8th EDITION

Applied Pharmacology for the Dental Hygienist

Elena Bablenis Haveles

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Applied Pharmacology for the Dental Hygienist

EIGHTH EDITION

Elena Bablenis Haveles, BS Pharmacy, PharmD, RPh

Adjunct Associate Professor of Pharmacology, Gene W. Hirschfeld School of Dental Hygiene, College of Health Sciences, Old Dominion University, Norfolk, Virginia

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3251 Riverport Lane
St. Louis, Missouri 63043

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Reviewers

Celeste M. Abraham, BS, DDS, MS Associate Clinical Professor, Periodontics, Texas A&M University College of Dentistry, Dallas, Texas

Jocelyne King, HD, Diploma in Dental Hygiene, Registrant of CDHO Collège Boréal, Écoles des sciences de la santé (ESS), Collège Boréal, Sudbury, ON, Sudbury, ON, Canada

Elizabeth Morch, RDH AGDDE Med. Registrant: College of Dental Hygienists of BC, Faculty, Dental Programs, Camosun College, Victoria, BC, Canada

Amilia Peskir, HD, BSc, CPEC Diploma in Dental Hygiene from John Abbott College, License with L'Ordre des hygieniestes dentaire du Québec, (license in good standing with the Order of Dental Hygienists of Québec), BSc General Agriculture, major Microbiology from McGill University, Diploma in Education from the University of Sherbrooke, Teacher, Dental Hygiene, John Abbott College, Sainte-Anne-de-Bellevue, Québec, Canada (H9X 3L9)

Paula D. Silver, BS Biology, PharmD. Medical Instructor, MA/LPN/RN, ECPI University, Newport News, Virginia

Rebecca G. Tabor, RDH, MEd Associate Professor, Allied Health, Western Kentucky University, Bowling Green, Kentucky

Dedication

To my husband, Paul, and sons, Andrew and Harry

Preface

Elena Bablenis Haveles

Knowledge of pharmacology is imperative to the success of a dental hygiene student. *Applied Pharmacology for the Dental Hygienist*, Eighth Edition, is written with the specific needs of the dental hygienist in mind to help ensure your success in this subject matter.

Society is information-conscious, and it is expected that the dental hygienist be knowledgeable about medications. Dental hygienists are called on to complete medication and health histories, administer certain medications, provide counseling about oral hygiene, and, in some states, prescribe medication and provide counseling about medications.

The primary goal of this book remains to produce safe and effective dental hygienists and to offer them the tools that they need to continue to learn throughout their lifetimes. This textbook provides the dental hygienist with the necessary knowledge of pharmacology to assess for medical illness, adverse reactions, and drug interactions that may affect oral health care and treatment. It is not intended that the dental hygienist take the place of the dentist in providing the patient with information about the various medications but that the hygienist will work with the dentist in providing appropriate patient care.

Intended audience

The primary intended audience of this specific textbook is the dental hygiene student. However, practicing dental hygienists and dentists may find this book useful for a quick review of

pharmacology. The information may also benefit dental students as a classroom text or resource.

Importance to the profession

Continual learning after the completion of a formal education is especially critical in the dynamic area of pharmacology. New drugs are constantly being discovered and synthesized. New effects of old drugs are identified. New diseases and drugs for the treatment of those diseases are being studied. Today's dental hygiene student will need to be able to access new information about new drugs and intelligently communicate with others (professionals and patients) using the unique medical and pharmacologic vocabularies. It is hoped that this textbook will also help dental hygiene students to accomplish the following goals:

1. Students should achieve an understanding of the need and importance of obtaining and using appropriate reference material when needed. When confronted with a patient taking a new or unfamiliar drug, the dental hygiene student will use the appropriate references to learn about the effects of the drug. Pharmacology is a field in which new information is constantly becoming available.
2. Students should develop the ability to find the necessary information about drugs with which they are not familiar. The textbook encourages the use of the current reference sources that will be available where dental hygienists practice.
3. Students should develop the ability to apply that information to their clinical dental patients within a reasonable time.

Organization

The material has been organized to create a readable and clinically applicable resource in pharmacology that specifically addresses the needs of the dental hygiene student. The textbook is divided into

four sections:

PART ONE: General Principles includes general information about pharmacology, pharmacokinetics, drug action and handling, adverse reactions, prescription writing, autonomic pharmacology, the role of the dental hygienist, and pharmacology in oral health care.

PART TWO: Drugs Used in Dentistry includes the pharmacology of nonopioid analgesics, opioid analgesics, antibiotics, antifungals, antiviral drugs, antianxiety drugs, local anesthetics, and general anesthetics with a special emphasis on nitrous oxide. It also has chapters on the treatment of oral conditions and dental hygiene-related disorders. Each chapter focuses on dental-related adverse effects, how the drug may affect oral health care, and the specific dental hygiene considerations.

PART THREE: Drugs That May Alter Dental Treatment includes the more common disease states or medical conditions that patients may present with, as well as how those medications or the disease states themselves can affect oral health care. Each chapter also focuses on dental-related adverse effects, how the drug may affect oral health care, and specific dental hygiene considerations.

PART FOUR: Special Situations includes significant information on treating emergency situations, women who are pregnant or lactating, patients with substance abuse issues, and those patients self-treating with herbal remedies or supplements. Each chapter also focuses on dental-related adverse effects, how the drug may affect oral health care, and specific dental hygiene considerations.

Key features

This book includes many features and learning aids to assist the student studying pharmacology:

- Dental Hygiene Focus: Although pharmacologic basics are covered overall and for specific types of drugs, interactions of clinical interest in oral health care are incorporated throughout the book. These sections offer explanations on why certain drugs are used or contraindicated in a dental treatment plan, providing students with targeted

information they will need for practice.

- Consistent Presentation: Information about each drug varies, but all drugs are presented using a similar format so that sections can be easily identified. Each drug group is discussed and includes the group's indications (for what purpose the drugs are used), pharmacokinetics (how the body handles the drugs), pharmacologic effects (what the drugs do), adverse reactions (bad things the drugs do), drug interactions (how the drugs react with other drugs in the body), and the dosage of the drugs (how much is indicated).
- Academic Skills Assessment: Review questions are included at the end of each chapter, and answers are available to instructors. These questions help students to assess their knowledge and gauge comprehension of chapter material.
- Clinical Case Study: A clinical case with questions is included at the end of each chapter and answers are available to instructors. These cases and questions help students to assess their knowledge and gauge comprehension of chapter material by means of clinical application of the material.
- Key Terminology: Key terms are bolded throughout and appear in color within chapter discussions; each term is defined in a back-of-book glossary. The language of pharmacology is new to many dental hygiene students, and the in-text highlights draw students' attention to terms they may need to review. The glossary provides a centralized, quick, and handy reference.
- Summary Tables and Boxes: Throughout, concepts are summarized in boxes and tables to accompany narrative discussions, providing easy-to-read versions of text discussions that support visual learners and serve as useful tools for review and study.
- Note Boxes: Boxes are interspersed throughout text discussions to briefly convey important concepts, indications, contraindications, memory tools, warnings, and more. They are easy to see and provide quick statements or phrases that are easy to remember.

- Dental Hygiene Considerations Boxes: Each chapter concludes with a compilation of the most relevant dental-specific information, which is summarized in terms of how that chapter's content specifically relates to the day-to-day practice of dental hygiene. These sections help to explain to students the need for an understanding of pharmacology and its importance in helping them achieve maximal oral health for their patients.
- Writing Level: Certain content areas and tables throughout the book have been simplified to better explain difficult concepts, such as receptors and metabolism. Pharmacology is a complex subject matter, and this book attempts to present information in a way that helps to ensure that students can fully comprehend the content and apply it to the practice of dental hygiene.
- Art Program: Approximately one-third of the images are new to this edition, and many of those that appeared in the previous edition have been updated and improved. The new images are more targeted and visually appealing and help support text discussions so that students can see key concepts at work.
- Reference Citations: Chapters contain bibliographical information as necessary, directing students to targeted sources of information where additional dental-related information can be located.
- Appendixes: Resources such as the *What If* scenarios that quickly outline situations in which relatively quick assessments and decisions are required and the calculation of children's dosages highlight additional information that proves useful in the clinical environment.
- Drug Index: A separate index covers the mention of all the drugs discussed within the book, allowing readers to quickly access targeted information about specific drugs or drug classes.

Ancillaries

A companion Evolve website has been created specifically for

Applied Pharmacology for the Dental Hygienist and can be accessed directly from http://evolve.elsevier.com/Haveles/pharmacology. The following resources are provided:

For the Instructor

- TEACH Instructor's Resource (TIR)—A complete and detailed course-planning resource includes the following features, all designed around standard 50-minute classes:
    - Lesson Plans with detailed content mapping to chapter objectives, case scenarios, and activities for inside and outside the classroom
    - Lecture Outlines consisting of PowerPoint slides with talking points
    - Answer Keys and rationales to the Clinical Skills Assessments in the textbook
- Test Bank—Approximately 900 objective-style questions—multiple-choice, true/false, matching, and short-answer—are provided, with accompanying rationales for correct answers and page-number references for remediation.
- Image Collection—All of the book's images, organized by chapter with correlating figure numbers to the textbook, are available for download into PowerPoint or other presentations and materials.
- Color Pill Atlas—Labeled color image for the pills most commonly prescribed is included.

For the Student

- Practice Quizzes—Approximately 600 questions are provided in an instant-feedback format to allow students to assess their understanding of content and prepare for examinations. Rationales and page-number references are provided for remediation.
- Drug Guides—The major groups and specific drugs covered within each chapter are organized and summarized in

terms of classification and mechanism of action for a quick study tool.

- Case Studies—Case presentations are followed by thought questions that deal with drug indications, contraindications, interactions, and more. Answers are provided.

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Thank you to my peers and administrators at the Gene W. Hirschfeld School of Dental Hygiene, Old Dominion University, for their support.

To my father, Harry C. Bablenis, thank you for always believing in me and encouraging me to be my very best.

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To my husband, Paul, thank you for your guidance and support as I try to juggle this and everything else in our lives. I love you.

EBH

How to Be Successful in Pharmacology

Before the lecture, read the syllabus outline for the subject to be covered during the class period. Become familiar with the vocabulary. Guess what might be said about the various topics. Think of what has been said in pharmacology about the topic; look at your pharmacology notes to see what you already know about the topic. Skim the textbook chapter(s) assigned to identify areas to be covered.

Attend class, take notes in your syllabus, and ask yourself questions about what was said. Compare what was said with what you previously thought about the topic.

Reread your lecture notes before the next class. Add and complete things you remember from class. Ask fellow classmates for clarification if you have questions. Read notes from previous classes.

Read the textbook assignment. Note especially those areas discussed in class. Let the textbook assignment answer questions you might have had in class. Answer general course objectives in the front of your syllabus for the drug group covered.

Look up in a medical dictionary any words for which you do not know the meaning. Construct a vocabulary list for each subject. Pay attention to the derivatives of the unknown medical word—its stem, prefixes, and suffixes.

Use active learning when studying. Be able to determine what portion of your study time is spent in active learning. Use the

examples below to classify your study methods.

- Active: Writing things down, making up flash cards, speaking out loud, discussing the concepts with classmates, asking each other questions, giving a lecture (to your parrot) without notes, making a video or audio recording of your performances (for your own practice), or writing everything you know about a drug on an empty blackboard.
- Not active: Looking over notes, reading the book, listening in lecture, and reviewing your notes.

Did you answer the Academic Skills Assessment questions and the Clinical Case Study questions? These questions and cases are included at the end of each chapter so the learner can check to see if he or she knows the answers to these questions. It is a review for your benefit. Answers are only available through your instructor.

Did you think about what the information may mean to the dental hygienist? Trying to understand why things happen will make learning more efficient and more fun, too. What problems might be encountered when treating a patient taking this medication? How can the chance that something untoward will happen be minimized?

Did you think of examples in "real life"? By thinking of real-life examples, readers can transform a topic into a picture in their brain. For example, the "fight or flight" response associated with the sympathetic nervous system can be visualized as a caveman, his eyes big and his heart pounding, being chased by a hungry tiger.

Use of objectives to focus studying

Find out what the objectives are for your pharmacology class. These are some objectives that may give you an idea about the organization of the material.

Goals for **commonly prescribed dental drugs** include the following:

- State the therapeutic use(s) for each drug group.

- Discuss the mechanism of action of the drug, when applicable.
- Explain the important pharmacokinetics for the drug group.
- List and describe the major pharmacologic effects associated with the drug group. State and discuss the important adverse reactions or side effects and their management or minimization.
- Describe any contraindications/cautions to the use of the drug group.
- Recognize clinically significant drug–drug, drug–disease, and drug–food interactions.
- Describe "patient instructions" for each drug group that could be prescribed.

Goals for drugs patients may be taking that can alter dental treatment:

- Determine the "dental implications" of each drug group for the management of dental patients using that drug group.
- Determine whether any dental drugs are likely to have drug interactions with these groups.
- State change(s) in the treatment plans that would be required for patients taking medications.

PART I

General Principles

1

Information, Sources, Regulatory Agencies, Drug Legislation, and Prescription Writing

LEARNING OBJECTIVES

1. Discuss the history of pharmacology and its relationship to the dental hygienist.
2. List where detailed and updated information on medications can be found.
3. Define the ways in which drugs are named and the significance of each.
4. Define generic equivalence and how it is related to drug substitution.
5. Describe the acts and agencies within the federal government designed to regulate drugs.
6. Identify the four phases of clinical evaluation involved in drug approval and the five schedules of drugs.
7. Discuss the history of drug legislation, including:
    - List the five schedules of controlled substances.

- Explain package inserts and black box warnings.
- Differentiate between labeled and off-label uses.
- Explain orphan drugs and drug recalls.

8. Prescription writing. Become familiar with the basics of prescription writing as well as describing the parts of the prescription and prescription label regulations.

http://evolve.elsevier.com/Haveles/pharmacology

Pharmacology is derived from the Greek prefix *pharmaco-*, meaning "drug" or "medicine," and the Greek suffix *-logy*, meaning "study." Therefore pharmacology is the study of drugs and their interactions with living cells and systems. Drugs are chemical substances that are used in the diagnosis, treatment, or prevention of disease or other abnormal conditions. They can be used in both humans and animals. Drugs include synthetically derived compounds, vitamins, and minerals as well as herbal supplements —although these last substances are marketed not as drugs but as food supplements. In addition to pharmacology, the dental hygienist should know about its related disciplines, as listed and defined in Table 1.1.

Table 1.1

Disciplines Related to Pharmacology

Area of Pharmacology	Definition
Pharmacotherapy	The use of medications to treat different disease states
Pharmacodynamics	The study of the action of drugs on living organisms
Pharmacokinetics	The study of what the body does to a drug; the measurement of the absorption, distribution, metabolism, and excretion of drug from the body
Pharmacy	The practice of compounding, preparing, dispensing, and counseling of patients about their medications
Toxicology	The study of the harmful effects of drugs on living tissues

History

In the beginning, plants were discovered to produce beneficial effects.

Pharmacology had its beginning when our human ancestors noticed that ingesting certain plants altered body functions or awareness. The first **pharmacologist** was a person who became more astute in observing and remembering which plant products produced predictable results. From this humble beginning, a huge industrial and academic community concerned with the study and development of drugs has evolved. Plants from the rain forest and chemicals from tar have been searched for the presence of drugs. The agents discovered and found to be useful are then prescribed and dispensed through the practice of medicine, dentistry, pharmacy, and nursing. Health care providers who can write prescriptions include physicians (for humans), veterinarians (for animals), dentists (for dental problems), and optometrists (for eye problems). Physicians' assistants, nurse practitioners, pharmacists, and dental hygienists can prescribe drugs under certain guidelines and in certain states.

Role of the dental hygienist

Knowledge of a patient's medication/health history is necessary to provide optimal oral health care.

In today's ever-changing health care environment, it is important that the dental hygienist know more than the name and color of a medication. Patients rely on the dental hygienist to provide them with the correct information regarding their medication and oral health care. Although dental hygienists do not normally prescribe drugs, it is important that they have knowledge of pharmacology and its related disciplines to provide more effective care for the

patient.

Medication/Health History

As a result of the many breakthroughs in medicine and pharmacy research, more and more diseases can be treated; therefore, more and more people are taking medication. More often than not, the dental hygienist is the first health professional in the dental practice to assess the patient's medication history. Obtaining a medication/health history is the first step in safely treating a patient. Patients may be taking any number of medications that interact with medications used in oral health care or that may adversely affect oral health. An understanding of the actions, indications, adverse reactions, and therapeutic uses of these drugs can help determine potential effects on dental treatment. Comparing the medical conditions of the patient with the medications he or she is taking often raises questions in the interview. Examples include the risk of xerostomia in patients taking calcium channel blockers for hypertension and the increased risk of gingival bleeding in patients taking an aspirin each day to prevent a heart attack or stroke which will be further addressed in Chapter 12. A detailed health/ medication history allows the dental hygienist to provide the best possible health care to the patient (Box 1.1).

Box 1.1

Obtaining a Medication History

1. Do you take any medications for_____?
    - Heart/high blood pressure/angina
    - Lungs/asthma/Chronic Obstructive Pulmonary Disease (COPD)
    - Diabetes/sugar
    - Ulcer/reflux/heartburn
    - Mental health issues
    - Arthritis

- Seizures

2. What are the names of your medicines and how many times a day do you take them?
3. How many times a day did your health practitioner tell you to take them?
4. Have you taken your medicine today?
5. Do you take any medicine that you can buy without a prescription? For example,
    - Acetaminophen, aspirin, ibuprofen, naproxen
    - Antihistamines/decongestants
    - Omeprazole (Prilosec OTC), lansoprazole (Prevacid 24HR), omeprazole/sodium bicarbonate (Zegerid OTC), nizatidine (Axid AR), famotidine (Pepcid AC), cimetidine (Tagamet HB), ranitidine (Zantac 75)
6. Do you take any herbal supplements? If so, please tell me their names and why you are taking them.
7. Have you noticed any problems (side effects) when you take your medicine?
8. Do you have any allergies to medicine? If yes, what medicine?
9. What happened to you when you took the medicine?

Medication Administration

Because the dental hygienist administers certain drugs in the office, knowledge of these agents is crucial. For example, the oral health care provider commonly applies topical fluoride (Chapter 26), and in some states, both the dentist and the dental hygienist administer local anesthetics and nitrous oxide (Chapter 10). In-depth knowledge of these agents is especially important because of their frequent use.

Emergency Situations

The ability to recognize and assist in dental emergencies requires knowledge of certain drugs, all of which will be discussed in greater detail in Chapter 21. The indications for these drugs and their adverse reactions must be considered. For example, in a patient having an anaphylactic reaction, epinephrine must be

administered quickly.

Appointment Scheduling

Patients taking medication for systemic diseases may require special handling in the dental office. For example, asthmatic patients who experience dental anxiety should schedule their appointments early in the morning, when they are not rushed or under pressure, in order to avoid an asthma attack (Chapter 17). Diabetic patients should schedule their appointments 90 minutes after meals and medication administration. Certain patients may need to take medication before their appointments (Chapter 18). Patients with a history of infective endocarditis need to be premedicated with antibiotics before some of their dental or dental hygiene appointments (Chapter 7).

Nonprescription Medication

More and more patients are self-treating with nonprescription drugs. Also, nonprescription or over-the-counter (OTC) products may be recommended for certain patients. The study of pharmacology will assist the oral health care provider in making an intelligent selection of an appropriate OTC product. Although patients tend to forget that OTC products are drugs, knowledge of pharmacology will allow the dental hygienist to evaluate the patient for therapeutic OTC drug effects and adverse effects.

Nutritional or Herbal Supplements

Many patients self-treat or are prescribed nutritional or herbal supplements for any number of disease states, as will be further discussed in Chapter 24. Although the vast majority of these supplements do not carry US Food and Drug Administration (FDA) approval for treating disease states, patients still use them. These supplements are drugs and can cause adverse effects and interact with other drugs.

Sources of information

Always keep reference guides or electronic devices close by so you can quickly look up information regarding medication therapy.

Many different medications are available, and it is important for the dental hygienist to know where to look for information about prescription medications, nonprescription medications, and herbal supplements. There are many sources, including reference texts, association journals, and the Internet, where pertinent drug information can be found. Box 1.2 reviews the different sources of information.

Box 1.2

Pharmacologic References and Resources Recommended for the Dental Office

Drug Information Reference Books

American Hospital Formulary Service (AHFS) Drug Information
United States Pharmacopeia-Drug Information (USP-DI)
Drug Facts and Comparison
Physicians' Desk Reference (PDR)
Handbook of Nonprescription Drugs: An Interactive Approach to Health Care
PDR for Nonprescription Drugs, Supplements, and Herbs
PDR for Herbal Medicines
Natural Products: A Case-Based Approach for Health Care Professionals
Merck Manual for Medical Information
Drug Interaction Facts
Goodman and Gilman's The Pharmacologic Basis of Therapeutics

Dental Drug Reference Books

Mosby's Dental Drug Reference
Lexi-Comp's Drug Information Handbook for Dentistry

Selected Journals

Journal of Dental Hygiene
Dimensions in Dental Hygiene
Registered Dental Hygienist (RDH) Magazine
Pharmacy Today
Drug Topics
New England Journal of Medicine
Journal of the American Dental Association

Websites

www.epocrates.com
www.davis'sdrugguide.com
www.lexicomp.com
www.pdr.net
www.rxlist.com
www.drugs.com
www.fda.gov/medwatch
www.medscape.com
www.mayoclinic.com
www.nlm.nih.gov/medlineplus/

Newsletters

Pharmacist Letter
The Medical Letter

Printed Resources

Each publication type can be selected according to its lack of bias, its publication date (when the current edition was released), its readability (vocabulary, simplicity of explanations, and presence of visual aids), its degree of detail (all you want to know and much more, just the right amount of information, or not enough to understand what is being said), and its price. Some publications are specific for disease states, geriatric or pediatric patients, drug interactions, or prescription drugs or nonprescription drugs. Reference books can be updated monthly, quarterly, and annually. Every dental office should have at least one reference book that lists the names of both prescription and OTC drugs. Further, a standard

pharmacology textbook would be helpful in understanding the reference books. Because of the continual release of new drugs, a recent edition (not more than 1 or 2 years old) of a reference book is needed.

Computer and Online Resources

Although books serve as the usual source of information on drugs, many health care providers are using electronic resources, such as computer software and Internet-based services. Computer tablets and smart phones are also being used more and more for recording and storing patient information, calculating drug doses, and consulting medication information databases. Many online resources are available; they include *Davis's Drug Guide* (http://www.drugguide.com/ddo/), Epocrates (www.epocrates.com), and Lexi-Comp (www.lexicomp.com). These sites have applications (apps) that can be downloaded to smart phones as well as computer-based online sites. Lexi-comp also has apps specific for dentistry. In addition, many pharmacology textbooks include CD-ROMs that supplement the written material.

Journals are another source of information that provide the dental hygienist with the most current information regarding medication and oral health care therapy. More than 3000 journals are available online and can be accessed through Medline (www.medline.com) and PubMed (www.pubmed.com), as well as at specific journal websites.

In addition, the practicing pharmacist can be a source of information. It is particularly important for the dental professional to establish a professional relationship with a local pharmacist, who may assist him or her in understanding the possible effects of a new drug on a patient.

Drug names

It is important for the dental hygienist to understand the ways in which a drug can be named, because he or she must be able to discuss drugs with both the patient and the provider of the patient's care. The ability to refer to a drug's name(s) is complicated

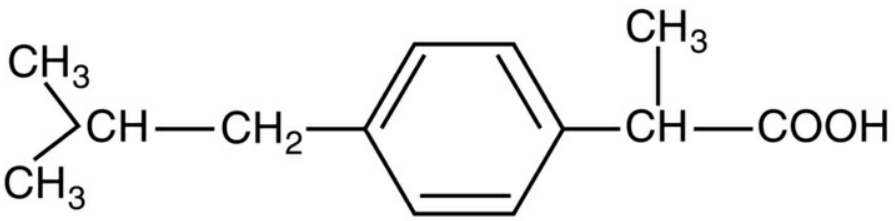
by the fact that all drugs have at least two names, and many have more.

When a particular drug is being investigated by a company, it is identified by its chemical name, which is determined by its chemical structure. If the structure is unknown at the time of investigation, a code name, usually a combination of letters and numbers, is assigned to the product (e.g., RU-486). Often the code name is used even when the chemical structure is identified and named. It is much easier to speak and write the code name than the full name of the chemical structure.

Each drug has only one generic name but may have several trade names.

If a compound is found to be useful and it is determined that the compound will be marketed commercially, the pharmaceutical company discovering the drug gives the drug a trade name (e.g., Motrin). This name, which is capitalized, is usually chosen so that it can be easily remembered and promoted commercially. This trade name, registered as a trademark under the Federal Trademark Law, is the property of the registering company. The trade name is protected by the Federal Patent Law for 20 years from the earliest claimed filing date, plus patent term extensions. Although the brand name is technically the name of the company marketing the product, it is often used interchangeably with the trade name.

Before any drug is marketed, it is given a generic name that becomes the "official" name of the drug. For each drug, there is only one generic name (e.g., ibuprofen), selected by the United States Adopted Name Council, and the name is not capitalized. This Council selects a generic name that hopefully does not conflict with other drug names. However, the names of several marketed drugs have been changed because they were confused with the names of other drugs that had already been marketed. After the original manufacturer's patents have expired, other companies can market the **generic drug** under a trade name of their choosing (e.g., Advil). Fig. 1.1 compares the chemical, generic, and trade names of ibuprofen.



Chemical Name: (±)-2-(p-isobutylphenyl) propionic acid
Generic Name: Ibuprofen
Trade: Motrin, Advil

FIG. 1.1 A comparison of the chemical, generic, and trade names of ibuprofen.

Drug Substitution

For dental drugs, generic substitution provides equivalent therapeutic results at a reduced cost.

In the discussion of generic and trade names, the question of generic equivalence and substitution arises. Are the various different generic products equivalent? Once the patent of the original drug expires, other companies can market the same compound under a generic name. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, which allowed generic drugs to receive expedited approval. The FDA still requires that the active ingredient of the generic product enter the bloodstream at the same rate as the trade name product. The variation allowed for the generic name product is the same as for the reformulations of the brand name product. For the few drugs that are difficult to formulate and have narrow **therapeutic indexes**, no differences exist between the trade name product and the generic product; therefore, generic substitution drugs give equivalent therapeutic results and provide a cost savings to the patient.

Drugs can be judged "similar" in several ways. When two formulations of a drug meet the chemical and physical standards established by the regulatory agencies, they are termed *chemically*

equivalent. If the two formulations produce similar concentrations of the drug in the blood and tissues, they are termed *biologically equivalent*. If they prove to have equal therapeutic effects in a clinical trial, they are termed *therapeutically equivalent*. A preparation can be chemically equivalent yet not biologically or therapeutically equivalent. These products are said to differ in their bioavailability. Before generic drugs are marketed, they must be shown to be biologically equivalent, which would make them therapeutically equivalent.

Federal regulations and regulatory agencies

Many agencies are involved in regulating the production, marketing, advertising, labeling, and prescribing of drugs.

Harrison Narcotic Act

In 1914 the Harrison Narcotic Act established regulations governing the use of opium, opiates, and cocaine. Marijuana laws were added in 1937. Before this law, mixtures sold OTC could contain opium and cocaine. These mixtures were promoted to be effective for many "problems."

Food and Drug Administration

The FDA, which is part of the Department of Health and Human Services (DHHS), grants approval so that drugs can be marketed in the United States. Before a drug can be approved by the FDA, it must be determined to be both safe and effective. The FDA requires physical and chemical standards for specific products and quality control in drug manufacturing plants. It determines which drugs may be sold by prescription or OTC and regulates the labeling and advertising of prescription drugs. Because the FDA is often more stringent than regulatory bodies in other countries, drugs are often marketed in Europe and South America before they are available in the United States.

Federal Trade Commission

The Federal Trade Commission (FTC) regulates the trade practices of drug companies and prohibits the false advertising of foods, nonprescription (OTC) drugs, and cosmetics.

Drug Enforcement Administration

The Drug Enforcement Administration (DEA) of the Department of Justice administers the Controlled Substances Act of 1970. This federal agency regulates the manufacture and distribution of substances that have a potential for abuse, including opioids (narcotics), stimulants, and sedatives.

Omnibus Budget Reconciliation Act

The newest federal regulation concerning drugs is the Omnibus Budget Reconciliation Act (OBRA) of 1990. It mandates that, beginning January 1, 1993, pharmacists must provide patient counseling and a prospective drug utilization review (DUR) for Medicaid patients. Although this federal law covers only Medicaid patients, state boards of pharmacy are interpreting this law to apply to all patients. Dental patients who have their prescriptions filled at a pharmacy should receive counseling from the pharmacist about their prescriptions.

Clinical evaluation of a new drug

It takes almost 12 years from the time a drug is synthesized in the laboratory to its availability on pharmacy shelves, at a cost of more than 350 million dollars. Before a discovered or synthesized compound is approved for marketing, it must pass through many steps (Fig. 1.2). Animal studies begin by measuring both the acute and chronic toxicity. The median lethal dose is determined for several species of animals. Long-term animal studies continue, including a search for teratogenic effects. Toxicity and **pharmacokinetic** properties are also noted. This process, referred to as *preclinical testing*, usually lasts about 3 years. After the preclinical trials have been completed, an investigational new drug application

(INDA) must be filled out and submitted before any clinical trials can be performed.

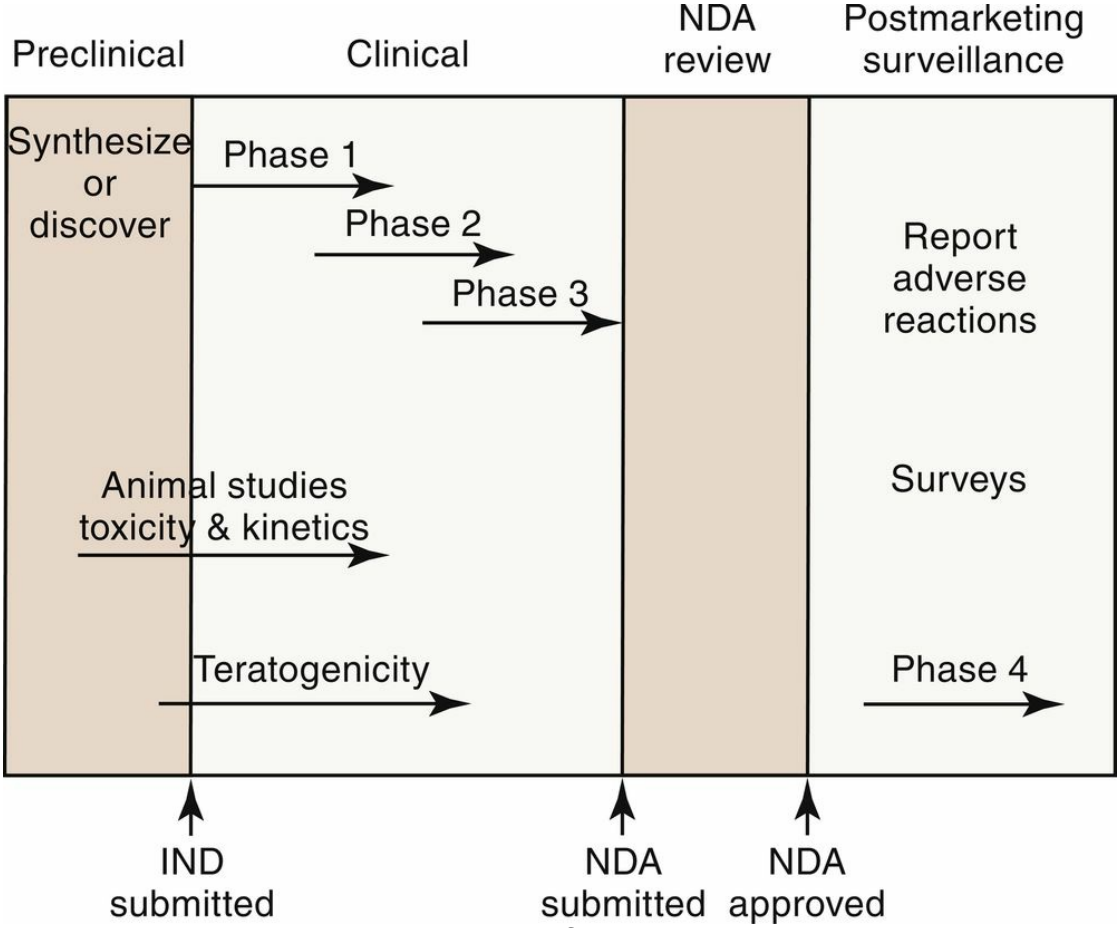


FIG. 1.2 Development of a new drug. *IND,* Investigational new drug; *NDA,* new drug application.

Clinical studies of drugs involve the following four phases:

Phase 1: Small and then increasing doses are administered to a limited number of healthy human volunteers, primarily to determine safety. This phase determines the biologic effects, metabolism, safe dose range in humans, and toxic effects of the drug.

Phase 2: Larger groups of humans are given the drug and any adverse reactions are reported to the FDA. The main purpose of phase 2 is to test effectiveness.

Phase 3: More clinical evaluation takes place involving a large number of patients who have the condition for which the

drug is indicated. During this phase, both safety and efficacy must be demonstrated. Dosage is also determined during this phase.

Phase 4: This phase involves postmarketing surveillance. The toxicity of the drug that occurs in patients taking the drug after it is released is recorded. Several drugs in recent years have been removed from the market only after phase 4 has shown serious toxicity.

Drug legislation

History

The Food and Drug Act of 1906 was the first federal law to regulate interstate commerce in drugs. The Harrison Narcotic Act of 1914 and its amendments provided federal control over narcotic drugs and required registration of all practitioners prescribing narcotics.

The Food and Drug Act was rewritten and became the Food, Drug, and Cosmetic Act of 1938. This law and its subsequent amendments prohibited interstate commerce of drugs that have not been shown to be safe and effective. The Durham-Humphrey Law of 1952 is a particularly important amendment to the Food, Drug, and Cosmetic Act because it required that certain types of drugs be sold by prescription only. This law required that these drugs be labeled as follows: "Caution: Federal law prohibits dispensing without prescription." The law also prohibits the refilling of a prescription unless directions to the contrary are indicated on the prescription. The Drug Amendments of 1962 (Kefauver-Harris Bill) made major changes in the Food, Drug, and Cosmetic Act. Under these amendments, manufacturers were required to demonstrate the effectiveness of drugs, to follow strict rules in testing, and to submit to the FDA any reports of adverse effects from drugs already on the market. Manufacturers were also required to list drug ingredients by generic name in labeling and advertising and to state adverse effects, **contraindications**, and efficacy of a drug.

The Drug Abuse Control Amendments of 1965 required accounting for drugs with a potential for abuse such as **barbiturates** and amphetamines.

The Controlled Substance Act of 1970 replaced the Harrison Narcotic Act and the Drug Abuse Control Amendments to the Food, Drug, and Cosmetic Act. The Controlled Substances Act is extremely important because it sets current requirements for writing prescriptions for drugs often prescribed in dental practice.

Scheduled Drugs

Federal law divides controlled substances into five schedules according to their abuse potential (Table 1.2). The rules for prescribing these agents, whether prescriptions can be telephoned to the pharmacist and whether refills are allowed, differ depending on the drug's schedule. New drug entities are evaluated and added to the appropriate schedule. Drugs on the market may be moved from one schedule to another if changes in abuse patterns are discovered.

Table 1.2

Schedules of Controlled Substances

Schedule	Abuse Potential	Examples	Handling
I	Highest	Heroin, LSD, marijuana, hallucinogens	No accepted medical use; experimental use, only in research
II	High	Oxycodone, morphine, amphetamine, secobarbital, hydrocodone (alone or in combination with ibuprofen or acetaminophen)	Written prescription with provider's signature only; no refills
III	Moderate	Codeine mixtures (Tylenol #3)	Prescriptions may be telephoned; no more than five prescriptions in 6 months
IV	Less	Diazepam (Valium), tramadol (ultram)	Prescriptions may be telephoned; no more than five prescriptions in 6 months
V	Least	Some codeine-containing cough syrups	Can be bought over-the-counter in some states

LSD, Lysergic acid diethylamide.

The current requirements for prescribing controlled drugs (Controlled Substance Act of 1970) are as follows:

- Any prescription for a controlled substance requires a DEA number.
- All Schedule II through IV drugs require a prescription.
- Any prescription for Schedule II drugs must be written in pen or indelible ink or typed. A designee of the dentist, such as the dental hygienist, may write the prescription, but the prescriber must personally sign the prescription in ink

and is responsible for what any designee has written.

- Schedule II prescriptions cannot be telephoned to the pharmacist (except at the discretion of the pharmacist for an emergency supply to be followed by a written prescription within 72 hours).
- Because Schedule II prescriptions cannot be refilled, the patient must obtain a new written prescription to obtain more medication.
- Certain states require the use of "triplicate" or "duplicate" prescription blanks for Schedule II drugs. These blanks, provided by the state, are requested by the dentist. After a prescription is written, the dentist keeps one copy and gives two copies to the patient. The patient presents these two copies to the pharmacist, who must file one copy and send the other to the State Board of Pharmacy. These consecutively numbered blank prescription pads provide additional control for Schedule II drugs.
- Prescriptions for Schedule III and IV drugs may be telephoned to the pharmacist and may be refilled no more than five times in 6 months, if so noted on the prescription.

Package Inserts

Package inserts (PIs) contain literature about the drug and is negotiated between the manufacturer and the FDA. The PI provides information regarding the chemical makeup of the drug, FDA-approved indications for use, contraindications, warnings, adverse reactions, drug interactions, dose and administration, and how it is supplied. PIs now contain a "Highlights of Prescribing Information" section that summarizes key information. This section is followed by the "Table of Contents" and the "Full Prescribing Information" main section. The labeling changes were made because the existing labeling was too complicated and too long, and so finding important information took an unacceptably long time. The PI for any new drug or being rewritten for a new indication for an existing drug must include the new formatting.

Black Box Warning

A black box warning is about a drug that the FDA has required a manufacturer to prominently display in a box in the PI. The intent of the black box is to draw attention to the specific warning and make sure that both the prescriber and patient understand the serious safety concerns associated with that drug. Generally the FDA uses black box warnings to bring attention to potentially fatal, life-threatening, or disabling adverse effects of different medications.

Some examples of black box warnings include:

January 13, 2011: Manufacturers of prescription drug products that contain acetaminophen are asked to limit the strength of acetaminophen to no more than 325 mg per tablet, capsule, or other dosing unit. In addition, the FDA has required that a black box warning label be included on all packaging for acetaminophen products highlighting the potential for severe liver damage and a warning highlighting the potential for allergic reactions (e.g., swelling of the face, mouth, and throat, difficulty breathing, itching, and rash).

November 14, 2007: Manufacturer of the prescription drug product rosiglitazone agreed to add new information to an existing black box warning regarding the potential increase in the risk of heart attacks for patients taking rosiglitazone.

March 2, 2006: Long-acting β_2-agonists containing salmeterol xinafoate (Serevent Diskus) and fluticasone propionate/salmeterol xinafoate (Advair Diskus) now carry the warning that their use may increase the risk of asthma-related deaths.

Labeled and Off-Label Uses

The FDA approves the use of drugs for specific indications, which are listed or labeled on the PI of the drug. Any information or use outside the labeled indications is considered *off-label*. Prescribers are allowed to use a drug for an off-label use if good medical practice justifies such use, the use is well-documented in the medical literature, and the drug meets the current standard of medical care. However, drug manufacturers are not allowed to bring up off-label

uses when speaking with the prescribing practitioner or patient, nor can they distribute written material regarding off-label uses.

Orphan Drugs

Orphan drugs are developed to specifically treat rare medical conditions. Rare medical conditions with *orphan* status are diseases that occur in less than 200,000 people in the United States. The assignment of orphan status to a disease and to any drug developed to treat that disease has resulted in medical breakthroughs that may never have occurred because of the cost associated with the research and development of new drugs.

Drug Recall

Medications can be recalled from use by the manufacturer itself, at the request of the FDA, or by FDA order under statutory authority. Medications are recalled if there is reasonable probability that their use will have serious adverse health consequences or death. Patients taking a drug that is recalled should call their health care providers about the best course of action.

Prescription writing

Dental hygienists need to become familiar with the basics of prescription writing for the following reasons:

- Correctly written prescriptions save time for the office personnel, the dentist, and the pharmacist who must call to clarify an incorrectly written prescription.
- Prescriptions written carefully are less likely to result in mistakes.
- A record of the prescription should be included in the patient's record.
- Prescriptions should be written out and Latin abbreviations should be avoided to minimize the risk for errors.

Some drug abusers ("shoppers") search for dental offices that

might provide them with prescriptions for controlled substances or prescription blanks that they can use to forge their own prescriptions. Every dental office should keep prescription blanks in a secure place. The prescriber's DEA number should not be printed on the prescription blanks but should be written in only when needed. The dental hygienist should watch to see that prescription blanks are not scattered around the office. If the dentist practices in a state that requires "triplicate" or "duplicate" prescription blanks for Schedule II prescriptions, pads for those prescriptions must be stored under lock and key to prevent them from being stolen.

Measurement

Metric System

The metric system is the primary measuring system for compounding and dispensing medication.

In pharmacy, the primary measuring system is the metric system. Solid drugs are dispensed by weight (milligrams [mg]) and liquid drugs by volume (milliliters [mL]). It is rarely necessary to use units other than the milligram or the milliliter in prescription writing; occasionally grams (gm) or micrograms (μg) are used. In addition to the milliliter, the liter (L) is also used to measure volume.

Household Measures

Although clinicians will direct the pharmacist to dispense a liquid preparation in milliliters, the pharmacist generally converts metric measurements into a convenient household unit of measurement to be included in the directions to the patient. Liquids are converted into teaspoonfuls (tsp or t; 1 tsp equals 5 mL) and tablespoonfuls (tbsp or T; 1 tbsp equals 15 mL). The pharmacist supplies a calibrated oral syringe or dropper for infants and younger children. Most liquid dose forms come with calibrated dosing cups for both adults and children. Household utensils should not be used. The dosing cups are available in 2.5-, 5-, and 10-mL volumes with

milliliters marked along their lengths.

Prescriptions

Format

The parts of the prescription are divided into three sections. They are the heading, body, and closing (Fig. 1.3).

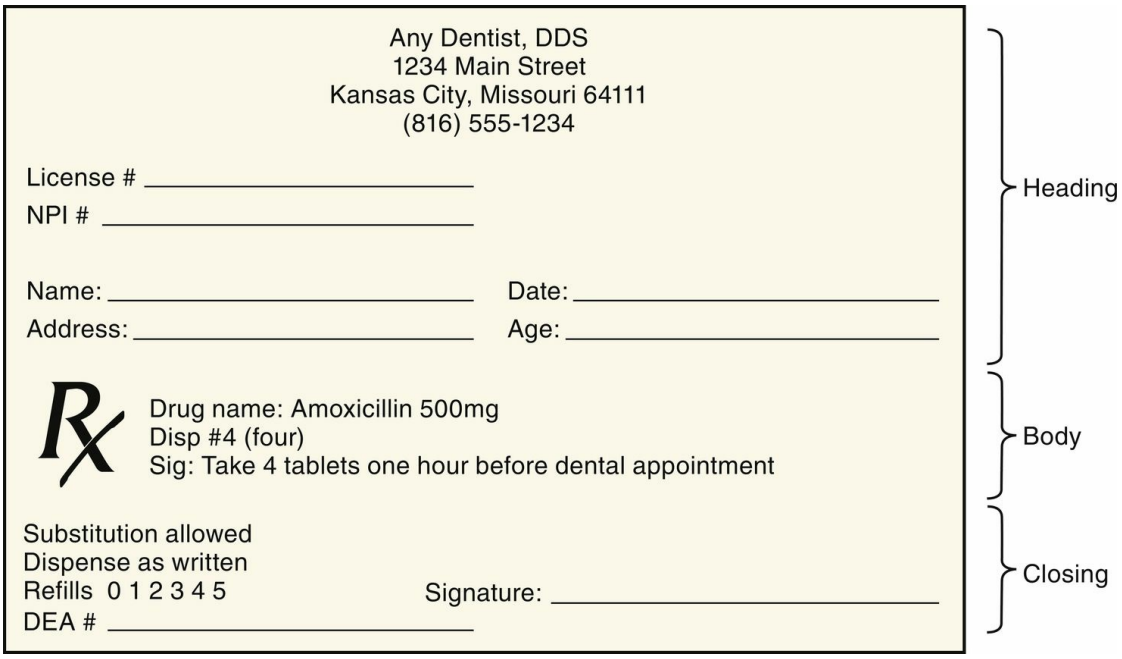


FIG. 1.3 A typical prescription form.

Heading

The heading of the prescription contains the following information:

- Name, address, and telephone number of the prescriber (printed on the prescription blank)
- Name, address, age, and telephone number of the patient (written)
- Date of prescription (not a legal prescription unless filled in with date); often missing

The name, address, and telephone number of the prescriber are important when the pharmacist must contact the prescribing

clinician for verification or questions. The date is particularly important because it allows the pharmacist to intercept prescriptions that may not have been filled at the time of writing. For example, a prescription for an antibiotic written 3 months before being presented to the pharmacist might be used for a different reason from that the dentist originally intended. Likewise, a prescription for a pain medication that is even a few days old requires the pharmacist to question the patient as to why the prescription is being filled so long after it was written. The age of the patient enables the pharmacist to check for the proper dose.

Body

The body of the prescription contains the following information:

- The Rx symbol
- Name and dose size or concentration (liquids) of the drug
- Amount to be dispensed
- Directions to the patient

The first entry after the Rx symbol is the name of the drug being prescribed. This is followed by the size (milligrams) of the tablet or capsule desired. In the case of liquids, the name of the drug is followed by its concentration (milligrams per milliliter [mg/mL]). The second entry is the quantity to be dispensed—that is, the number of capsules or tablets or milliliters of liquid. In the case of tablets and capsules, the word "Dispense" is often replaced with #, the symbol for a number. When writing prescriptions for opioids or other controlled substances, the prescriber should add in parentheses the number of tablets or capsules written out in longhand. This practice reduces the possibility that an intended 8 could become an 18 or 80 at the discretion of an enterprising patient. Directions to the patient are preceded by the abbreviation "Sig:" (Latin for *signa*, "write"). The directions to the patient must be completely clear and explicit and should include the amount of medication and the time, frequency, and route of administration. The pharmacist will transcribe any Latin abbreviations (Table 1.3) into English on the label when the prescription is filled.

Table 1.3

Abbreviations Commonly Used in Prescriptions

Abbreviation	Definition
a or $\bar{a}$	before
ac	before meals
bid	twice a day
$\bar{c}$	with
cap	capsule
d	day
disp	dispense
gm	gram
gr	grain
gtt	drop
h	hour
hs	at bedtime
$\bar{p}$	after
pc	after meals
PO	by mouth
prn	as required, if needed
q	every
qid	four times a day
$\bar{s}$	without
sig	write (label)
$\overline{ss}$	one half
stat	immediately (now)
tab	tablet
tid	three times a day
ud	as directed

Closing

The closing of the prescription contains the following:

- Prescriber's signature
- DEA number, if required
- Refill instructions

After the body of the prescription, space is provided for the prescriber's signature. Certain states have more than one place to sign. Certain institutions also provide a space on which to print the

prescriber's name. This is not necessary for dentists with their own prescription blanks. If there are several dentists in one office, the names of all the dentists in the practice should be included on the prescription blanks. Then the individual dentist should check a box or circle his or her name so the pharmacist will know who signed the prescription.

Prescription Label Regulations

In addition, the law requires that all prescriptions be labeled with the name of the medication and its strength. Fig. 1.4 is a sample prescription label. This labeling allows easy identification by other practitioners or quick identification in emergency situations. One should note that the name, address, and telephone number of the pharmacy; the patient's and dentist's names; the directions for use; the name and strength of the medication; and the original date and the date filled (refilled) are required. The quantity of medication dispensed (number of tablets) and the number of refills remaining are noted as well. If a generic drug is prescribed, then the generic name of the drug and the manufacturer's are also required to be shown on the label. If the trade drug is used, only the trade name must be shown.

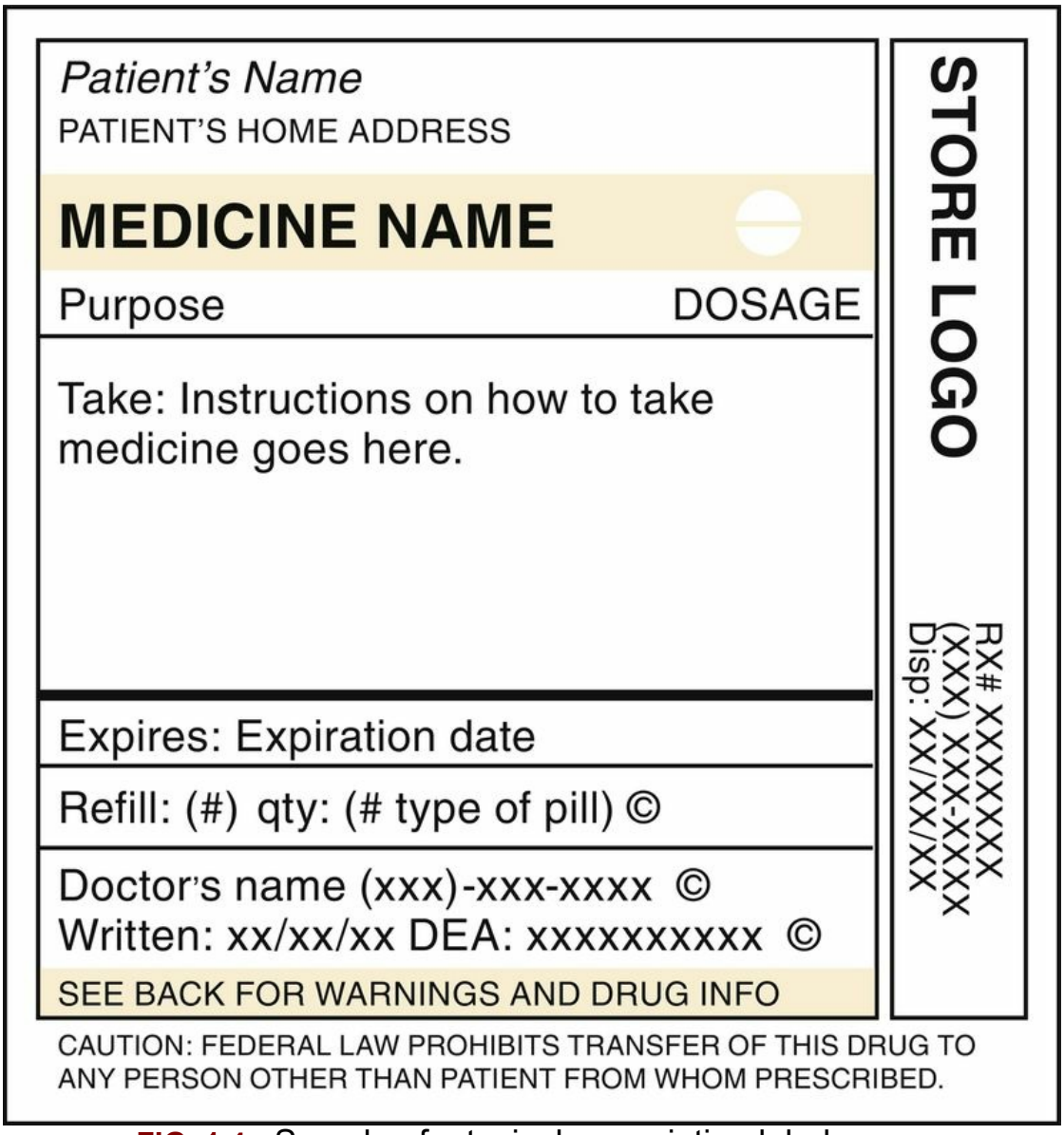


FIG. 1.4 Sample of a typical prescription label.

In most states, before a dentist can legally write a prescription for a patient, the following two criteria must be met:

Patient of record: The person for whom the prescription is being written is a patient of record (no next-door neighbors or relatives, unless they are also patients of record).

Dental condition: The condition for which the prescription is being prescribed is a dental or related condition (no birth control pills or thyroid replacement drugs).

Abbreviations

A few Latin abbreviations are used in prescription writing to save time. The abbreviations also make alteration of a prescription by the patient more difficult. In some cases they are necessary to get all the required information into the space on the prescription form. Some abbreviations that may be useful are shown in Table 1.3. If abbreviations are used on a prescription, they should be clearly written. For example, the three abbreviations qd (every day), qod (every other day), and qid (four times a day) can look quite similar, and choosing the wrong one could be disastrous.

Electronic and Fax Prescribing

Electronic prescribing (e-prescribing) is the electronic transmission of a prescription to a pharmacy, which reduces the incidence of errors in reading handwritten prescriptions and the patient's ability to tamper with a prescription. Electronic prescriptions are uploaded to a transaction hub, which provides the common link between the prescriber and the pharmacy, thereby reducing the risks associated with traditional prescription writing. Once in the hub, the information is sent to the pharmacy benefits manager, who assesses patient eligibility. Once this step has been completed, the prescription is sent to the pharmacy, which in turn notifies the prescriber of receipt of the prescription (Fig. 1.5). A written record of the prescription is kept in the patient's record. Prescriptions can also be faxed to a pharmacy. The inclusion of e-prescribing in the Medicare Modernization Act of 2003 (MMA) gave momentum to its use in provider practices across the country. The MMA expanded Medicare to include a drug benefit program (Medicare Part D), which began in 2006.

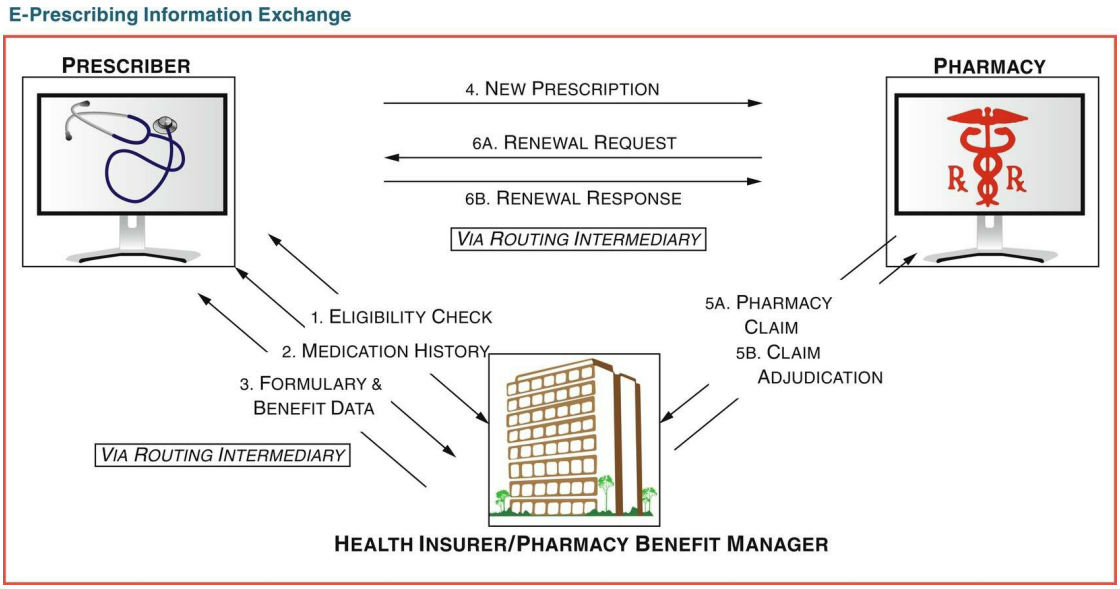


FIG. 1.5 Electronic Prescription Processing. (Source: *RAND, A Toolset for E-Prescribing Implementation, Santa Monica, Calif. (forthcoming).*)

Role of the Dental Hygienist and Patient Adherence to Medication Therapy

Patient adherence to medication therapy is vital to the success of therapy. Adherence to therapy implies that the patient takes the medication as prescribed. Many different factors can contribute to nonadherence to therapy; they include poor understanding of the disease and a need for medication, fear of medication side effects, distrust of health care professionals, economic factors, and forgetfulness. Also, the longer the duration of therapy and the higher the number of times a day the patient must take a prescription, the higher the risk for nonadherence to medication therapy.

The dental hygienist should be able to answer the patient's questions about the prescription and should make sure that the patient knows how to take the medication prescribed (how long and when), what precautions to observe (drug interactions, possible side effects, driving limitations), and the reason for taking the medication. Information about the consequences of nonadherence should be included. A patient who is informed about the prescribed medication is more likely to adhere to therapy. A patient should

never get home and not know which drug is the antibiotic (for infection) and which is the analgesic (for pain). Side effects, such as drowsiness and stomach upset, should be noted on the label.

Dental hygiene considerations

1. The dental hygienist should understand the importance of obtaining a patient health/medication history.
2. The dental hygienist should have an in-depth understanding of pharmacology because many dental hygienists are now licensed to administer local anesthetics and nitrous oxide.
3. The dental hygienist should be able to explain to the patient how to take a prescription or nonprescription medicine.
4. The dental hygienist should discuss the name of the drug prescribed, what it is used to treat or prevent, the dose, the amount prescribed, and how often it should be taken.
5. The dental hygienist should also tell the patient what to do if the patient feels that he or she is experiencing a side effect or allergic reaction.
6. The dental hygienist should have the patient repeat back what he or she has been told. This step should help determine whether there are any knowledge gaps.
7. The dental hygienist should answer any questions that the patient may have.

Academic skills assessment

1. Define the term *pharmacology.*
2. Explain why the oral health care provider should have a knowledge of pharmacology.
3. Explain the importance of conducting health/medication histories.
4. Why should a dental practice keep more than one type of reference book?
5. Discuss the most important features of a good reference book.

6. Define and give an example of the following terms:
    a. Chemical name
    b. Trade name
    c. Brand name
    d. Generic name
7. Explain why a list of the most current drugs should be available in every dental office.
8. Name three federal regulatory agencies and state the major responsibility of each.
9. Explain the various stages of testing through which a drug must pass before it is marketed for the general public.
10. List the information required in a prescription.
11. Explain two precautions that should be taken in the dental office to discourage drug abusers.
12. List the components of the Controlled Substance Act.

Clinical applications

Toula Pappas is new to your practice. She is 40 years old and has three children. Because this is her first appointment, you must conduct the medication/health history.

1. What types of questions would you ask during a medication/health history?
2. What is the importance of the medication/health history?
    During the history you learn that Mrs. Pappas is a healthy individual whose only prescribed medication is esomeprazole 40 mg once daily. Upon further questioning, you learn that Mrs. Pappas self-treats with an occasional acetaminophen or ibuprofen.
3. Where can you look up information regarding esomeprazole.
4. What is a good reference source for over-the-counter (OTC) medications?
5. Why might Mrs. Pappas take the OTC drugs?
    Mrs. Pappas returns for another visit and is prescribed an antibiotic for an abscess. The

prescription reads as follows: Amoxicillin 250 mg
Sig: 1 tid for 10 days.

6. Please explain this prescription to Mrs. Pappas.