not putting anything unnatural into her body. It is most accurate to say that most modern medications are
   A. natural products derived from plants
   B. natural products derived from minerals
   C. synthetic products manufactured in laboratories
   D. synthetic modifications of natural products

2. The nurse is taking care of a man who is confused about the different medications he is prescribed. He notes that some of the drug names have changed over the course of time he has been taking them. When counseling him, it is most important to keep the following statement in mind:
   A. A drug can belong to only one group or classification.
   B. A prototype drug is the standard by which similar drugs are compared.
   C. Drug groups and prototypes change frequently, and knowledge about a prototype cannot guide knowledge about other drugs in the same class.
   D. The generic name of a drug changes among manufacturers.

DRUG MARKETING

A patent protects a new drug for several years, during which time only the pharmaceutical manufacturer that developed it can market it. The company views this protection as a return on its investment in developing the drug, which might have required years of work and millions of dollars, and as an incentive to develop other drugs. Other pharmaceutical companies cannot

manufacture and market the drug until the patent expires. However, for new drugs that are popular and widely used, other companies often produce similar drugs, with different generic and trade names.

PHARMACOECONOMICS

Pharmacoeconomics involves the costs of drug therapy, including costs of purchasing, dispensing (i.e., salaries of pharmacists, pharmacy technicians), storage, administration (i.e., salaries of nurses, costs of supplies), and laboratory and other tests used to monitor patient responses, as well as losses due to expiration. Length of illness or hospitalization is also a consideration. The goal of most pharmacoeconomic research is to identify drug therapy regimens that provide the desired benefits at the lowest cost.

PHARMACOGENOMICS

Pharmacogenomics is the study of how one's genetic inheritance affects the body's response to drugs. The term comes from the words *pharmacology* and *genomics* and is a combination of drugs and genetics. Because essentially all diseases and conditions have a genetic or genomic component, the use of this information in prevention, screening, diagnosis, and treatment and effectiveness enhances the likelihood of best practice in drug therapy.

ACCESS TO DRUGS

Prescription and Nonprescription Drugs

Legally, American consumers have two ways to access therapeutic drugs. They can obtain them as prescription drugs, which require a written order. A licensed health care provider such as a physician, dentist, or nurse practitioner writes the prescription. Alternatively, they can purchase **over-the-counter** (OTC) drugs, which do not require a prescription. Various laws regulate these routes. Acquiring and using prescription drugs for

nontherapeutic purposes by people who are not authorized to have the drugs or for whom they are not prescribed is illegal.

American Drug Laws and Standards

Current drug laws and standards have evolved over many years. Their main goal is to protect the public by ensuring that drugs marketed for therapeutic purposes are safe and effective. Table 1.1 further describes and summarizes the main provisions.

TABLE 1.1

American Drug Laws and Amendments

Year	Name	Main Provision(s)
1906	Pure Food and Drug Act	Established official standards and requirements for accurate labeling of drug products Established the forerunner of FDA
1912	Shirley Amendment	Prohibited fraudulent claims of drug effectiveness
1914	Harrison Narcotic Act	Restricted the importation, manufacture, sale, and use of opium, cocaine, marijuana, and other drugs that the act defined as narcotics
1938	Food, Drug, and Cosmetic Act	Revised and broadened FDA powers and responsibilities; gave the FDA control over drug safety Required proof of safety from the manufacturer before a new drug could be marketed Authorized factory inspections Established penalties for fraudulent claims and misleading labels
1945	Amendment	Required governmental certification of biologic products, such as insulin and antibiotics
1951	Durham-Humphrey Amendment	Designated drugs that must be prescribed by a physician and dispensed by a pharmacist (e.g., controlled substances, drugs considered unsafe for use except under supervision by a health care provider, and drugs limited to prescription use under a manufacturer's new drug application)
1962	Kefauver-Harris Amendment	Required a manufacturer to provide evidence (from well-controlled research studies) that a drug was effective for claims and conditions identified in the product's labeling Gave the federal government the authority to standardize drug names
1970	Comprehensive Drug Abuse Prevention and Control Act; Controlled Substance Act	Regulated distribution of narcotics and other drugs of abuse Categorized these drugs according to therapeutic usefulness and potential for abuse Title II, Controlled Substances Act Updated or replaced all previous laws regarding narcotics and other dangerous drugs
1978	Drug Regulation Reform Act	Established guidelines for research studies and data to be submitted to the FDA by manufacturers Shortened the time required to develop and market new drugs
1983	Orphan Drug Act	Decreased taxes and competition for manufacturers who would produce drugs to treat selected serious rare diseases
1987		Established new regulations designed to speed up the approval process for high-priority medications
1992	Prescription Drug User Fee Act	Allowed the FDA to collect user fees from pharmaceutical companies, with each new drug application, to shorten the review time (e.g., by hiring more staff) Specified a review time of 12 mo for standard drugs and 6 mo for priority drugs
1993	NIH Revitalization Act	Requires inclusion of women and minorities in NIH-funded research studies, including Phase III clinical drug trials
1997	FDA Modernization Act	Updated regulation of biologic products Increased patient access to experimental drugs and medical devices Accelerated review of important new drugs Allowed drug companies to disseminate information about off-label (non–FDA-approved) uses and costs of drugs Extended user fees
2002	Best Pharmaceuticals for Children Act	Encouraged pharmaceutical companies to conduct studies and label drugs for use in children Provided funds for 5 y for pediatric drug studies
2003	Medicare Prescription Drug Improvement and Modernization Act	Afforded the largest overhaul of Medicare in the 38-y history of the program Provided entitlement benefit for prescription drugs and other benefits for seniors and those with medical disabilities
2005	Combat Methamphetamine Epidemic Act	Established federal law that regulates retail over-the-counter sales of ephedrine, pseudoephedrine, and phenylpropanolamine products due to their use in the manufacturing of illegal drugs. Specifically, these drugs are: • Kept behind the counter or in a locked case • Limited in purchase to no more than 3.6 g a day and 9 g a month • Dispensed after purchasers produce identification and sign a sales log • Handled by employees who are properly trained Geared at curtailing clandestine production of methamphetamine

Year	Name	Main Provision(s)
2008	Ryan Haight Online Pharmacy Consumer Protection Act	Applies to all controlled substances in all schedules Established federal law that it is illegal to deliver, distribute, or dispense a controlled substance by means of the Internet unless the online pharmacy holds a modification of DEA registration authorizing it to operate as an online pharmacy
2018	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act	Dedicates more federal resources to combat the opioid crisis through alternate strategies for pain management, including increased focus on nonopioid pain relief, expanded treatment options for people with substance abuse disorders, greater access to APRN-delivered care and telehealth services Amends the Controlled Substances Act to permanently authorize Nurse Practitioners and provide a 5-y authorization for clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives to prescribe Medication-Assisted Treatments (MAT for opioid use disorders; expands Medicaid coverage for MAT)

APRN, Advanced Practice Registered Nurses; DEA, Drug Enforcement Administration; FDA, U.S. Food and Drug Administration; MAT, medication-assisted treatment; NIH, National Institutes of Health.

The Food, Drug, and Cosmetic Act of 1938 and its amendments regulate the manufacture, distribution, advertising, and labeling of drugs. The law also requires that official drugs (i.e., those listed in the United States Pharmacopeia and designated USP) must meet standards of purity and strength as determined by chemical analysis or by animal response to specified doses (bioassay). The Durham-Humphrey Amendment designates drugs that must be prescribed by a licensed physician or nurse practitioner and dispensed by a pharmacist. The U.S. Food and Drug Administration (FDA) is charged with enforcing the law. In addition, the Public Health Service regulates vaccines and other biologic products, and the Federal Trade Commission can suppress misleading advertisements of nonprescription drugs.

The Comprehensive Drug Abuse Prevention and Control Act was passed in 1970. Title II of this law, called the Controlled Substances Act, regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, and anabolic steroids and requires the pharmaceutical industry to maintain physical security and strict record keeping for these drugs and substances. These drugs are categorized according to therapeutic usefulness and potential for abuse (Box 1.1) and are labeled as **controlled substances** (e.g., morphine is a C-II or Schedule II drug).

BOX 1.1 *Categories of Controlled Substances*

Schedule I

Drugs that have no accepted medical use, have lack of accepted safety, and have high abuse potentials: heroin, lysergic acid diethylamide (LSD), 3,4-methylenedioxy-methamphetamine (MDMA or ecstasy), mescaline, and peyote.

Schedule II

Drugs that are used medically and have high abuse potentials: opioid analgesics (e.g., codeine, hydromorphone, methadone, meperidine, morphine, oxycodone), central nervous system (CNS) stimulants (e.g., cocaine, methamphetamine), and barbiturate sedative–hypnotics (e.g., pentobarbital).

Schedule III

Drugs with less potential for abuse than those in Schedules I and II, but abuse of which may lead to psychological or physical dependence: androgens and anabolic steroids, some depressants (e.g., ketamine, pentobarbital), some CNS stimulants (e.g., methylphenidate), and mixtures containing small amounts of controlled substances (e.g., codeine, barbiturates not listed in other schedules). These drugs and substances have an accepted medical use in the United States.

Schedule IV

Drugs with an accepted medical use in the United States but with some potential for abuse: benzodiazepines (e.g., diazepam, lorazepam), other sedative–hypnotics (e.g., phenobarbital, chloral hydrate), and some prescription appetite suppressants (e.g., phentermine).

Schedule V

Products containing moderate amounts of controlled substances. They may be dispensed by the pharmacist without a physician's prescription but with some restrictions regarding amount, record keeping, and other safeguards. Included are cough suppressants containing small amounts of codeine and antidiarrheal drugs, such as diphenoxylate and atropine (Lomotil).

The Drug Enforcement Administration (DEA) enforces the Controlled Substances Act. Individual people and companies legally empowered to handle controlled substances must register with the DEA, keep accurate

records of all transactions, and provide for secure storage. The DEA assigns prescribers a number, which they must include on all prescriptions they write for a controlled substance. Prescriptions for Schedule II drugs cannot be refilled; a new prescription is required. Nurses are responsible for storing controlled substances in locked containers, administering them only to people for whom they are prescribed, recording each dose given on agency narcotic sheets and on the patient's medication administration record, maintaining an accurate inventory, and reporting discrepancies to the proper authorities.

An approach known as medication-assisted treatment (MAT) may be used in the management of substance abuse disorders. MAT involves the use of FDA-approved medications in combination with counseling and behavioral therapies. The Substance Abuse and Mental Health Services Administration program provides a "whole-patient" approach to the treatment of substance use disorders that is consistent with the latest regulations that address the opioid crisis. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act assists states in implementing updates to their plans of safe care and improving data sharing between states. It can help some people to sustain recovery.

In addition to federal laws, state laws also regulate the sale and distribution of controlled drugs. These laws may be more stringent than federal laws; if so, the stricter laws usually apply.

DRUG APPROVAL PROCESSES: FOOD AND DRUG ADMINISTRATION

The FDA is responsible for ensuring that new drugs are safe and effective before approving the drugs and allowing them to be marketed. The FDA reviews research studies (usually conducted or sponsored by pharmaceutical companies) about proposed new drugs; the organization does not test the drugs.

Testing Procedure

Since 1962, newly developed drugs undergo extensive testing before being marketed for general use. A clinical trial proceeds through five phases if there is continuing evidence of drug safety and effectiveness. Initially, drug testing occurs in animals and small groups of humans (Phase 0), and the FDA's Center for Drug Evaluation and Research (CDER) reviews the test results. Next, researchers perform clinical trials in more humans (Phases 1–4), usually with a randomized, controlled experimental design that involves selection of subjects according to established criteria, random assignment of subjects to experimental groups, and administration of the test drug to one group and a control substance to another group.

In Phase 1, a few doses are given to a certain number of healthy volunteers to determine safe dosages, routes of administration, absorption, metabolism, excretion, and toxicity. In Phase 2, a few doses are given to a certain number of subjects with the disease or symptom for which the drug is being studied, and responses are compared with those of healthy subjects. In Phase 3, the drug is given to different populations and different dosages and by using the drug in combination with other drugs. In double-blind, placebo-controlled designs, half of the subjects receive the new drug and half receive a **placebo** (an inactive substance similar in appearance to the actual drug), with neither subjects nor researchers knowing who receives which formulation. In crossover studies, subjects serve as their own control; each subject receives the experimental drug during half of the study and a placebo during the other half. Other research methods include control studies in which some patients receive a known drug rather than a placebo; in subject matching, patients are paired with other individuals of similar characteristics. Phase 3 studies help determine whether the potential benefits of the drug outweigh the risks. Testing may be stopped during any of the early phases if inadequate effectiveness or excessive toxicity becomes evident. In Phase 4, the FDA allows the drug to be marketed and requires manufacturers to continue postmarketing monitoring and electronic report submission of the drug's safety and effectiveness.

Historically, drug research involved mainly young, white males. In 1993, Congress passed the National Institutes of Health (NIH) Revitalization Act, which formalized a policy of the NIH that women and minorities be included in human subject research studies funded by the NIH and that women and minorities be included in clinical drug trials. Now, major drug trials must recruit female subjects and include outcome data on

women. In addition, all newly developed drugs must include gender-related effectiveness and safety information in the initial FDA application. Knowledge about the drug effects in women has increased but is still relatively limited because many commonly used drugs were developed before enactment of these regulations.

Subsequent withdrawal of approved and marketed drugs has occurred, usually because of serious adverse effects that become evident only when the drugs are used in a large, diverse population. In addition, over the past 25 years, the FDA has issued

about drugs that can cause serious adverse effects. The warning appears on the label, package insert, and any marketing literature; these BBWs are identified in this text (see Chap. 2 for additional information).

In response to growing public concern regarding health risks posed by approved drugs, the FDA requested that the Institute of Medicine (IOM) conduct an independent assessment of the FDA's drug safety system in the United States. Their 2006 report released in 2006 recounted major deficiencies and made recommendations to improve risk assessment, surveillance, and the safe use of drugs. Ongoing assessment of deficiencies and identification of additional error reduction strategies persists.

Approval of Prescription and Nonprescription Drugs

The FDA's CDER approves many new prescription drugs annually, and it also approves drugs for OTC availability. With prescription drugs, a health care professional diagnoses the condition, often with the help of laboratory and other diagnostic tests, and determines a need for the drug. With OTC drugs, the consumer must make these decisions, with or without consultation with a health care provider. The CDER handles the transfer of drugs from prescription to OTC status and may require additional clinical trials to determine the safety and effectiveness of OTC use. For prescription drugs taken orally, the switch to OTC status may mean different indications for use and lower doses. FDA approval of a drug for OTC availability involves evaluation of evidence that the consumer can use the drug safely,

using information on the product label, and shifts primary responsibility for safe and effective drug therapy from health care professionals to consumers.

Having drugs available OTC has potential advantages and disadvantages for consumers. Advantages include greater autonomy, faster and more convenient access to effective treatment, possibly earlier resumption of usual activities of daily living, fewer visits to health care providers, and possibly increased efforts by consumers to learn about their symptoms/conditions and recommended treatments. Disadvantages include inaccurate self-diagnoses and potential risks of choosing a wrong or contraindicated drug, delayed treatment by health care professionals, and development of adverse drug reactions and interactions. When a drug is switched from prescription to OTC status, sales and profits of pharmaceutical companies increase and costs of insurance companies decrease. Costs to consumers increase because health insurance companies do not cover most OTC drugs.

Clinical Application 1.1

Ms. Clark analyzes drug safety, including the national organizations charged with ensuring it.

- What is the role of the U.S. Food and Drug Administration (FDA) in the drug approval process?
- What is the role of the Drug Enforcement Administration (DEA) and the nurse with regard to controlled substances?

NCLEX Success

3. In understanding the use of controlled substances for patients, it is important that the nurse knows that controlled drugs are
   A. categorized according to prescription or nonprescription status
   B. regulated by state and local laws more than federal laws
   C. those that must demonstrate high standards of safety
   D. scheduled according to medical use and potential for abuse

4. A patient is asking what the difference is between a prescription for 800 mg of a medication that can be purchased on an OTC basis as a 200-mg tablet. To address this issue, it is important that the nurse knows that OTC drugs
   A. are considered safe for any consumer to use
   B. are not available for treatment of most commonly occurring symptoms
   C. often differ in indications for use and recommended dosages from their prescription versions
   D. are paid for by most insurance policies

SAFETY IN DRUG ADMINISTRATION

At least 7 million preventable adverse drug events costing more than 21 billion dollars occur in the health care system each year (New England Health Institute). As described previously, multiple safeguards to promote drug safety in packaging, drug laws, and approval processes are in place. Just as critical are safeguards to promote the safe administration of drugs at the point of care.

Rights of Medication Administration

Patient safety with medication administration begins by adhering to the rights of medication administration. The 10 rights of medication administration include the right drug, right dose, right patient, right route, right time, right reason, right documentation, right patient education, right

evaluation, and right to refuse the medication. These rights are goals of the medication administration process, and discussion of the effort to reduce medication errors and harm has expanded over the years. However, the focus on rights has been on the nurse and not the system in which medication administration takes place. Chapter 3 discusses the medication rights and their application to the nursing process.

QSEN Alert: Quality Improvement

Smetzer, Baker, Byrne, and Cohen (2010) reported on a nurse who mistakenly administered epidural pain medication intravenously to a pregnant woman in a birthing suite. Complications developed, and although cesarean section resulted in the delivery of a healthy infant, the teenage mother died from cardiovascular collapse. Media publicity called attention to the error when a nurse was charged with a criminal offense.

As part of the investigation of this issue, the hospital's medication and safety procedures were analyzed using a root cause analysis. In addition, an external review team evaluated the organization's medication system and processes, patterns of staffing, leadership, and institutional culture; identified problems; and suggested improvements. Enhanced safety initiatives included team training for staff working in the birthing suites, implementing consistent procedures for scanning-adherence tracking, and streamlining the bar code scanning tracking of medications. This incident identified system gaps and process failures within an organization that led to the death of a patient. Prudent nursing actions support an organization's culture of safety by complying with processes (safety nets and fail-safe mechanisms) that are aimed at preventing and/or reducing environmental effects to prevent medication errors.

New technology in medication administration has expanded required competencies for safe medication administration. Electronic charting, automated drug-dispensing systems, and bar code medication administration have required enhanced nursing skills to manage these complex systems. The entire process of medication administration in a hospital is distracting, causing the nurse to lose focus on the task at hand; multiple interruptions and the extended hours that nurses work inevitably lead to the possibility of unintended consequences.

QSEN Alert: Safety

Error-reduction strategies during medication administration include the following:

- Having a "quiet zone" to prepare medications
- Placing "quiet zone" signs at the entrance to the medication room or above the automated medication-dispensing system
- Following protocols and checklist outlining medication administration
- Wearing a sash or vest to signal others to avoid interrupting the nurse during medication administration
- Educating staff to reduce interruptions of nurses administering medications
- Having a drug guide available during drug administration

Multiple national strategies have been implemented to reduce medication errors since the seminal work of the IOM (2000) , which highlighted the breadth of preventable medical errors in the United States. Examining human factors and the response of nurses to workflow changes

and technology have led to more successful system design, operation, and usability.

Quality and Safety Education for Nurses Project

The Quality and Safety Education for Nurses (QSEN) project, sponsored by the Robert Wood Johnson Foundation, is committed to the continuous improvement in the quality and safety of health care systems by focusing on the needed knowledge, skills, and attitudes (KSA) required in the preparation of future nurses in six areas: patient-centered care, teamwork and collaboration, evidence-based practice, quality improvement, safety, and informatics. Using the IOM competencies for nursing, QSEN faculty outlined prelicensure and graduate quality and safety competencies for nursing. Additionally, recommended targets for the KSA that need to be developed in prelicensure nursing students for each competency have been established. The QSEN competencies in the six areas are highlighted throughout the text as they relate to medication administration. Box 1.2 outlines these competencies and their definitions.

BOX 1.2 *Quality and Safety Education for Nurses (QSEN) Competencies and Definitions*