PHARMACY EDUCATION SERIES

PHARMACY

What It Is and How It Works

Fourth Edition

WILLIAM N. KELLY

ROUTLEDGE

PHARMACY

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Foreword

At the time of the publication of this textbook, we find ourselves in the most dynamic, and simultaneously turbulent, moments in the evolution of healthcare, possibly since the early sixteenth and seventeenth centuries. It was during that time period that scientific methods and discovery gained firm traction, leading to advances in surgical interventions, improvements in human anatomical exploration, and enhanced understanding of medicinal agents for the curing of disease.

During that time period there existed the presence of intense skepticism of the "new" discoveries. Scientific discovery was viewed with doubt and cynicism; those individuals seeking new discoveries were subject to multiple levels of derision, or worse, bodily harm. Ultimately, their discoveries would be accepted, and establish a new platform for the translation and implementation of healthcare for many centuries to come. In this early part of the twenty-first century, we find ourselves at a new point of healthcare evolution. Exponential technological advancements will fundamentally, and permanently, change our approaches to the delivery of healthcare.

As healthcare systems have evolved, so has their complexity. Government-sponsored insurance versus private-pay insurance; single-payer systems and competitive healthcare markets; accountability for health outcomes; scrutinized reimbursement schedules for health providers; and equitable access to healthcare by persons from all communities. This complexity is not confined to the United States of America; many of these points touch on almost all communities across the world. Healthcare providers around the world face these facts, and still willingly dedicate their lives to assisting and treating people suffering from countless ailments. And therein lies the necessity of this textbook; the entire healthcare evolution that has occurred over many centuries has always focused on improving the human condition, to seek to improve and maintain the quality of life for people in communities through multiple medical means.

The profession of pharmacy is undergoing the same intense evolution that all of medical practice has endured. Pharmacy as a profession is complex, diverse, and very necessary. Differential diagnosis of patients is not enough to treat them adequately. I have often taught my students that once a diagnosis is made, the only interventions are (1) physical manipulation (surgery, therapy, etc.); (2) medication administration; (3) lifestyle modification; or (4) nothing. Of course, to do nothing is in direct violation of our professional oaths as clinicians. The profession of pharmacy, with all of its intricacies, has always been one of the most critical components of healthcare. This shall remain the case for many decades to come.

Medication management (including administration, distribution, therapeutic monitoring, safety monitoring, policy development, education, and innovation) is among the most important medical interventions to treat patients effectively and make earnest attempts to improve their condition. While physician practice is segmented into multiple specialties, pharmacy practice is multifaceted as well. In fact, there is almost no medical specialty that does not require a pharmacist to be knowledgeable about all aspects of that specialty. Dr. William Kelly has compiled the most comprehensive textbook outlining numerous facets of the pharmacy profession, all while establishing and maintaining concentration on the patient as the focal point of our professional efforts.

Healthcare has evolved from the sixteenth and seventeenth centuries to now include genomics, pharmacogenomics, analytics, informatics, big data, and artificial intelligence as

key emerging components for the delivery of care. I once saw on social media "Data and analytics may one day become more important than the clinician!" Despite these technological advances, the human body remains terrifically consistent with regard to drug receptors, organ systems, human emotions, and the basic necessities of food and shelter. This textbook by Dr. Kelly, with assistance from colleagues, makes the case for the profession of pharmacy to be its own sub-specialty, and describes how pharmacists interact with all of the aforementioned aspects of healthcare. The pharmacy profession must now morph and adjust to the ambiguity of healthcare, without vacating the core DNA of the pharmacy profession. Every reader will extract key components to augment their professional progression and understanding, which will lead to a higher quality of care provided to people in all communities.

I am sure the pharmacy community, along with medical and business communities, will embrace the efforts of Dr. William Kelly to carefully and thoroughly describe the pharmacy profession in fantastic detail. I congratulate him for his vision to move all of healthcare forward with this textbook.

Kevin Sneed
Dean of the University of South Florida College of Pharmacy

Preface

I was 8 years old when I fell in love with pharmacy. In the early 1950s, pharmacy was much different from today. The corner drugstore was the only place you could go to have your prescription dispensed. My corner drugstore was Barber's Drugstore. The large glass window in front of the store framed several "show globes"—large, clear glass containers dispensed with colored water—a symbol of pharmacy at the time. Some of the show globes sat in ornate stands or were hung from the ceiling. The window also had interesting displays of medical items and the latest merchandise to purchase. It was the job of the pharmacy intern to change the displays every several weeks.

The corner drugstore was more than a store and a pharmacy. It was a neighborhood asset. Barber's Drugstore had a soda fountain where you could purchase a Coke: 5¢ for a small one and 10¢ for a large one. It was a place where you would see and chat with your neighbors and friends, and for us kids, where we could "hang out."

There was no self-service at the drugstore. Products were stored behind the counters in glass cases. You had to ask for what you wanted. After purchasing an item, you waited as white paper was pulled off a roller, cut to size, and your package was neatly wrapped and tied with string.

I was intrigued with the pharmacist, Mr. Barber. He wore a crisp, clean, white druggist's jacket; was well respected in the community; and was everyone's friend. He always took time to say hello to everyone who came in the store. I asked Mr. Barber so many questions about pharmacy that he finally invited me behind the counter to watch him work with the medicine. I loved what I saw—all of the chemicals, bottles, and equipment. Mr. Barber compounded most of the medications, measuring and mixing the ingredients, pouring the medicine into tiny colored capsules, and then putting the capsules into small cardboard boxes that measured just 2 or 3 inches wide. He carefully placed a label on top of each box.

When Mr. Barber asked me to be the delivery boy and to do odd jobs around the pharmacy, I was delighted. I swept the sidewalk, washed the front window, took out the trash, and delivered medicine on my bike each day after school. When I could, I watched Mr. Barber prepare and dispense medication. I could not read the prescriptions because they were in Latin.

When I reflect on those days and think about what pharmacy is like today, I see tremendous change and progress. Fifty years ago, pharmacists earned a 4-year bachelor-of-science degree. Today, they earn a 6-year doctor of pharmacy degree. There were no residency programs, just internships—additional on-the-job apprenticeships.

Back then, pharmacists dispensed prescriptions as they were written unless the prescription was for an obvious overdose. Pharmacists were not to question the doctor about the patient or the intended use of the prescription. This interfered with the "doctor–patient" relationship. Today, pharmacists are taking responsibility for the patient and for the outcome patients receive from their medication. Some pharmacists are allowed to prescribe medication, monitor a patient's therapy, and recommend initial therapy for patients. Some doctors request pharmacists to perform complex mathematical calculations to dose critically sick patients with powerful drugs.

Patients' and doctors' respect for pharmacists has never been higher. Pharmacists in some community pharmacies work with patients, the patient's doctor, and the patient's insurance company to manage the patient's disease states. Some community pharmacists are providing immunizations for patients.

There are times I have been impatient with the profession not moving forward quickly enough. That changed when I reread the 2009 Whitney Award (the highest award in organized pharmacy practice) address by Paul Abramowitz, PharmD. Paul graduated shortly after me from the University of Michigan, so he has watched most of the same changes I have witnessed in pharmacy.

In explaining the metamorphosis of the profession, Dr. Abramowitz covered the period from 1978 to 2009. I was surprised at his documentation of so many changes, many of which I had forgotten. This long list of accomplishments changed my perception that the profession moves too slowly. When I stood back and looked, I could see how many changes have been made during my time as a pharmacist.

Doug Hepler, the chief architect of pharmaceutical care, in his 2010 Whitney Award address, "A Dream Deferred," discussed the issue of why, after 30 years, pharmaceutical care has not been universally implemented. Although the reasons for this are diverse, the dream is not dead, just deferred. At the end of his address, Dr. Hepler challenged new members to accept the legacy built by the many hard-working pharmacists before them and to keep pursing the dreams of the profession.

Since 2010, the profession has been plodding along, trying to determine how it can better explain its societal value, how it fits into the new era of healthcare reimbursement (accountable care), and if it can become a "paid provider" (paid for clinical services—those provided beyond dispensing).

Since the last edition of this book (2012), the major changes have been in: informatics, with some clinical pharmacists gaining more practice flexibility using collaborative practice agreements with physicians; medication therapy management (MTM); antimicrobial stewardship; pharmacogenomics; transitions in care; and 340B payment compliance.

This book is written to teach you about pharmacy but to encourage you to seize the vision, and to assert your professional autonomy on behalf of patients and for achieving the dream. After 50 years of practicing pharmacy, I can say confidently that your job as a pharmacist is to always (1) be patient-centered, (2) practice at the top of your license, (3) keep up-to-date on your drug knowledge, (4) practice autonomously (guard it against outside intrusion by non-pharmacists), and (5) improve the profession.

If you are reading this book because you are a student, please know you are about to become a member of one of the greatest professions, and that we are right on the cusp of achieving the goal of becoming a true clinical profession. If you are a student pharmacist reading this, I want you to know that I believe the highest and most dramatic improvements in the profession are going to occur during your lifetime. Writing the book has been a wonderful experience. This is the fourth edition, and I am still awed and proud of the rich history and accomplishments of pharmacy. Many pharmacists have worked hard to make pharmacy what it is today. After writing the book, I am more fascinated with pharmacy than ever before.

I hope you enjoy the book.

Acknowledgments

I could not have completed this edition of *Pharmacy: What It Is and How It Works* without the help of my wife Trudy, who is a superb reference librarian. She has worked on all four editions, doing the research, sending out the copyright permissions, and proofreading. This book is starting to feel like a third child of ours.

For this edition, several people helped with revision of some of the chapters. Thanks go to Laurie Wesolowicz for revising the chapter on managed care pharmacy; to Dennis Tribble for revising the chapter on pharmacy informatics; to Sarah Steinhardt for producing a medication profile image for the chapter on the drug use process; and to Blake Shay and Les Louden for helping revise the chapter on supportive personnel.

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About the Author

William N. Kelly has 50 years of experience in healthcare as a pharmacy executive, researcher, professor, and clinician. He has published over 100 peer-reviewed manuscripts and 12 book chapters, and has presented his work both nationally and internationally. He is also a full professor, and special assistant to the Dean for innovative practice at the College of Pharmacy of the University of South Florida in Tampa, Florida. Dr. Kelly is also president of William N. Kelly Consulting & Publishing, Inc., a company devoted to advancing medication safety and the practice of pharmacy, senior vice president of scientific affairs for Visante, and vice president of Vivace Health Solutions.

Dr. Kelly is the author of *The Good Pharmacist: Characteristics, Virtues, and Habits*, published in 2011; *Prescribed Medication and the Public Health: Laying the Foundation for Risk Reduction*, published in 2006; and, co-author of *Leadership and Management in Pharmacy Practice* (2nd ed.), published in 2015.

He lives with his wife, Trudy, in Clearwater, Florida, and enjoys reading, swimming, golf, spending time with his children and grandchildren, stamp collecting, and serving as a medical missionary in Central America.

1 What Is Pharmacy?

INTRODUCTION

When asked about pharmacy, most people will say that a pharmacy is a drugstore or a place where you purchase medication. Some may talk about pharmacists (sometimes incorrectly referred to as druggists) and drugs. Most people do not think about pharmacy as a profession.

This chapter is a brief introduction to pharmacy. It considers four basic questions:

1. What is pharmacy?
2. What is the purpose of pharmacy?
3. What is the value of pharmacy?
4. What is its future?

To address these questions, this chapter begins with information on the nature of pharmacy as a profession. It then examines a brief history of pharmacy, what shapes it, and how it is still evolving as a profession. It ends with a discussion on the value of pharmacy and its future.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Provide at least five reasons why pharmacy is a profession.
- State the purpose of pharmacy.
- Provide three factors that control pharmacy.
- State at least three ways the pharmacy profession is shaped.
- Discuss how pharmacy is changing.
- Make a convincing argument that the pharmacy profession provides value to society.
- Define the term "provider status," and discuss (briefly) pharmacy's current efforts to achieve that status.
- Discuss briefly what the author believes the future is for pharmacy, along with your ideas.

PHARMACY

Pharmacy is a place, a profession, and sometimes a business. A pharmacy is a place where licensed pharmacists oversee the dispensing of medicine after receiving a valid *prescription* or *drug order* written or electronically transmitted (*e-prescribing*) by a legal prescriber. A pharmacy is not a drugstore. Some businesses today do not have pharmacies but do sell medicines bought without a prescription (over the counter [OTC] drugs) along with other nonmedical items such as cosmetics, hardware, and magazines. A pharmacy can be a free-standing building, or it may be found inside other places, such as a drugstore, a medical building, or a hospital.

The word *medicine* in defining pharmacy (as a place) is preferable to the word *drug*, as is the word *pharmacist* over the word *druggist.* In today's society, *drug* usually suggests an unlawful drug or drug abuse. The word *medicine* is more positive; its consumption usually improves health. The word *druggist* is derived from the negative word *drug*; thus, *druggist* is a less-acceptable term for pharmacist.

Pharmacists are registered by a board of pharmacy and therefore are designated *registered pharmacists* (RPh). However, this title is only conferred after passing rigorous national, state practice, and law examinations. The preferred term is *licensed pharmacist*.

The last part of defining pharmacy (as a place) includes the words *legal prescriber*. This is someone approved by the state legislature to prescribe drugs—a licensed physician, dentist, or veterinarian and sometimes a physician's assistant or nurse practitioner, depending on the state. *Note*: Pharmacists must always be vigilant for bogus prescriptions written by drug abusers who are trying to obtain narcotics and other controlled substances illegally.

Pharmacy also means the practice of pharmacy as a profession. To discuss this further, we need to explore what it means to be a profession and a member of a profession (a professional).

WHAT IS A PROFESSION?

A *profession* is a disciplined group of individuals who adhere to ethical standards and uphold themselves to and are accepted by the public. The individuals in the group possess special knowledge and skills in a widely recognized body of learning derived from research, education, and training at a high level. They are prepared to exercise this knowledge and these skills in the interest of others.[1]

There are three widely and commonly recognized characteristics of a profession: study and training, measure of success, and associations.[2]

Study and Training

Instruction and specialized training provided by a professional college over an extended period of time provide professional students with the knowledge and specific skills to practice their profession. In addition, professional students learn the history, attitudes, and ethics of the profession. They also must accept the duties and responsibilities of being a professional. Before being allowed to practice in the profession, a pharmacy graduate must submit to comprehensive national and state examinations. This is to assure the public that the applicant meets the minimum requirements to practice the profession.

Pharmacists must have 2–4 years of college education before being accepted into a 4-year Doctor of Pharmacy (PharmD) program at a college or university, for a total of 6–8 years. There is a trend by many pharmacy schools to require (such as medical schools) a four-year degree prior to being accepted into a pharmacy school.

They must then have 1000–2000 hours of internship training before eligibility to take licensure examinations on drugs, professional practice, and the law.

Measure of Success

Success in the profession is based on service to the needs of people, for which the professional usually receives a fee. However, the primary reward for a true professional is in providing service to the client. Note that in healthcare, the client is the patient. The focus of a pharmacist's

practice should be on the patient and the patient's needs. Counseling patients about their medication and disease without financial compensation has been a part of pharmacy practice since its beginning.

Associations

As a profession, each member works closely with other members and members of other professions. One of the mechanisms for close association is international, national, state, and local societies composed of members of the profession. Members network with one another, work on developing or improving standards of the profession, and attend educational sessions to improve their skills or learn new methods.

Pharmacists have many professional organizations at the local, state, national, and international level (see Chapter 16, "Pharmacy Organizations"). Generously sharing information with each other without hesitation is one of the strengths of the pharmacy profession.

The Business of Pharmacy

Pharmacy can also be a business. Pharmacists who own their own pharmacy or are managers of a pharmacy are business men and women as well as *practitioners*—patient care providers. Thus, they have two goals: (1) to care for patients and (2) to make enough profit to stay in business.

It is equally important for pharmacists, pharmacy interns, and other pharmacy workers in a pharmacy business to understand the goals of the business and to do all they can to help make the business successful. The more they do this, the more successful the business will be, and in turn, the more successful they will become.

A BRIEF HISTORY OF PHARMACY

Early Development

No one can be sure when pharmacy started.[3] However, early humans most likely discovered that applying water, mud, and some plants soothed the skin. By simple trial and error, humans slowly discovered things in nature that helped them.

The earliest known record of the art of the *apothecary*—the forerunner of the pharmacist—is in Babylon (today's Iraq), the jewel of ancient Mesopotamia (now Iran and previously Persia). Practitioners at this time (ca. 2600 BC) were priests, pharmacists, and physicians, all in one. The Chinese also contributed to early pharmacy (ca. 2000 BC).

From this point forward in history, the art of crude medicine preparation and pharmacy was increasingly refined by the Egyptians, the Greeks, and the Romans. One Roman in particular, Galen (130–200 AD), is of special note. He practiced and taught pharmacy and medicine in Rome and is revered by both professions today. His principles of preparing and *compounding* (mixing ingredients) ruled in the Western world for 1500 years.

Separation of pharmacy and medicine took place in about 300 AD and is portrayed by twin brothers of Arabian descent, Damian, the apothecary, and Cosmas, the physician. These twin brothers are considered the "patron saints" of pharmacy and medicine, respectively. The word *apothecary* (meaning "pharmacist") is of European origin and is the antecedent of the word *druggist*. There are still apothecaries in the United States today, and they restrict their community practices to prescriptions and specialty medical products.

Plants with medicinal value were cultivated in monasteries by monks between the fifth and twelfth centuries. The Arabs were the first to have privately owned drugstores called apothecary shops. These shops were open street stalls that sold wines, sweets, syrups, perfumes, and medicines.[4] Public pharmacies like these did not appear in Europe until the seventeenth century.

The first official compendium of drugs, or *pharmacopoeia*, originated in Florence, Italy. It was compiled in 1498 by the Guild of Apothecaries and the medical society. The Society of Apothecaries of London was the first organization of pharmacists in the Anglo-Saxon world. It was formed by pharmacists who broke away from the Guild of Grocers, which had jurisdiction over them. Early English apothecaries compounded and dispensed drugs and provided medical advice.[4]

Community Pharmacy in Early America

Apothecary shops in the United States first appeared in Boston, New York, and Philadelphia.[5] Apothecaries prescribed as well as dispensed drugs, as did some physicians. Few of these apothecaries were formally trained as pharmacists.

No one knows for sure who the first apothecary was in America. However, an Irish immigrant, Christopher Marshall, developed a pioneer pharmaceutical enterprise. The Marshall Apothecary in Philadelphia (Figure 1.1) was a leading retail pharmacy, a large-scale chemical manufacturer, a place for training pharmacists, and an important supply depot during

FIGURE 1.1 The Marshall Apothecary Shop in Philadelphia, 1729. (From Bender GA and Thom RA, *Great Moments in Pharmacy; The Stories and Paintings in the Series, A History of Pharmacy in Pictures, by Parke Davis & Company*, Detroit, MI: Northwood Institute Press, 1965. Courtesy of Pfizer Inc. and Northwood Institute Press.)

the American Revolution. Eventually, the apothecary shop was managed by Christopher Marshall's granddaughter, Elizabeth. She is considered to be America's first female pharmacist.

Most of the early American apothecaries sold various items, including crude drugs, chemicals, imported nostrums (secret cures), spices, teas, and coffees. Various European settlements (Dutch, German, Spanish, French, and English) and the American Indians made important contributions to the unique and developing *materia medica* in the American colonies.[6]

By 1721, there were 14 apothecary shops in Boston, and by 1840 some apothecaries were starting to become wholesalers, importing and buying large quantities of medicinal agents to be sold to other apothecaries. The terms *druggist* and *drugstore* may have had their beginnings here.[4]

Patents were first granted in 1790 by the newly founded United States of America. Such patents were granted for so-called secret cures. Patents granted protection of the knowledge of the ingredients for 17 years. The trade in English and American patent medicines became the backbone of American drugstores.[7,8]

Apothecaries made their own private-label *patent medicines*, and companies were formed to produce various curious mixtures.[9] Patent medicines flourished, and their popularity moved west with the settlers in the United States. Pioneers often used patent medicines before they went to a doctor for help.

America's first association of pharmacists, the Philadelphia College of Pharmacy, was founded in 1821 at Carpenter's Hall, the same place that birthed the country's Declaration of Independence. The reasons for forming this association were to improve the practice of pharmacy and the discriminatory classification by the University of Pennsylvania medical faculty in granting an unearned master of pharmacy degree to a number of "deserving apothecaries" in Philadelphia. William Proctor Jr., who served the college for 20 years, is considered by some to be the father of American pharmacy.

The American Pharmaceutical Association (APhA), now the American Pharmacists Association, began in 1852. It was started to improve communication among pharmacists, to develop standards for education and apprenticeship, and to improve the quality control of imported drugs.

The extraordinary financial demands of the Civil War resulted in patent medicines becoming taxed in 1862.[10] Revenue stamps had to be affixed on the patent medicines in such a way that the stamp was torn when the container was opened (see Figure 1.2). Although this helped make patent medicines the domain of large companies, drugstores flourished, and apothecaries (now called druggists) became managers as well as practitioners.

From early 1900 through the early 1940s, druggists continued to compound and prepare medicines for patients. However, drug manufacturers were starting to discover the active ingredients of various products derived from nature. Gradually, medicines were made with active ingredients and made available for druggists to dispense directly to patients.[11]

The abundance of drugstores made competing difficult. Shortly after World War II (1945), a young entrepreneur from Erie, Pennsylvania, named Jack Eckerd, made his mark by cutting prices and introducing self-service in the pharmacy.[12] Up until the late 1950s, all goods in drugstores were behind the counter in glass cases. Customers had to ask for the items they wished to buy. Eckerd also made sure each employee had a stake in the business. These principles paid off, and Eckerd expanded his business to a chain of drugstores in New York and Delaware. Other chain drugstores following Eckerd's business principles soon sprang up in other parts of the country.

FIGURE 1.2 Examples of tax stamps used on patent medicines in the late 1800s and early 1900s in the United States.

Hospital Pharmacy in Early America

The first hospital pharmacy (Figure 1.3) was established at the Pennsylvania Hospital, founded in 1752 by Benjamin Franklin, in Philadelphia.[13] The first hospital pharmacist was Jonathan Roberts. However, it was his successor, John Morgan, who made the biggest impact. Morgan, as a pharmacist and later as a physician, championed prescription writing and the separation of the two professions. By 1812, the New York Hospital also had a full-time pharmacy practitioner.[13]

Hospital pharmacy practice developed slowly. By 1921, it was estimated that only 500 of the 6000 hospitals in the United States had pharmacists on staff.[14] Most immigrants to the United States were Roman Catholic, and they built Catholic hospitals. The number of pharmacists was increased by the willingness of the Catholic Church to provide training in pharmacy for nuns.[13]

Between 1920 and 1940, an awakening came about because of hospital pharmacists' growing awareness of the problems and the potential of their specialty.[15] The first hospital pharmacy internship program was started by Harvey Whitney in 1927 at the University of Michigan Hospital in Ann Arbor, Michigan.

A section for hospital pharmacists within the APhA was established in 1936. The American Society of Hospital Pharmacists (ASHP) was formed in 1942 and ended joint membership with the APhA in 1972. In 1995, the organization changed its name to the American Society of Health-System Pharmacists since many of its members were practicing in organized healthcare settings rather than exclusively in hospitals.

Pharmacists made many contributions to the American Revolutionary War, World Wars I and II, and the Korean, Vietnam, and Gulf Wars. The contributions of pharmacists during World War II are documented by Worthen.[16,17]

For more information on the history of American pharmacy, consult the American Institute of the History of Pharmacy, located at the School of Pharmacy at the University of Wisconsin (http://www.aihp.org) in Madison.

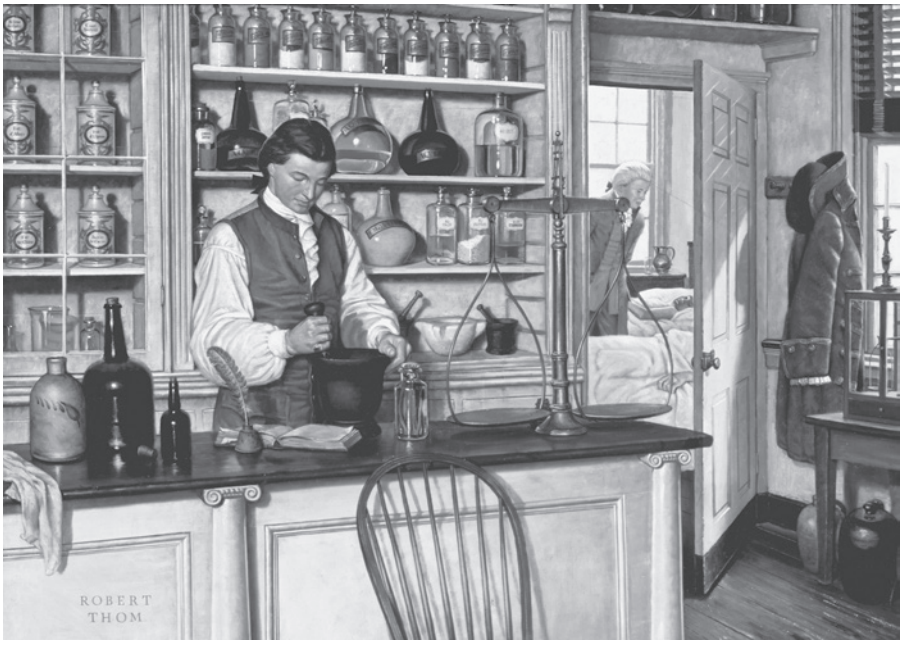

FIGURE 1.3 The first hospital pharmacy in colonial America at the Pennsylvania Hospital in Philadelphia, 1752. (From Bender GA and Thom RA, *Great Moments in Pharmacy; The Stories and Paintings in the Series, A History of Pharmacy in Pictures, by Parke Davis & Company*, Detroit, MI: Northwood Institute Press, 1965. Courtesy of Pfizer, Inc. and Northwood Institute Press.)

WHAT IS THE PURPOSE OF PHARMACY?

Quite a few people, even new student pharmacists, answer the question, what is the purpose of pharmacy, by saying "to supply medication." However, if this is the primary purpose, why have pharmacists do it? Why not have vending or automatic teller machines? If supplying the medication is the primary purpose of pharmacy, is a person with 6–8 years of college education needed to perform this function?

The purpose of pharmacy practice is to help patients make the best use of their medication. From a public health point of view, pharmacists are needed to ensure the rational and safe use of medication. As a minimum, pharmacists are needed as a double check in the drug use process.

WHAT CONTROLS PHARMACY?

To understand pharmacy, one needs to understand what controls and shapes the profession. Some controls for pharmacy are licensure, laws, and rules and regulations. Compliance with pharmacy laws, drug laws, and rules and regulations is checked by announced and unannounced visits to the pharmacy by various agencies. The State Boards of Pharmacy, the U.S. Health Department, the Bureau of Narcotics and Dangerous Drugs (BNDD), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) can show up for an inspection at any time. When this happens, inspectors should identify themselves before they are allowed to access patient records, and the pharmacist should document the event in detail.

Pharmacy Licensure

Licensure is a major controlling force in pharmacy. Pharmacists, pharmacy interns, and pharmacies are licensed by a state board of pharmacy. It is important to note that a pharmacist is designated as a RPh. However, this designation is only provided after passing a state board of pharmacy examination. Thus, all *registered pharmacists* are also *licensed pharmacists*.

State Pharmacy Laws

The regulation of pharmacy practice is the function of state government, per the U.S. Constitution. An example of a pharmacy law would be as follows: "To practice pharmacy in the State of Georgia you must be licensed by the Georgia State Board of Pharmacy." Such laws (also called *statutes*) are issued by the state legislature and put forth in the State Pharmacy Act. However, other laws (state and federal laws developed by the U.S. Congress) concerned with drugs and controlled substances also affect pharmacists and the practice of pharmacy. An example of a federal drug law would be "Certain drugs can only be prescribed by a licensed physician." Pharmacists must also know and comply with these laws to practice pharmacy.

State Pharmacy Rules and Regulations

Rules and regulations are written details on how to comply with the law and are developed by an appropriate government agency (such as a state board of pharmacy). Rules and regulations carry the weight of the law and usually detail the penalties for not complying with the law. For example, a pharmacy law may say the following: "Pharmacists must counsel all patients about their medication." A pharmacy rule and regulation under this law might be: "When counseling patients, pharmacists will indicate what the drug is for, how it is to be used, what usual side effects to expect, and what to do if they have any problems or questions."

Federal Laws

Pharmacy is also controlled by federal laws such as the Food, Drug, and Cosmetic Act; the Health Insurance Portability and Accountability Act; and the Medicare Prescription Drug Improvement and Modernization Act. Pharmacists need to know and comply with the details of these acts to help patients and not break the law.

WHAT SHAPES PHARMACY?

In general, society grants pharmacy (and the other health professions) much leeway on how the profession is practiced.[18] In return, society expects pharmacy to help patients in the medication use process. Thus, outside the law, pharmacists have the power to shape the profession, make changes to improve the practice, and make it better for patients. This is done in organized and interesting ways.

Scope of Practice

Pharmacists operate within their profession by practicing within their *scope of practice*. New roles for pharmacists do not automatically become functions within the profession's

scope of practice but must be justified as being "value added" and accepted by other health practitioners. For example, a position paper published by the American College of Physicians discussed new roles for pharmacists, such as patient education, attending rounds with physicians, immunization, and collaborative practice.[19] Innovative practices such as pharmacists prescribing according to the use of physician-approved protocols that have been used and accepted within the Veterans Affairs medical centers take time to be accepted in all practice settings.[20] Thus, pharmacy's scope of practice is continually evolving.

Organizations

Various pharmacy organizations, such as the APhA, the ASHP, the American College of Clinical Pharmacy (ACCP), the American Society of Consultant Pharmacists (ASCP), the American Association of Colleges of Pharmacy (AACP), and the Academy of Managed Care Pharmacy (AMCP), represent the interests of pharmacists practicing in different settings. These organizations are similar in that they improve communication among their members, serve as forums for discussion, help reach consensus on important issues, provide education, and strive to improve the profession and services pharmacists provide to patients. In addition, there are many state and local pharmacy organizations.

House of Delegates

Many pharmacy organizations have delegates elected (usually representing a state or geographic area) to serve in their house of delegates. This is where the official business of a pharmacy organization takes place. It is also where important issues are discussed, debated, amended, and approved or disapproved. It is the way of reaching consensus on key issues, statements, or standards of practice within the profession.

Standards of Practice

A critical role of a pharmacy organization's House of Delegates is to approve *standards of practice*. Standards of practice are critical; therefore, they are usually developed slowly and carefully within the organization before coming forward for a vote. Standards of practice are meant to improve practice, or keep it safe and to serve as self-policing policies within an organization. However, once standards of practice are in place, they become *quasi-legal* doctrine. Therefore, the standards of practice of an organization can be used in a court of law against a member pharmacist for not following the standard. However, if no law applies, the court uses the community standard of practice (how many pharmacists are following the standard) as its best judge of reasonable and prudent behavior. An example of a standard of practice is, "The allergies of patients should be recorded in the patient's pharmacy profile."

Consensus conferences, conference proceedings, white papers, and study commissions are also major mechanisms for improving and moving the profession forward.

Consensus Conferences

Before developing a new standard of practice or recommending a major change in practice, pharmacy organizations call a conference and invite leaders in the profession to discuss new directions and reach consensus on a new direction. As shown in Table 1.1, pharmacy has convened several successful, future direction conferences since 1984 that have helped shape the profession.

TABLE 1.1
Examples of Consensus Conferences Helping Shape Pharmacy

Conference[21–24]	Year	Sponsor	Subject
Pharmacy in the 21st Century	1984	Various	The progress pharmacy could achieve under a variety of different social and economic scenarios
Directions for Clinical Practice	1985	ASHP Foundation	Pharmacy's societal purpose and pharmaceutical care
Pharmacy in the 21st Century	1989	Various	The future impact of changing social, economic, technologic, and healthcare forces on the profession in the twenty-first century
Implementing Pharmaceutical Care	1993	ASHP Foundation	Clarifying the concept of pharmaceutical care and developing approaches that can be taken at the practice level to hasten its implementation
Pharmacy in the 21st Century	1994	JCPP*	Building on the first two Pharmacy in the 21st Century conferences, how pharmacy can survive in the twenty-first century
Invitational Conference	2001	NCCMERP**	Requiring and standardizing bar codes on all unit-of-use drug packaging
The Pharmacy Workforce	2001	Pharmacy Manpower Project	Delineate and project the need for pharmacy services over the next 20 years
Pharmacy Practice Model Summit	2010	ASHP	Reaching a consensus on optimal practice models that are based on the effective use of pharmacists as direct patient care providers
Charting Pharmacy Education's Accreditation Future	2012	ACPE	An interdisciplinary task force report focusing on employer expectations of new pharmacy graduates
Pharmacy Forecast 2016–2020	2015	ASHP Foundation	Strategic planning advice for pharmacy departments in hospitals and healthcare systems

*Joint Commission of Pharmacy Practitioners
**National Coordinating Counsel for Medication Error Reporting and Prevention

Conference Proceedings and White Papers

Conference proceedings, sometimes called *white papers*, are published for all pharmacists to read and provide comments. An example of a white paper is "Automation in Pharmacy," developed by the Automation in Pharmacy Initiative, a coalition of pharmacy associations, members of state boards of pharmacy, and representatives from the pharmacy automation industry.[25] Pharmacists may comment by writing directly to the organization sponsoring the conference or white paper or by writing a letter to the editor of the journal in which the proceedings or white paper were published.

Study Commissions

Sometimes organizations appoint expert panels (usually interdisciplinary) to study a major issue or the status or direction of the profession. These expert panels spend long periods of time studying the issue and developing recommendations based on their findings. Examples of some commissioned study reports in pharmacy are shown in Table 1.2.

TABLE 1.2
Examples of Some Commissioned Study Reports in Pharmacy

Report[25–31]	Year	Sponsor	Contents
The Pharmaceutical Survey (Elliott Commission)	1946–1949	ACE*	Recommended increasing the educational requirements for pharmacists
Mirror to Hospital Pharmacy	1957–1963	ASHP	A comprehensive study of pharmacy in the United States
Communicating the Value of Comprehensive Pharmaceutical Services to Patients (the Dichter Report)	1973	APhA	Identified the value-added pharmacy services appreciated by patients
Pharmacists for the Future (Millis Commission Report)	1973–1975	AACP	Defined pharmacy as a knowledge-based profession
Commission to Implement Change in Pharmaceutical Education	1990–1991	AACP	Recommended the BS and PharmD degrees as entry-level degrees for the profession

*American Council on Education.

Leadership

The pharmacy profession is fortunate to have had excellent leadership. Three of the most prominent awards in pharmacy recognize leaders in the profession. *The Remington Honor Medal* provided by the APhA was started in 1918 to recognize distinguished service for American pharmacy during the preceding year. *The Harvey A. K. Whitney Award* was established in 1950 and is awarded each year by the ASHP to honor outstanding contributions to the practice of hospital (now health system) pharmacy. *The Francke Medal* was established in 1971 by ASHP to honor individuals who have made significant international contributions to health system pharmacy. Table 1.3 lists past recipients of these prestigious awards.

Pharmacy is striving to be recognized by the public as a true clinical profession. To accomplish this goal in the shortest period of time will take strong leadership. As Joe Smith pointed out in his Harvey A. K. Whitney lecture in 1988, many leaders in pharmacy are developed through postgraduate residency programs.[32] However, most of these leaders spend their careers in organized healthcare settings where the pharmacist's clinical role is being accepted. The public's impression of the profession is garnered mostly from what it sees in community pharmacy practice, much of which is commercialized by corporate ownership.

Peer Review

An important feature in all health professions is *peer review*. The essence of peer review is that someone within the same rank (a peer) reviews the practice procedures of a colleague and cites any major deficiencies. The basis for review is the law, rules and regulations, and practice and ethical standards. Peer review in pharmacy takes place both formally and informally. Formal peer reviews do not take place often, but they are done at the request of a pharmacy manager who would like an outside opinion of the pharmacy to improve and move forward.[33]

Informal peer review in pharmacy can take place between two pharmacists, one spotting a failing of the other, and discussion between the two. This can take place in the same

TABLE 1.3
Recipients of the Remington Medal (APhA), the Harvey A. K. Whitney Award (ASHP), and the Francke Medal (ASHP), 1980–2016

Year	Remington Medal	Whitney Award	Francke Medal
1980	Joseph D. William	Donald C. Brodie	
1981		Kenneth N. Barker	
1982		William E. Smith	
1983	Takeru Higuchi	Warren E. McConnell	
1984	William M. Heller	Mary Jo Reilly	
1985	William L. Blockstein	Fred M. Eckel	
1986	Irving Ruben	John W. Webb	Joseph A. Oddis
1987	Gloria N. Francke	John J. Zugich	
1988	Peter P. Lamy	Joe E. Smith	
1989	Lawrence C. Weaver	Wendell T. Hill	
1990	Joseph A. Oddis	David A. Zilz	
1991	George B. Griffenhagen	Harold N. Goodwin	
1992	Jere E. Goyan	Roger W. Anderson	
1993	Robert C. Johnson	Marianne F. Ivey	
1994	James T. Deluisio	Kurt Kleinman	
1995	Maw W. Eggleston	Paul G. Pierpaoli	Gloria N. Francke
1996	Maurice Q. Bectal	William A. Zellmer	Carl D. Lyons
1997	C. Douglas Hepler and Linda M. Strand	Max D. Ray	
1998	Kenneth N. Barker	John A. Gans	
1999	Carl F. Emswiller	William A. Gouveia	
2000	Daniel Nona	Neil M. Davis	
2001	Jerome A. Halperin	Bernard Mehl	Joaquin R. Beltran
2002	Richard P. Penna	Michael R. Cohen	
2003	Mary Louise Anderson	James A. McAllister III	Toby Clark
2004	Lowell Anderson	Billy Woodward	Dwight Tousignaut
2005	Robert J. Osterhaus	Thomas Theilke	Colin Hitchings
2006	Robert D. Gibson	Sara J. White	Philip J. Schneider and Thomas S. Thielke
2007	Ernest Mario	Henri R. Manassee Jr.	Toshitaka Nabeshima
2008	J. Lyle Bootman	Philip J. Schneider	Jacqueline Surugue
2009	John A. Gans	Paul W. Abramowitz	William A. Zellmer
2010	Mary Anne Koda-Kimble	C. Douglas Hepler	Agathe Wehrli
2011	Paul W. Lofholm	Daniel M. Ashby	Barry R. Goldspeil
2012	William E. Evans	Rita R. Shane	Henri R. Manasse, Jr.
2013	Dennis K. Helling	Jannet M. Carmichael	Eduardo Osvaldo Savio Quevdo
2014	Marilyn K. Speedie	John E. Murphy	Andrew Lofts Gray
2015	Calvin H. Knowlton	Sharon Murphy Enright	Roberto Frontini
2016	Leslie Z. Benet	Sister Louise Degenhart	Lee C. Vermeulen
2017	Daniel A. Hussar	Max L. (Mick) Hunt	Marianne F. Ivey

pharmacy or between pharmacists working in two different pharmacies. Although these conversations can be delicate, they are necessary, and pharmacy has handled this business well, which is the mark of a truly collegial profession.

Pharmacy Ethics

Another reason pharmacy is a collegial profession is that pharmacists feel the honor of the profession and respect what has been handed down from one generation of pharmacists to the next. In addition, all pharmacists share and subscribe to a code of ethics that has been handed down through decades.

Ethics are standards of conduct. They are also about what a person carries within: attitude, disposition, relationship to self, and relationship to others. Ethics is about style and about adhering to certain principles. For pharmacists, it is about treating others with respect and adhering to the profession's code of ethics.

A code of ethics for a profession does more than spell out rules of conduct for its members. A code of ethics for a profession sets it apart from broader groups of occupations or careers. It is the glue that keeps the profession distinctive and together. The constant sense of the ethics of the profession is what is distinctive about the *good pharmacist* versus the technically expert pharmacist.

Concern for ethical behavior in pharmacy dates from 1852, when the newly formed APhA obliged its members to subscribe to a strict code of ethics.[34] Five revisions of the code of ethics of pharmacy have taken place since 1852.[35,36] The latest revision of the code of ethics of pharmacy took place in 1994 and is shown in Table 1.4. The pharmacy code of ethics, like the code of ethics in medicine, has evolved and is less paternalistic than in the past. Today, it provides more respect for patient determination once the patient is properly informed.

At graduation, pharmacy students recite the Oath of a Pharmacist (Table 1.5)[37] for all to witness the graduating pharmacists' commitment to the patient and the profession.

TABLE 1.4
Code of Ethics for Pharmacists

Preamble

Pharmacists are health professionals who assist individuals in making the best use of medication. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

Principles

I. A pharmacist respects the covenant relationship between the patient and pharmacist.
Interpretation: Considering the patient–pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimal benefit from their medications, to be committed to their welfare, and to maintain their trust.

II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.
Interpretation: A pharmacist places concern for the welfare of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.

III. A pharmacist respects the autonomy and dignity of each patient.
Interpretation: A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients.

(*Continued*)

TABLE 1.4 (Continued)
Code of Ethics for Pharmacists

IV. A pharmacist acts with honesty and integrity in professional relationships.
Interpretation: A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.

V. A pharmacist maintains professional competence.
Interpretation: A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.

VI. A pharmacist respects the values and abilities of colleagues and other health professionals.
Interpretation: When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.

VII. A pharmacist serves individual, community, and societal needs.
Interpretation: The primary obligation of the pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.

VIII. A pharmacist seeks justice in the distribution of health resources.
Interpretation: When health resources are allocated, a pharmacist is fair and equitable, balancing the needs of patients and society.

TABLE 1.5
The Oath of a Pharmacist

I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In full dispensing this vow:
I will consider the welfare of humanity and relief of human suffering my primary concerns.
I will apply my knowledge, experience, and skills to the best of my ability to assure optimal drug outcomes for my patients.
I will respect and protect all personal and health information entrusted to me.
I will accept the lifelong obligation to improve my keep abreast of developments and maintain professional knowledge and competence.
I will hold myself and my colleagues to the highest principles of our profession's moral, ethical, and legal conduct.
I will embrace and advocate changes that improve patient care.
I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists.
I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.

Source: American Association of Colleges of Pharmacy. Oath of a Pharmacist, Alexandria, VA: American Association of Colleges of Pharmacy, 2007. http://www.aacp.org/resources/academicpolicies/studentaffairspolicies/Documents/Oathofapharmacist2008-09.pdf. With permission of American Association of Colleges of Pharmacy.

THE VALUE OF PHARMACY

The pharmacy profession would not exist if it was not needed. Those in society say that there need to be pharmacists in the healthcare system. The role of pharmacy is to oversee the drug use process, to make it safe, and to make it efficient. It also exists to help patients make the best use of their medications.

Pharmacists have been consistently rated the most trusted professionals by annual Gallup polls in the United States.[38] However, in the 2000 Gallup poll, nurses were added to the

survey, and pharmacists were rated second only to nurses for honesty and ethical standards.[39] The gap between the two is closing. Pharmacy has worked to earn respect from patients and earns it one pharmacist and one patient at a time.[40]

PHARMACY'S PURSUIT OF PROVIDER STATUS

Lack of *provider status* has haunted pharmacy (the profession) for a longtime. *Provider status*, granted by healthcare payers (most importantly by Medicare through the Social Security Act and followed by state and private health plans), allows an *approved provider* (the most notable are physicians, physician assistants, nurse-practitioners, dentists, and psychologists) to bill and receive payment for *allowable services* provided. Pharmacies may bill for the *allowable service* of providing medication, but pharmacists and pharmacies cannot receive payment from most payers for "clinical" or cognitive service, the one exception being for *medication therapy management* (MTM) under the Part D Medicare benefit.

In 2013, the profession, largely through the leadership of American Pharmacists Association (APhA), began a campaign for pharmacists to become paid providers by helping to introduce U.S. Senate and House of Representative bills to achieve provider status to pharmacists. If passed, it will be known as the Pharmacist and Medically Underserved Areas Enhancement Act.

There was early support for this, but also some resistance by other health providers, so the bills were revised to include only services in rural or underserved areas. This strengthened support for the bills (42/100 co-sponsors in the senate and 282/425 co-sponsors in the house in 2016) and they were reintroduced into the legislative process in 2017.

Although this effort has strengthened the profession by pulling its special interest segments to work together, it may be an effort that is "too little, too late." It will be nice if it happens, but most likely will not be needed in the new era of accountable care and how healthcare will be paid.

Provider status is based on the old, but long standing practice of *fee-for-service*—getting paid to do something without regard for outcome. For example, if a cardiologist performs a cardiac catheterization (estimated that 30% are not needed), he or she is paid, even though the patient may not get better, or may even get worse.

The problem for pharmacy is that most healthcare experts agree that *fee-for-service* is dying, based on the passage of the *Affordable Care Act* (Obamacare) and new accountable care payment strategies by the Center for Medicare and Medicaid Services (CMS). Payments will be based mostly on achieving better outcomes and quality measures, and avoiding (not paying for) negative outcomes (such as 30-day hospital readmissions and preventable problems such as people falling out of their hospital bed, medication errors, and hospital acquired infections.)

Based on this new payment system that is picking up speed rapidly, it is not a question of what clinical pharmacists will get paid to do, but rather what outcomes pharmacists can improve. It is doubtful pharmacists will be paid for just improving laboratory measures (such as A1Cs and blood pressure). These are *process indicators*, rather than outcome measures, and even if they improve, the outcome may not. The outcomes pharmacists may get paid on fall into three domains:

1. *Decreasing Preventable Medication-Related Morbidity and Mortality:* Pharmacists have a longstanding interest and effort in preventing *medication-related problems* (MRPs—allergic and adverse reactions, interactions, and errors). They have done this without regard to payment, and it has been engrained as an accepted and expected

part of practice. In fact, it is the main reason pharmacists are licensed—to protect the patient from the harm of medication. Therefore, critics say, why should you be paid? Some pharmacist believe this as well. They say, "it's our job." However, there is a compromise—getting paid for preventing an MRP that without a doubt would end badly (death, an emergency room visit, or hospitalization) may be viable.

The challenge is taking the time document interventions (to prevent fraud) and agreement that the intervention by the pharmacist prevented the potentially drastic outcome. How to do this so as to satisfy pharmacists and payers is the challenge. The creation of predetermined payable prevention likelihood ratios may be a way to set up policy to be paid.

2. *Improving Healthcare Utilization:* This domain has the most potential for payment to pharmacists because it is all about the money—big money! The estimated cost of unneeded hospital, physician, and emergency room visits is in billions. The biggest expense (far and away) is going to the hospital. Anything a pharmacist can do to keep a patient from having to use these services because of therapeutic failure, poor medication adherence, or experiencing an MRP may be potentially reimbursable. What pharmacist interventions are *evidence-based*? This subject will be discussed in depth and documented in Chapter 7, "Pharmaceutical Care." But, here are the evidence-based pharmacy interventions that can positively improve patient outcomes:
   - Reviewing and adjusting a patient's medication regimen for evidence-based therapy (guideline-based)
   - Reviewing and adjusting a patient's medication regiment to avoid potential MRPs or to remove one after therapy is initiated
   - Checking, providing, or changing to the most preventive therapy (such as immunizations; a daily low dose aspirin; cholesterol medication)
   - Checking and improving medication adherence

   Like the previous domain, proving what the pharmacist did related directly to preventing the unneeded healthcare utilization will be difficult. Also, there may be a mixed intervention effect, as the pharmacist may not be the sole reason for the better outcome. However, there is one barometer the pharmacists can use to prove their merit, and that is medication adherence measures.

   The evidence is robust—moving medication adherence to 80% or higher relates directly to lower physician, emergency room, and hospital visits.[41] Clinical improvement and savings can be significant, and appealing to payers. Thus, incentive pay for pharmacists who can show significant improvement in baseline medication adherence to 80% or above should be presented to payers as a proposal.

   As a side note, pharmacy should claim medication adherence monitoring and counseling as an important professional responsibility and include it in its scope of practice.

   In order to do the documentation correctly, those paying or showing pharmacy claims (pharmacy benefits managers, insurance companies, pharmacy software venders) need to provide the dispensing pharmacist with the current adherence rate for each of the patient's drugs. When adherence rises by a certain significant amount from the baseline and to 80% or above, the pharmacy should receive a decent automatic incentive payment, and in turn, part paid to the pharmacist in a quarterly bonus.

   Directors of Pharmacy (DOPs) and *Chief Pharmacy Officers* (CPOs) in hospitals need to convince hospital administration (the C-Suite) to provide incentive pay

to pharmacists based on the new *value-based purchasing* program by CMS (for Medicare patients). This program penalizes hospitals for poor 30-day readmission rates for several chronic diseases, and no payment for preventable mishaps such as medication errors that prolong hospital stay.

Pharmacists can prevent 30-day readmissions before discharge by making sure the therapy is evidence-based and the patient understands the importance of taking their medication and how to take it, and make follow up calls to patients within seven days of discharge. The key here is discussion and negotiation with hospital administration. If needed, a pilot project to show value should be suggested.

3. *Improving Quality Measures:* Thus far we have been discussing community and hospital pharmacists. Now let's turn to clinical pharmacists embedded in ambulatory medical practices such as multispecialty clinics and medical homes. These practices receive incentive payments based on improving quality measures (such as *Medicare Star Ratings* and *HEDIS Scores* for commercial insurance). More than half of the measures concern the proper use of medication for which the pharmacist should be responsible. Here the key is establishing a trust level with the rest of the team—the physician (who sees high risk patients), the nurse-practitioner (who sees lower risk patients), and the medical assistant (who saves time by doing the routine work needed prior to an examination).

   The key for the ambulatory clinical pharmacist is *risk stratification*—to identify and perform interventions solely on patients at high risk for high healthcare utilization or whose quality measures are low. Having an enhanced *collaborative practice agreement* (CPA) in place is critical to success. The CPA should allow pharmacists to make changes without having to check with the physician each time a change in therapy or dosage is needed. The keys here are sophisticated software that identifies the high risk patient, and an enhanced CPA.

   If quality measures improve, the group practice receives added incentive pay. For example, moving patients from a star rating of three to four (for Medicare Part C patients) results in a huge increase in incentive payment to the practice. Currently these payments are usually kept within the practice plan (for the owners and physicians) and not shared with the other team players, and yet the pharmacist can be the key driver in reducing healthcare utilization if practicing correctly. Therefore, the keys here are for the pharmacist to gain the trust of the rest of the team and to show what they can do. If they are making a difference in patient outcomes, they should make a strong argument to be included in pay-for-performance bonuses.

   Under the new accountable care payment model, it is not important for the pharmacist to have provider status, as this is based on the retiring "fee-for service" model. It is important for the pharmacist to be part of an integrated, collaborative patient team, to gain their trust, and to show how they can help decrease healthcare utilization and improve quality measures.

THE FUTURE OF PHARMACY

It is easier to think and dream about pharmacy's future, than to predict it. The author's observation is that most pharmacists dream of more clinical involvement, more public recognition as a true clinical profession, and payment for cognitive services. Predictions of pharmacy's future or what is needed to achieve the profession's dream abound, but one serious effort in the form of a commentary by Zellmer is worth reading.[42]

SUMMARY

Pharmacists exist because society says there needs to be someone in the healthcare system to oversee the drug use process. The profession of pharmacy has a long and proud history. Pharmacy is controlled not only by laws and regulations but also by the profession by approving standards of practice, peer review, a code of ethics, and excellent leadership. Pharmacy has been consistently rated the most trusted profession.

DISCUSSION QUESTIONS AND EXERCISES

Read the first three questions. After reading each one, reflect and record a few answers for each question.

1. What led you to choose pharmacy as a career?
2. What about pharmacy attracts you?
3. What will pharmacy allow you to accomplish?
4. Of the answers provided in questions 1–3, circle the two most important answers.
5. Currently, what do you think your first job will be as a pharmacist?
6. Without consulting anything or anybody, make a list of career opportunities you know are available for pharmacists.
7. Circle two to three opportunities on the list in question 6 that appeal to you. How do these compare to what you answered in question 5?
8. Do you think there are more opportunities for pharmacists than you listed in question 6?
9. If your answer to question 8 is yes, how will you investigate these opportunities?
10. How does the public form their opinion of pharmacy?

CHALLENGES

1. One of the greatest challenges facing the profession is raising the public image of the profession to that of a true clinical profession. For extra credit and with the approval of your professor, write a concise report stating the problem and make convincing arguments on how the profession should tackle this important issue.
2. Some innovative thinkers have argued that the profession should try to expand its scope of practice into managing pharmaceutical clinical technology (PCT). Advocates of this expansion feel that it adds a theoretical foundation, something present in medicine and nursing but absent in pharmacy. "PCT adds the use of clinical technologies used in the entire process of care: from diagnostics to devices, instruments, biotech products and single use items."[43] For extra credit and with the approval of your professor, write a concise report about PCT and make pro and con arguments for PCT; finally, state your opinion.

WEBSITES OF INTEREST

American Association of Colleges of Pharmacy: http://www.aacp.org
American Institute of the History of Pharmacy: http://www.aihp.org
American Pharmacists Association: http://www.aphanet.org
American Society of Health-System Pharmacists: http://ashp.org
National Community Pharmacists Association: http://ncpanet.org
If you are a high school student and thinking of going into pharmacy, please go to the following site: http://www.pharmacist.com/AM/Template.cfm?Section=Shall_I_Study_Pharmacy_.

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2 The Pharmacist

INTRODUCTION

All pharmacists, regardless of practice setting or experience, share the same mission: to help patients make the best use of their medication. You will now be introduced to the pharmacist—one of the public's most trusted professionals.

This chapter presents the general characteristics of pharmacists and how they are educated and trained. It also covers information on what pharmacists do, their titles and career paths, how much demand there is for pharmacists, and the rewards of being a pharmacist. The chapter ends with information about job satisfaction, job stress, career development, and the job outlook for pharmacists.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Discuss how pharmacists are educated.
- Discuss how pharmacists are trained.
- Explain the characteristics of pharmacists.
- Explain the virtues commonly associated with pharmacists.
- Explain the habits of pharmacists.
- Explain what pharmacists do.
- Discuss the titles and career paths of pharmacists.
- Discuss the supply and demand for pharmacists.
- Discuss some rewards, stresses, and the job outlook for pharmacists.

WHO ARE PHARMACISTS?

In 2014, pharmacists held about 291,000 jobs in the United States (see Table 2.1).[1] This makes pharmacy the nation's third-largest health profession. About 65% of pharmacists work in community pharmacy and 22% work in hospitals. However, pharmacists work in all areas of health care, health care education, and medical research. They are employed in community pharmacies, hospitals, managed care organizations, drug companies, academia, nursing homes, home health care agencies, clinics, physician offices, government, professional pharmacy organizations, pharmacy software companies, and as private consultants.

Pharmacists hold positions as staff members, supervisors, managers, teachers, researchers, and entrepreneurs. Some pharmacists have advanced training in pharmacy and work in specialized areas. Some have added education and training in other fields and combine this knowledge with their background in pharmacy to become experts.

EDUCATION AND TRAINING

Pharmacy is a knowledge-based profession. Earning this knowledge takes study and training. Pharmacists, and those choosing to be pharmacists, have various ways to gain knowledge. Once the knowledge is gained, pharmacists receive credentials. A *credential* is documented

TABLE 2.1
Active Nurses, Doctors, and Pharmacists in the United States, 2000–2014

	Personnel (1000s)				
	2000	**2006**	**2010**	**2013**	**2014**
Registered Nurses	2190	2417	2655	2662	2687
Nurse Practitioners	–	–	–	113	122
Physicians	814	902	985	1046	–
Physician Assistants	55	–	81	88	92
Pharmacists	213	240	268	287	291

Source: Data from National Center for Health Statistics. Tables 84 and 87. Health, United States, 2015. https://www.cdc.gov/nchs/data/hus/hus15.pdf. Accessed January 10, 2017.

evidence of a pharmacist's qualification. A credential can be in the form of a diploma, a license, a certificate, statement of continuing education, or certification.

Formal Education

Today, students of pharmacy must study for 6–8 years at the college level to earn the doctor of pharmacy degree (PharmD). The first two years (about 60 semester credits) are considered prepharmacy requirements that can be earned at a college or university before being accepted into a college or school of pharmacy. Most of the prepharmacy requirements are in biology, chemistry, and liberal study, and some schools also require physics and calculus.

In 2016, 136 colleges of pharmacy (up from 119 in 2010) in the United States offered accredited degree programs, and this number keeps growing. To be admitted to most pharmacy schools, the candidates must have superior grades, especially in mathematics, biology, and chemistry. They also must have strong interpersonal skills and enjoy working with and helping people, especially people who are sick.

Ethical behavior is a must. It also helps if the candidate loves to learn. Other traits pharmacy schools are seeking in a potential student include: understanding, drive, flexibility, perseverance, being goal oriented and organized, being decisive, having a good knowledge of pharmacy, and having varied personal interests. Having some or all the skills and virtues common to pharmacists (discussed further in this chapter) also helps (Table 2.2).[2]

Course work is offered in the four basic areas.

Accreditation is the process by which a private association, organization, or government agency, after initial and periodic evaluations, grants recognition to an organization that has met certain criteria or standards. The American Council for Pharmaceutical Education (ACPE) is the organization that grants accreditation for colleges of pharmacy in the United States.

The four years of pharmacy school following the two years of prepharmacy include didactic courses in basic science, pharmacy administration, and clinical science. In addition, there are introductory (during the first 3 years) and advanced (during the fourth year) clinical rotations. Although some pharmacy schools can be expensive, particularly private schools, educational loans are plentiful, as are jobs as pharmacy technicians or interns.

In at least one state (Tennessee), pharmacists may use the designation "PD" (pharmacy doctor) after their names. This is not a designation of an earned educational degree like the

TABLE 2.2
Required Elements of the Didactic Doctor of Pharmacy Curriculum, 2016

Biomedical Sciences	Pharmaceutical Sciences	Social/Administrative/ Behavior Sciences	Clinical Sciences
Biochemistry	Clinical Chemistry	Cultural Awareness	Clinical Pharmacokinetics
Biostatistics	Extemporaneous Compounding	Ethics	Health Informatics
Human Anatomy	Medicinal Chemistry	Healthcare Systems	Health Information Retrieval and Evaluation
Human Physiology	Pharmaceutical Calculations	History of Pharmacy	Medication Dispensing, Distribution, and Administration
Immunology	Pharmaceutics/ Biopharmaceutics	Pharmacoeconomics	Natural Products and Alternative and Complementary Therapies
Medical Microbiology	Pharmacogenonmics/ Genetics	Pharmacoepidemiology	Patient Assessment
Pathology/ Pathophysiology	Pharmacokinetics	Pharmacy Law/ Regulatory Affairs	Patient Safety
	Pharmacology	Practice Management	Pharmacotherapy
	Toxicology	Professional Communication	Public Health
		Professional Development/ Social and Behavioral Aspects of Practice	Self-Care Pharmacotherapy
		Research Design	

doctor of pharmacy degree (PharmD), but may be used by any pharmacist licensed by that state's board of pharmacy.

Internship

Pharmacy interns are student pharmacists licensed by a state board of pharmacy to work with a licensed pharmacist and learn how to practice pharmacy. Their work hours count toward meeting the training requirement of the board (usually 1000–2000 hours). Pharmacy students usually acquire internship hours during holidays and vacations. In some states, academic experiential training is accepted as partial fulfillment of internship hours. Pharmacy interns can do most, but not all, of the work pharmacists do if they work under the direct (within earshot) supervision of a licensed pharmacist.

Licensure

Once student pharmacists complete the educational requirements of a school of pharmacy successfully, they graduate. Once they graduate and have completed internship requirements in their states, they may sit for the board examination. The *board examination* involves passing the national pharmacy examination (North American Pharmacy Licensure Examination, NAPLEX) or a state examination, a state jurisprudence (law) examination, and sometimes a laboratory examination or an oral examination. Licensure indicates that the pharmacist has met the minimum requirements of the state in which he or she intends to practice.

The NAPLEX is a computer-adaptive, competency-based examination that assesses the candidate's ability to apply knowledge gained in pharmacy school to real-life practice. The NAPLEX was developed by the National Association of Boards of Pharmacy (NABP) and is available for use by state boards of pharmacy to assess competence to practice pharmacy.

The NAPLEX helps the state boards of pharmacy in fulfilling one of their responsibilities: safeguarding the public health and welfare. Most states also require candidates to take a state-specific pharmacy law examination. Most states use the Multistate Pharmacy Jurisprudence Examination (MPJE) from NABP. The NAPLEX and MPJE examinations are administered by daily appointment throughout the year at test centers found in all 50 states.

If candidates pass these examinations, they are granted a license to practice in that state. To practice in another state, pharmacists must either take the board of pharmacy examination in that state or reciprocate their license from one state to the other and pass the jurisprudence examination for the new state. *Reciprocation* is not transferring a license, but it forms the basis for licensure in another state. Florida and California do not reciprocate with other states. Some pharmacists are licensed in more than one state.

Postgraduate Training

Postgraduate training is available in the form of residencies and fellowships. According to the American College of Clinical Pharmacy (ACCP):[3]

Residencies exist chiefly to train pharmacists in professional practice and management activities. Residencies provide experience in integrating pharmacy services with the comprehensive needs of individual practice settings and provide in-depth experiences leading to advanced practice skills and knowledge. Residencies foster an ability to conceptualize new and improved pharmacy services. Within a given residency program, there is considerable consistency in content for each resident. In addition, accreditation standards and program guidelines produced by national pharmacy associations provide considerable program content detail and foster consistency among programs.

Residencies

A residency is typically 1 year (PGY1) or may be 2 years (PGY2) in duration, and the resident's practice experiences are closely directed and evaluated by a qualified practitioner–preceptor.

Postgraduate year one (PGY1) of pharmacy residency training is an organized, directed, accredited program that builds on knowledge, skills, attitudes, and abilities gained from an accredited professional pharmacy degree program. The first-year residency program enhances general competencies in managing medication use systems and supports optimal medication therapy outcomes for patients with a broad range of disease states.[3]

Postgraduate year two (PGY2) of pharmacy residency training is an organized, directed, accredited program. It builds on the competencies established in PGY1 of residency training. The second-year residency program is focused on a specific area of practice. The PGY2 program increases the resident's depth of knowledge, skills, attitudes, and abilities to raise the resident's level of expertise in medication therapy management and clinical leadership in the area of focus. In those practice areas where board certification exists, graduates are prepared to pursue such certification.[3]

A residency may occur at any career point following an entry-level degree in pharmacy; however, most residencies start on July 1. Individuals planning practice-oriented careers are encouraged to complete all formal academic education before entry into a residency.[3]

Examples of pharmacy residencies include pharmacy practice, infectious disease, ambulatory care, critical care, primary care, community pharmacy, and drug information. A growing number of residencies are in community pharmacy and managed care settings, in part because of a partnership between the American Society of Health-System Pharmacists (ASHP),

American Pharmacists Association (APhA), and Academy of Managed Care Pharmacy (AMCP) to foster such residencies.

To apply for an ASHP accredited residency, you need to go to ASHP's Pharmacy Online Residency Centralized Application Service (Phorcas) located at: http://www.ashp.org/menu/Residency/Residency-Resources/phorcas.aspx.

The application for residency training requires: demographics, academic history (colleges attended), transcript, a curriculum vitae, personal statement/letter of intent, a listing of extracurricular activities, and references.

On successful completion of a residency, the resident receives a certificate of residency training. The annual stipend offered to residents is approximately half of a pharmacist's salary and varies by location and type of residency. Specific information about individual residencies is also at the ASHP website.[4]

Residency programs are accredited by ASHP. Each spring, applicants apply for residency programs and residency programs submit their available residency positions. A computer program tries to match candidates with programs. The match results for 2015 and 2016 are shown in Table 2.3. No salary information was available.

According to ASHP, going into the 2017 residency match (as of February 19, 2017) there were 1282 PGY1 and 891 PGY 2 residency programs (total of 2173). For PGY1 programs: 1014 were hospital programs; 144 were community programs; 49 were managed care programs; and 75 were combined PGY1/PGY2 programs. However, these numbers are dynamic and shift as the match gets closer.

Residency candidates need to select the correct residency. The search is less daunting when candidates know what kind of residency they would like to do and perform a thorough search and investigation of available programs. The starting point for finding available residencies and fellowships is accessing the ASHPASHP and ACCPACCP websites concerning residencies and fellowships (these websites are listed at the end of this chapter). Signing up for the residency matching program and attending the ASHP Residency Showcase and Personal Placement Service at ASHP's Mid-Year Clinical (MYC) meetingASHP's Mid-Year Clinical (MYC) meeting that takes place in early December are highly recommended.

It is important that candidates for pharmacy residencies understand the criteria residency directors and preceptors use to select residents. The number one criterion for selecting pharmacy residents is the personal interview.[7] Other highly ranked criteria, in descending order, are clinical course grades, letters of recommendation, pharmacy-related work experience, rotation grades, and the candidate's personal statement.[8] The criteria most commonly deemed least important are the reputation of the college of pharmacy attended, publications, prepharmacy or undergraduate grades, and the completion of rotations at the institution to which the applicant is applying.[9]

TABLE 2.3
Results of the 2015 and 2016 ASHP PGY-1 Residency Matching Program

Year	Residency Applicants	Applicants Matched	Residency Programs	Residency Positions	Residency Positions Matched
2015	4358	2811 (64.5%)	1229	3081	2811 (91.2%)
2016	4864	3309 (68%)	1324	3323	3310 (99.6%)

Source: Reproduced with permission of ASHP.

The two most important questions students should ask when they rank a residency program are: (1) which program will provide the best training for my career? And, (2) where will I be the most comfortable?

The first, or screening, face-to-face interview (for residency programs) is usually conducted at ASHP's MYC meeting. The residency candidate should thoroughly investigate a residency program prior to going to the MYC meeting. It is recommended that the candidate write for an on-site interview and send a *curriculum vitae* (résumé) to programs of interest *before* the MYC meeting. The residency candidate should dress well and be on time for the interview. The interview goals for candidates are to discuss what they do not know about the residency program and, if interested, to impress the interviewer so that they will eventually invite you for an on-site interview.

Completing an accredited pharmacy residency makes a difference in a career. Many pharmacy practice leaders have completed pharmacy residency programs. Being a leader in pharmacy is the preeminent expectation when you complete a residency program.[10] It is a personal commitment to improve the profession by leading change.

Fellowships

According to the ACCP: The purpose of fellowship training programs is to develop competency and expertise in the scientific research process, including hypothesis generation and development, study design, protocol development, grant writing, study coordination, data collection, analysis and interpretation, technical skills development, presentation of results, and manuscript preparation and publication. A fellowship candidate is expected to possess appropriate practice skills relevant to the knowledge area of the fellowship. Such skills may be obtained through prior practice experience or completion of a residency program.

Under the close direction, instruction, and supervision of a qualified investigator–preceptor, the fellow receives a highly individualized learning experience, using the fellow's research interests and knowledge needs as a focus for his/her education and training. Fellowships are typically offered through schools/colleges of pharmacy, academic health centers, the pharmaceutical industry, and/or specialized care institutions. A fellowship graduate should be capable of conducting independent and collaborative research and functioning as a principal investigator.[5]

As of January 1, 2017, there were 49 fellowships listed by ACCP for 2017–2018 in the following areas and the number of fellowships in each area: academic research – 2, cardiology – 2, community pharmacy – 4, drug development – 6, drug information – 2, family medicine – 1, infectious diseases – 10, nephrology – 2, neurology – 1, outcomes research – 8, pediatrics – 1, pharmacogenomics – 1, pharmacokinetics – 1, pharmacotherapy – 1, regulatory affairs – 1, toxicology – 1, organ transplants – 3, and others – 2. The annual stipend range for these fellowships is $40,000–$55,000 with a median of $47,000.[6]

Specialty Certification

Pharmacists who specialize in a field (e.g., pharmacotherapy, psychiatric pharmacy, nuclear pharmacy, nutrition support pharmacy, ambulatory care pharmacy, or oncology [cancer] pharmacy) may seek *board certification* by voluntarily sitting for a rigorous examination. The Board of Pharmacy Specialties (BPS) oversees the certification process.[11] Pharmacists who pass the examination for the specialty practice may use designations after their names to show this competency. This is an example of how the designation would appear: Thomas R. Jones, PharmD, BCPS. The BPS designations are as follows: pharmacotherapy (BCPS),

nuclear pharmacy (BCNP), nutrition support pharmacy (BCNSP), psychiatric pharmacy (BCPP), ambulatory care pharmacy (BCACP), and oncology pharmacy (BCOP).

In December 2016, more than 28,000 pharmacists held BPS certification, distributed as follows: pharmacotherapy (19,872), nutrition support pharmacy (555), nuclear pharmacy (437), psychiatric pharmacy (978), oncology pharmacy (2,265), ambulatory care pharmacy (2,780), critical care pharmacy (1,158), and pediatric pharmacy (598). Pharmacists who want to keep BPS certification must confirm their competency every seven years through a recertification process. All eight examinations are offered during BPS's two 17-day testing windows (Spring and Fall of each year), in roughly 400 sites throughout the United States and in several other countries.

The BPS also recognizes pharmacists who meet rigorous requirements for added qualifications in cardiology or infectious disease, but only after the pharmacist has passed the board examination in pharmacotherapy.

As of January 1, 2017, the geriatric credential offered by the Commission for Certification in Geriatric Pharmacy (CCGP) is a part of BPS. The CGP credential will become the Board Certified Geriatric Pharmacy (BCGP) credential as of January 1, 2017. Either designation (CGP or BCGP) can be used until January 1, 2018. Four testing windows were available in 2017 and the examination will continue to be the 150-item examination used by CCGP. In 2018, the geriatric examination will be fully integrated into the BPS structure and will be administered under two testing windows (Spring and Fall) and will contain 175 questions, as does every other BPS specialty exam. As of January 1, 2017 there were 3,194 active BCGPs.[12]

Being a pharmacist means being a lifelong learner. The rate of new drug development has accelerated. Many drugs taught in pharmacy school are replaced by newer agents shortly after graduation. Therefore, pharmacists must keep up, and the primary ways to do this is through reading pharmacy and biomedical journals and gaining *continuing education* (CE).

Colleges of pharmacy, professional pharmacy organizations, and pharmaceutical manufacturers offer most of the CE programs for pharmacists. Most state boards of pharmacy require pharmacists to complete a certain number of CE units (CEUs) annually before they can renew their licenses. The CEUs must be earned through participation in a CE program whose provider has been approved by the ACPE. CEUs may be earned by attending education seminars, teleconferences, and meetings; reading approved journal articles; or completing home study courses or computer-assisted instruction. On completion of a CE program, participants are provided documentation that they attended the program.

Another form of CE is *certificate training programs*. Unlike a typical CE program that may be an hour or two of lecture, certificate training programs are structured, systematic education programs. These are smaller in extent and shorter in duration than degree programs. Certificate training programs are designed to instill, expand, or improve practice competencies through the systematic gaining of knowledge, skills, attitudes, and behaviors. The focus of certificate training programs is narrow. For example, there are certificate training programs in asthma, diabetes, immunization therapy, and dyslipidemias.[13]

Certificate training programs are offered by national and state pharmacy organizations and by schools of pharmacy and other educational groups. Some certificate training programs are offered at professional meetings and typically require at least 15 hours of contact time. A certificate is awarded on successful completion of the course, and usually CE credit is awarded if the program is approved by the ACPE.

Certificate training programs for pharmacists in managing disease states such as diabetes are becoming more important. A few insurance programs and pharmacy benefits management (PBM) companies (companies handling pharmacy claims for the insurance companies

or employers) are starting to pay pharmacists for *cognitive services*. Some pharmacists are being paid for monitoring therapy, adjusting therapy, and educating patients about their chronic disease, but only if the pharmacist has a certificate of training in that disease state.[14] Mississippi pays pharmacists who have a certificate of training to help manage Medicaid patients with diabetes, asthma, and hyperlipidemia and those taking anticoagulants.[15]

Attendance at CE programs is well and good, however, the least expensive, convenient, and most effective way for learning is reading routinely to keep up. Online accredited CE programs, some free, such as the ones offered by *Pharmacy Times* located at https://www.pharmacytimes.org/ce/study are helpful.

Postgraduate Education

The pharmacy field also has some master degrees (of science [MS] or of arts [MA]) and doctor of philosophy (PhD) degrees conferred after attending graduate school and meeting requirements. Common fields of study for master's programs include: business administration, clinical pharmacy, public health, and pharmacy administration. Common fields for doctoral studies include: pharmaceutical chemistry (chemical properties of drugs), pharmaceutics (physical properties of drugs and dosage forms), pharmacology (the action of drugs), and social and administrative sciences. There also are some combined degree programs such as PharmD/PhD and PharmD/MBA (master in business administration).

CHARACTERISTICS OF PHARMACISTS

Pharmacists receive formal education and training in the basic, clinical, and social sciences. They must have a certain knowledge base to be competent at what they do. Beyond knowledge, certain characteristics make pharmacists excellent practitioners. These characteristics are divided into three broad areas: skills and traits, virtues and character, and habits. All of these areas encompass *professionalism.*

Skills and Traits

Skills are expertise that comes with training and practice. The skills common among pharmacists usually existed in childhood or young adulthood or were instilled by a parent or a teacher, or existed or improved while attending pharmacy school. Once the candidate is judged to be able to do the academic work, some pharmacy schools use these skills to screen pharmacy school applicants during the interview process.

The following traits are common to pharmacists:

Empathy is the ability to sense what the patient is feeling and experiencing. This is a basic and essential trait a pharmacist needs to help care for patients.

Self-confidence is needed to excel as a pharmacist. Patients notice and want this feature in all health care providers, unless it is overstated.

Good organizational skills are needed to lessen confusion and to be efficient.

Assertiveness helps with patients who are undecided about health matters. It also helps in dealing with other health care providers when pharmacists need to protect patients from poor or dangerous drug therapy.

Common sense is often needed to help solve problems with patients and sometimes is the only thing to rely on in solving complex situations.

Character and Virtues

The ability to *analyze situations* and judge them is an asset common among pharmacists and is frequently needed.

Some pharmacists come by *critical thinking* naturally, whereas others pick it up when taking certain coursework such as physics and calculus. This trait helps when you are confronted with complex patient problems like complex medication regimens or poor medication adherence.

The ability to *problem solve* is a skill pharmacy schools work diligently at instilling in pharmacy students. It goes hand in hand with the skills of analysis and critical thinking.

Paying attention is a must for providing accuracy, doing high-quality work, and practicing safely.

Being a *good communicator* is an asset appreciated by most patients. This is mostly a learned skill, and communication is an important course in the pharmacy curriculum. There are some good sources of information on this important trait.[16,17]

Being a *team player* is critical as health care and pharmacy are team professions. Little gets done, and gets done efficiently, without teamwork.

Being a *lifelong learner* is critical to maintain competency as a pharmacist, to provide the best care for patients, and to continue to practice with confidence.

It takes more than knowledge, skill, and traits to be a good pharmacist. A "good pharmacist" is distinguished from the technically skillful pharmacist. Other than knowledge, skill, and technical ability, character and virtues are the essence of a "good pharmacist."

Pharmacists relate to patients in a special way because they claim to be helpers and therefore assume duties to the people who need them. A covenantal relationship is established between the patient and the pharmacist. The relationship is based on medical need and trust by the patient and help by the pharmacist. Pharmacists promise to help patients make the best use of their medication, and in return patients allow access to confidential information. This relationship and promise by the pharmacist results in a legal duty to the patient.

Based on the duty to help patients, the good pharmacist develops a healing ethos or way of being. A bond, a trust, and a friendship develop between the good pharmacist and the patient. This human partnership is referred to as the *pharmacist–patient relationship*. Based on this relationship, pharmacists are held to higher standards of conduct than the public. The dimensions of the pharmacist–patient relationship, like the physician–patient relationship, are varied.[18]

As eloquently described by Zellmer in his Whitney Award address, it is critical that the soul (*character*) of individual pharmacists be nourished to make sure the pharmacy profession survives as a clinical profession.[19] Character is formed by virtues.

The act of pharmacy, like all the healing professions, is personal. Buerki and Vottero wrote that by the end of the nineteenth century, the practice of pharmacy in the United States emerged as a socially necessary function.[20] Pharmacists of this generation prided themselves on personal service. They displayed a genuine concern for their patients that earned them respect and the informal title of "Doc." The basic value of pharmacy was built on personal service. This affirmed a pharmacist's belief as a health care professional.

To successfully fulfill the dimensions of the pharmacist–patient relationship takes more than courage and practice. To be a good pharmacist, certain virtues must be present and practiced daily:

Beneficence: The good pharmacist is benevolent. This is the essential medical virtue. The good pharmacist displays personal caring and compassion. There is goodness

in the sense of treatment of illness and in how the pharmacist relates to the patient. There is openness to a real relationship despite the patient's problems, and there is a commitment by the pharmacist to carry out medical acts according to the highest ethical standard. This also means the pharmacist believes what the patient says until proven otherwise.

Justice: Justice is about giving patients their due. It is also about fairness that is tempered by intelligence. Fairness does not mean treating everyone equally. Some patients need more help than others. The greatest injustice in the U.S. health care system is not that some individuals get more or better medical treatment than others, but that some get the best treatment and others get none at all. The good pharmacist helps lessen this disparity. Unfortunately, special effort is needed for the pharmacist to gain the virtue of justice, as little attention has been paid to justice in pharmacy training. However, this trait can be taught and modeled.

Fidelity: This virtue is about faithfulness. Good pharmacists live by their promises and maintain confidentiality well. Patients want assurance that the pharmacist can be trusted and is reliable. They also look for consistent service and performance. They want to be able to say "my pharmacist" rather than "the pharmacist."

All of these virtues are dependent on recognizing the value and dignity of human life. Without this belief, the virtues are hollow and meaningless.

Habits

Zellmer, in his article about habits that help make pharmacists successful, says: (a) the habit of empathy, (b) the habit of translating complexity into simplicity for patients, and (c) the habit of recognizing and acting on the obvious.[21]

Empathy: "Successful pharmacists have empathy; empathy with patients whose lives can be improved by the appropriate use of medicines; empathy with patients whose health has been compromised by the inappropriate use of medicines."[22] Pharmacy will not reach its potential as a true clinical profession until most of its practitioners are driven by a deep and enduring need to help people make the best use of their medication. You know you are empathetic when you feel the patient's vulnerabilities.

Translating complexity into simplicity for patients: This is about clear thinking and the power of simple words. "People judge the pharmacy profession by how pharmacists act and by what they say. Every time pharmacists speak to nonpharmacists about their work, they can influence what someone else thinks about the value of pharmacists."[21] All pharmacists have thousands of opportunities through their lifetime to influence those outside the profession. The pictures that can be created and the feelings that can be evoked with words have great power.

Zellmer goes on to say the following: "Imagine a pharmacist telling a nonpharmacist something like this, after being asked, 'What do you do for a living?'"[21]

"I have one of the best jobs in the world. I devoted more than six years of my life to preparing for this career, although the learning has never really stopped. I work closely with doctors, nurses, and patients, and my job is to help them make the best use of medicines. Medicines have tremendous power to do good or to do harm. Achieving the good is my area of expertise. I am a pharmacist."

Recognizing and acting on the obvious: It is easy "to accept as ***normal*** the things that we see in our everyday lives that in fact are ***not normal*** and that could be improved with

concentrated effort. Much of what pharmacists accept as ***normal*** does not square with pharmacy being a true clinical profession. And, unfortunately, because of the public's stereotype of the pharmacist, strangers passing through the community do not notice the disparity. But, a good pharmacist having this habit, recognizes the obvious difference and tries to lessen the gap between what is and what should be, and improving the image of pharmacy."[21]

For more on what it takes to be a good pharmacist, consult the book, *The Good Pharmacist—Characteristics, Virtues, and Habits*.[22]

Professionalism

Public trust is what sanctions a profession. To hold that trust, pharmacists must act professionally at all times. It is difficult to teach professionalism—it is best modeled. The American Pharmacists Association (APhA) has a pledge of professionalism for pharmacy students.[23]

As a student, I will:

DEVELOP a sense of loyalty and duty to the profession by contributing to the wellbeing of others and by enthusiastically accepting responsibility and accountability for membership in the profession.

FOSTER professional competency through life-long learning. I will strive for high ideals, teamwork, and unity within the profession in order to provide optimal patient care.

SUPPORT my colleagues by actively encouraging personal commitment to the "Oath of a Pharmacist" and the "Code of Ethics for Pharmacists" as set forth by the profession.

DEDICATE my life and practice to excellence. This will require an ongoing reassessment of personal and professional values.

MAINTAIN the highest ideals and professional attributes to ensure and facilitate the covenantal relationship required of the pharmaceutical care giver.

WHAT PHARMACISTS DO

Pharmacists do various tasks, and not all pharmacists do the exact same things because of the variety of job titles and job settings available today and the extent of education and training the pharmacist possesses. In general, pharmacists have the following roles: quality controller, caregiver, clinician, problem solver, advisor, teacher, manager, supervisor, leader, owner, researcher, sales representative, quality reviewer, and value-added.

Quality Controller

The term *quality controller* applied to a pharmacist may surprise nonpharmacists. Most nonpharmacists would probably have guessed the first function mentioned would be supplying the medication: retrieving the medication, typing the label, and counting out the medication. Think about it: Does it take someone with 6–8 years of college education and an internship to be able to do that? Almost anyone who can read, find a bottle of medication that is placed on a shelf alphabetically, and type a label—even with two fingers—can dispense (correct word is *dispense*) a prescription.

No, the primary function of pharmacists is to see that the medication is appropriate for the patient. *Appropriate* means the best medication for that patient. The first thing the pharmacist asks is, "Is the medication safe for this patient?" Then, "Will it work for the patient's

problem?" Next, "Is there a better medication?" Then, "Is there a cheaper medication that is as safe and as effective?" The pharmacist asks many other questions when receiving a prescription to dispense a medication for a patient. These points are discussed in more detail in Chapter 7, "Pharmaceutical Care."

The pharmacist's role as medication quality controller is broad. In organized healthcare settings—hospitals, clinics, managed care and extended care facilities—the pharmacist is responsible for something called the *drug use process*. Laws, rules and regulations, and standards set by various organizations and government agencies have made the director of pharmacy—the *chief pharmacist*—responsible for seeing that the drug use process is safe and efficient. The drug use process is broad and complex. It includes drug procurement and storage, prescribing, preparing, dispensing, and administering drugs and keeping records of all these things. This is further explained in Chapter 4, "The Drug Use Process."

The function of making sure the drug use process is safe and efficient is critical to the public's health. Society requires a pharmacist in the healthcare system to oversee the process of using medication (legitimate drugs). State boards of pharmacy license pharmacists to help protect the public from harmful medication errors—prescribing, dispensing, and administration—in the medication process, not just dispense medication.

Caregiver

Pharmacists are also caregivers. This is obvious from the dimensions of the pharmacist–patient relationship. The patient—not the physician, nurse, or any other healthcare provider—is the primary focus of the pharmacist. Good pharmacists dispense more than medication. At times, they dispense empathy, compassion, advice, and an encouraging word. They also make sure the patient understands what the medication is for, how to take it, and when the patient should contact his or her physician. On each dispensing of a prescription, the pharmacist should check (a) how well the medication is working, (b) any side effects, and (c) the patient's compliance with taking the medication as prescribed.

Clinician

For pharmacists to fulfill their role as caregiver, they must be clinicians.[24] A clinician in pharmacy is called a *clinical pharmacist*. Being a clinician requires knowledge of disease (anatomy, physiology, and pathology); drug therapy (medicinal chemistry, pharmacology, and therapeutics); and drug literature evaluation (drug information, research design, and biostatistics) and being able to understand and talk with patients (psychology and communication). This knowledge is used to assess patients and advise physicians and other health practitioners on drug selection, proper dosage, interactions, and side effects and how properly to monitor the drug.

In a strict sense, not all pharmacists are *clinical pharmacists*. However, all pharmacists practice some clinical pharmacy. A clinical pharmacist practices and sees patients on a full-time basis and rarely dispenses medication. Most, but not all, clinical pharmacists practice in organized healthcare settings. They are often part of patient care teams in the clinics or inpatient areas of the hospital.[25]

The goal for clinical pharmacists is to help people make the best use of their medication to achieve positive outcomes which lie in three areas:

Clinical Outcomes: Is the acute or chronic disease getting better? Are blood pressure, breathing, heart rate, serum glucose, and similar measures getting better? What

evidence is there that what a clinical pharmacist has done is making a difference in a patient?

Humanistic Outcomes: Is the patient able to function or sleep better? Has their quality of life improved?

Economic Outcomes: Is the patient going to the hospital, emergency room, or physician offices less often? Have their out-of-pocket healthcare expenses decreased?

Problem Solver

Pharmacists have a professional responsibility to problem solve the medication use process and the complex medical system on behalf of their patients. In 1986, Rucker outlined a method by which pharmacists may evoke assistance to help minimize patient risk that is not readily controlled at the treatment level when prescription therapy is authorized.[26] This approach is still viable today and is discussed in Chapter 7, "Pharmaceutical Care."

Advisor

The pharmacist is well qualified and in a unique position to help patients with their use of medicine and, in general, to advise them on health concerns. The good pharmacist listens carefully to patients' questions and problems and clarifies the situation by asking good questions. After listening and assessing the situation, the pharmacist has three options: (1) refer the patient for medical attention, (2) discuss various over-the-counter (OTC) medications with the patient, or (3) put the patient's mind at ease by letting him or her know the condition is self-limiting.

Unfortunately, the pharmacist's advisory role is underutilized by the public. This may be because most patients are unaware of the pharmacist's qualifications to fulfill this role. Many patients still think the pharmacist has only one role—to supply the medication. This problem is reinforced when the pharmacist looks busy with the dispensing process and is therefore not available to advise patients. This is further aggravated by the increasing volume of prescriptions to be dispensed in a given day.

Teacher

Pharmacy students are taught that when they become pharmacists they will also be teachers. Some will teach on a full-time basis and become faculty members at a college of pharmacy. Others will be teachers at their practice sites. The pupils are patients, pharmacy technicians, pharmacy students, pharmacy interns, pharmacy residents, and nurses. Pharmacists also train the staff working in the pharmacy about pharmacy, business, and the preferred way to provide service to patients. If pharmacists do not teach, then they are not practicing pharmacy as handed down from previous generations of pharmacists and as they have been taught.

An important distinction is needed here. Pharmacists do more than just teach pharmacy interns and residents. What they do is provide mentoring. This is different from teaching. *Mentoring* is a close and continuous relationship between a master and an apprentice that involves teaching, training, discussion, continuous monitoring by the master, and generous feedback to the apprentice.[27]

Manager, Supervisor, and Leader

Pharmacy students take coursework and receive training in management. These students learn proven methods in managing resources (human, physical, and fiscal). This prepares them for possible promotion into management positions in large pharmacies, hospitals, managed care organizations, and the pharmaceutical industry. Excellent supervisors are often promoted to managers, and the best managers often become leaders or chief executive officers of companies. However, to rise to management positions, pharmacists may need additional education by taking business courses and earning a degree in business administration (MBA).

Some pharmacists have a higher calling based on their exceptional leadership abilities. Therefore, they have an obligation to apply for leadership positions at their practice sites, like being a Director of Pharmacy (DOP) or Chief Pharmacy Officer (CPO) in a hospital. Some will emerge to lead the profession forward as the president of a state or national pharmacy organization. As a student pharmacist, do not underestimate your potential to make a difference to the profession.

Owner

Some pharmacists like working for themselves and seek the opportunity to be an entrepreneur. The joys and challenges of owning a pharmacy are well known. Owning a pharmacy used to be the dream of most new pharmacy graduates. Ownership today is more challenging because of third-party reimbursement, differential pricing of drugs by some drug manufacturers, and increasing competition by chain drugstores. However, this can be counterbalanced by providing new services and providing friendly, patient-focused care to patients.

Researcher

Some pharmacists with advanced education and training perform basic scientific and clinical research on drugs, health outcomes, or pharmacy practice. Most basic scientists (pharmacologists, pharmaceutical chemists, those working in pharmaceutics) have earned a doctoral degree. They hold positions in academia, the pharmaceutical industry, or private research companies. Most of the work is in the laboratory (*in vitro* experiments) and in animal models (*in vivo* experiments).

There are also pharmacist researchers in the social, management, and administrative pharmacy areas. These researchers usually work in academia, hold various degrees (MA, PhD, or PharmD), and have administrative and management training experience. Most of this work is performed by administering scientifically designed surveys that are statistically evaluated. Pharmacists working in clinical research usually have a doctor of pharmacy degree and advanced training to include a 1- or 2-year residency and a 2-year clinical fellowship in a defined area such as infectious disease, cardiology, psychopharmacy, clinical pharmacokinetics, or outcomes to name a few.

Sales Representative

Some pharmacists elect to work for a pharmaceutical company as a sales representative. Their job is to convince physicians to use the drugs of the company they represent. This can be difficult, as pharmacists are trained to treat a disease and to be aware of the advantages and disadvantages of all drugs available to treat a disease. At times, the pharmaceutical company's

drug may not be the best drug to treat the patient. This results in an ethical dilemma for the pharmacist, who must choose between being loyal to the company and keeping his or her ethical commitment to the profession. Fortunately, these difficulties do not occur often.

Today, many pharmaceutical companies are hiring pharmacists with doctor of pharmacy degrees and residency training. These pharmacists hold the title of *clinical liaison* rather than sales representative. These pharmacists practice differently from pharmaceutical sales assistants, who may not be pharmacists but are people with management or business training. Clinical liaisons call on targeted physicians (usually *opinion leaders*, those who influence other physicians) or physicians needing the latest clinical data on the company's drugs. This subject is discussed in more detail in Chapter 18, "Pharmaceutical and Biotechnology Industry."

Quality Reviewer

As previously mentioned, directors of pharmacy in organized healthcare settings are responsible for the drug use process within their institutions. To see how the drug use process is doing, it must be monitored. In the treatment phase of the drug use process, this monitoring is called *drug use review* and *drug use evaluation*, and these involve peer review. Drug use review is a potent tool for measuring the use and cost of drug therapy. Drug use evaluation measures the process and outcome of drug therapy and compares these results to national or local standards developed by an expert group of practitioners.

VALUE ADDER

The newest job for pharmacists is to make sure patients receive the best value for their medication therapy consistent with the newest development in healthcare called *value-added healthcare.*[28] In the inpatient setting, this is about pharmacists providing evidence-based therapy, avoiding *medication-related problems* (MRPs), and improving *transitions of care*. In the ambulatory environment, it is about pharmacists counseling the patient about medication and improving adherence.

TITLES AND CAREER PATHS

In Chapters 8 through 19, the various settings pharmacists work in are discussed in detail. There are other aspects of working as a pharmacist that need to be mentioned here: job titles and career paths for pharmacists.

Job Titles

Job titles are important as they describe and differentiate the job being done. Pharmacists also receive varying compensation depending on the job title held. Job titles in pharmacy include pharmacist (also called staff pharmacist) and clinical pharmacist. Sometimes, there are levels of these two kinds of pharmacists, often designated by the Roman numerals I, II, or III after the title (e.g., clinical pharmacist II). Other titles for pharmacists include supervisor, assistant or associate director, and manager or assistant manager. These titles are for management positions in pharmacy.

Career Paths

If the pharmacist's title has a Roman numeral after it, such as staff pharmacist II or clinical pharmacist III, it probably means there is a *career development ladder* in place. Career development ladders are common in hospitals. Each succeeding level requires more experience, exceptional annual performance reviews, and sometimes more training.

Career development ladders are helpful, as they encourage learning and growth. As pharmacists move up the ladder, they receive more pay. Sometimes, there is a bridge between the staff pharmacist ladder and the clinical pharmacist ladder. The Department of Veterans Affairs has a career ladder program with clinical privileges for pharmacists.[29] A report on a successful career ladder program in a tertiary care, academic medical center is available.[30]

EXPECTATIONS OF PHARMACISTS

Doctors, nurses, and patients have differing expectations of pharmacists. In a survey, 2600 practicing physicians in California were asked about their expectations of pharmacists. The authors concluded that, overall, doctors were not sure of what to expect of pharmacists.[31] Using a Likert scale of 1–5 (5 = strongly agree), scores above 4 included: "I expect pharmacists to be knowledgeable drug therapy experts"; "I expect community pharmacists to educate my patients about the safe and appropriate use of their medications"; and "I expect pharmacists to assist my patients in selecting appropriate nonprescription medications." Only one score was above 4 for physicians' current experience with pharmacists: "In my experience, pharmacists are a reliable source of general drug information (i.e., specific facts about drugs which can be found in standard references)."

SUPPLY AND DEMAND FOR PHARMACISTS

In 2014, there were about 291,000 pharmacists and about 67,000 pharmacies.[1] About three of five pharmacists worked in community pharmacies either independently owned or part of a drugstore chain, grocery store, department store, or mass merchandiser. Most community pharmacists are salaried employees; the others are pharmacy owners.

About one-fourth of salaried pharmacists work in hospitals, whereas others work in clinics, mail-order pharmacies, pharmaceutical wholesalers, long-term care, home healthcare agencies, academia, or the federal government. About one in five practicing pharmacists work part-time exclusively.[32]

American pharmacy can be proud that women were included in the profession almost from its beginning. However, until 1970, most pharmacy students were men. This has changed a great deal. Today, almost two-thirds of pharmacy school enrollments are women, and 13% are minority students.

Pharmacy has been fortunate. Unlike other professions, there has rarely, if ever, been a time when there have been too many pharmacists. However, there have been a few times when there have not been enough.

The pharmacy manpower project seeks to collect, analyze, and disseminate data on the supply of licensed pharmacists in the United States, the demand for pharmacy services, and related pharmacy student and workforce issues for educational, scientific, or charitable purposes. Data are routinely reported by a panel of persons who participate in the hiring of pharmacists on a direct and regular basis. It is intended that they represent the major geographic

and practice sectors of pharmacy practice in the United States.[33] The pharmacy manpower project routinely assesses the supply and demand for pharmacists by using an aggregate demand index (ADI):

5 = High demand: difficult to dispense open positions
4 = Moderate demand: some difficulty dispensing open positions
3 = Demand in balance with supply
2 = Demand less than the pharmacist supply available
1 = Demand much less than the pharmacist supply available

In March of 2016, the overall ADI was 2.94 versus 3.34 in 2010 and 4.21 in 2006. So, at this time, the supply and demand for pharmacists is about even. However, with the baby boomers approaching retirement age, the number of pharmacists may start to decrease rapidly as the volume of prescriptions rises due to more people receiving public insurance that covers some or all of the medication needed.[34]

THE REWARDS OF BEING A PHARMACIST

According to accepted theory, the rewards for work are based on intrinsic and extrinsic factors.[35] The theory goes on to explain that an employee will be motivated if the task allows for (a) achievement, (b) recognition for achievement, (c) increased responsibility, (d) opportunity for growth (professional), and (e) chance for advancement.

Intrinsic Factors

Intrinsic factors—or motivators—include achievement, recognition, the work itself, responsibility, and advancement. Most pharmacists pride themselves on the work and the quality of their work. Most also feel good about helping patients. Positive feedback from patients is a reminder of why pharmacists are doing what they are doing. Pharmacists, like most people, like accomplishing things and having their work noticed and appreciated. Some also like receiving more responsibility.

Pharmacists also like to be promoted, but this is a problem if the pharmacist prefers patient care and is not interested in management. In well-developed clinical pharmacy services in hospitals, there is someone who coordinates clinical pharmacy services and is called the *clinical coordinator*. The clinical coordinator provides clinical leadership and supervises other clinical pharmacists. However, beyond this position, there is little promotion opportunity for clinical pharmacy specialists other than management.

Extrinsic Factors

Extrinsic factors include company policy and administration, supervision, salary, interpersonal relations with coworkers, and working conditions. These factors are important to pharmacists. It is nice to work for a company where an individual who is trusted, ethical, fair, and consistent is making decisions. It is equally important to report to someone who is trustworthy and fair. Most pharmacies and pharmacy staffs are small; therefore, it is important that everyone work together as a team.

Pharmacists usually work in clean, well-lit, and well-ventilated areas. However, most pharmacists spend all day on their feet. In hospitals, pharmacists may prepare sterile

medication and must wear protective garments. In these settings, pharmacists can be exposed to potentially harmful substances such as oncology drugs, infectious diseases of patients, and contaminated blood. Of course, most pharmacists accept this, and all are trained in handling these situations.

Many community and most hospital pharmacies are open 24 hours a day; thus, some pharmacists must work the evening (usually 3 p.m. to 11 p.m.) and the night (often 11 p.m. to 7 a.m.) shifts. There is usually a shift differential in salary (usually 5%–10%) to work these off shifts. In addition, pharmacists often work weekends, holidays, and overtime. Most work about 40 hours per week.[33] Some—including most self-employed pharmacists—work more than 50 hours per week.

On January 10, 2017, the median salary for a staff pharmacist in the United States was $120,000 (range $74,000–$127,000).[36] Salary may vary by the amount of experience, location, and type of pharmacy, but not by gender.[37] Salaries for pharmacists are highest on the West Coast. Some pharmacists, especially those working for for-profit companies, receive bonuses, overtime, and profit sharing.

Because of increasing demand and the need for more pharmacists, salaries are increasing. Sometimes (based on location, hours, and competition), pharmacists make more than $120,000 per year, and those bold enough to step outside the bounds of traditional practice, such as consulting or starting an entrepreneurial venture, can reap $150,000 a year or more, but they must be willing to take a risk.[38]

Starting salaries for pharmacists working in hospitals may lag a bit behind community pharmacy salaries, but eventually will improve because of shortages and in order to retain staff. However, pharmacists in hospitals usually advance in their salaries and careers at a faster rate.

Pharmacists working for the federal government fall into several categories. The first category is that of the uniformed service commissioned officer pharmacists who work for the Department of Defense (DOD). These officers are active duty military working throughout the extensive network of DOD military installations and related organizations worldwide. Some pharmacists work for the uniformed service Commissioned Corp of the U.S. Public Health Service (USPHS), and may serve on active duty with the Department of Health and Human Services and other federal agencies (e.g., Centers for Disease Control [CDC], National Institutes of Health [NIH], Federal Drug Administration [FDA], Environmental Protection Agency [EPA], Bureau of Prisons, Indian Health Service, etc.).

USPHS Commissioned Corps officers, like DOD pharmacy officers, wear a uniform comparative to the U.S. Navy uniforms and hold rank like naval officers. However, USPHS pharmacy officers are not considered part of the "military" contingency and may be activated to military service at the discretion of the U.S. president only in times of national or worldwide wars or disasters.

Last, there are civil service pharmacists—nonmilitary federal employees who hold pay grades within the General Schedule (GS) system of the federal government. These pharmacists may serve wherever there is need for a federal GS pharmacist both within the United States (i.e., Veterans Affairs, NIH, DOD hospitals, etc.) and in federal facilities located overseas. These pharmacists have no relation to the military, and their jobs do not usually require relocation to meet the national or international needs of the military.

Most USPHS Commissioned Corps pharmacist officers enter active duty at a grade level of 0–3, which is equivalent to a captain in the U.S. Army or a lieutenant commander in the USPHS. In 2014, officers without dependents received roughly $75,708–$146,052 per year in base salary, depending on years of service, location, and the extent of housing allowance. The

gross annual income for officers with dependents was slightly higher. The housing allowance and other subsistence account for 12%–15% of this salary, and these are nontaxable benefits.

Grade level 0–4 officers with over 10 years of service can earn a base salary of $113,484–$147,360, and grade level 0–6 officers with over 20 years of service can earn a base salary of $146,052–$179,856. There is no cost to USPHS Commissioned Corps pharmacists for healthcare benefits and dental coverage, which are significant; or use of commissaries, post exchanges, and other facilities located on military installations. In addition, USPHS Commissioned officers (as with other uniformed services) may fly at no cost anywhere in the world on DOD aircraft when seating is available.[39]

Finally, USPHS Commissioned Corps pharmacists have the benefit of a 20–30-year noncontributory retirement (retirement after 20 years is voluntary and is prorated upward yearly until the officer reaches 30 years, when retirement is mandatory).

Considering benefits, the starting salary for commissioned pharmacy officers could easily equate to $76,000 per year. The USPHS has in recent years been successful in the passage of a Congressional bill that allows a $30,000 initial sign-on bonus for first-time pharmacy officers.

The second category of federal government pharmacists works for the Department of Veterans Affairs (VA) or the NIH. Pharmacist grades are GS-9 (graduate pharmacist or staff pharmacist with BS degree), GS-11 (staff pharmacist with a PharmD), GS-12 (clinical pharmacists I and II), GS-13 (clinical pharmacist with board certification), GS-14 (clinical pharmacist with board certification plus experience), and GS-13–15 (management positions). Salaries depend on the job description, education, and experience and are adjusted according to location (cost of living). As of October 24, 2016, salaries for staff pharmacist within the VA averaged $113,162 (range of $101,000–$122,000. Salaries are higher for clinical pharmacists who have completed a residency.

Salaries for full-time faculty at schools of pharmacy appointed for a calendar year vary by rank, years in rank, discipline, and school (private or public). Average salaries for the 2015–2016 calendar year for faculty with a PharmD were: dean, $246,829; associate dean, $168,658; assistant dean, $139,212; full professor, $150,282; associate professor, $120,301; assistant professor, $107,288; and instructor, $90,703.[40]

Note: Further information and detail on salaries of pharmacists working in the armed government services (such as the Army, Navy–Marines, Airforce, FBI) are discussed in Chapter 13, "Government Pharmacy."

Job Satisfaction

There have been four recent studies on pharmacist job satisfaction. One study found that overall, pharmacists were satisfied with their jobs, although those working in chain pharmacies were less satisfied than pharmacists working in other settings.[41] In another study, pharmacist job satisfaction was directly related to the number of clinical activities performed.[42] Age, income, and practice site predicts the extent of job satisfaction among pharmacists.[43] Another study showed that the most satisfied pharmacists were those who completed postgraduate training (i.e., a residency or fellowship).[44]

Job Stress

The main source of stress in pharmacy is workload. In a national study of independent and chain store pharmacists commissioned by *Drug Topics*, 52% classified their work as *heavy*, 30% as *moderate*, 17% as *extremely heavy*, and only 2% as *light*.[45]

Pharmacists taking part in this survey said they worked an average of 10 hours per day. Overall, these retail pharmacies dispensed an average of 182 prescriptions per day, with chain pharmacies dispensing more (236) than independently owned pharmacies (151). Individually, the pharmacist respondents reported dispensing an average of 120 prescriptions per day. Pharmacists working for chain pharmacies dispensed more (154 each) than pharmacists working in independently owned pharmacies (101).

North Carolina's Board of Pharmacy pioneered a regulation holding employers equally liable (with the employee pharmacist) for medication errors when a pharmacy's daily load exceeds 150 prescriptions. A recent proposal by this board would prohibit pharmacy owners from requiring their pharmacists to work more than 12 continuous hours per workday.[46] Other state boards of pharmacy are struggling with how to protect pharmacists from stress and work overload and yet not severely infringe on the rights of pharmacy owners.

LIFELONG LEARNING AND CAREER PLANNING

Graduation from pharmacy school is a beginning rather than an ending. Who teaches the pharmacist after the commencement exercise is over? No one does. The pharmacist must learn independently about the latest drugs, diseases, and drug therapy to remain competent.

Each new pharmacist needs to develop a strategy to keep up to date. Some of this will involve the consistent reading of clinical journals such as *Pharmacotherapy*, *Journal of the American Medical Association*, and the *Annals of Internal Medicine* or a specialty journal in the pharmacist's practice area. In addition, the pharmacist will want to keep up on the latest drugs and subscribe to a publication such as *The Medical Letter* or *The Pharmacist Letter* (recommend both). The cost of these publications can be shared with other pharmacists. It is recommended that pharmacists belong to some professional pharmacy organizations—local, state, and national—to keep abreast of what is happening in pharmacy. Most organizations have a journal and professional meetings throughout the year where pharmacists can take part in CE programs.

Lifelong learning and career development do not end until retirement (and sometimes not even then).[47] The challenge is to continually think about and plan for a career that will change several times before retirement. For example, a survey of 337 clinical pharmacists who began practicing clinical pharmacy during the years 1965–1974 and were about 40 years old at the time of the survey indicated these individuals changed jobs 2.1 times.[48] The percentage of the job functions of a hospital pharmacist and pharmacy faculty declined over time, whereas those in hospital pharmacy administration, academic administration, and the pharmaceutical industry increased. Thus, many pharmacy clinicians became managers, and clinical activity declined for these pharmacists.

It is also wise to consider differentiating. *Differentiation* develops competencies that collectively create a quality distinction.[49] Why is this important? It positions the pharmacist to compete more successfully for the most rewarding career opportunities. Two strategies may help make this happen. The first is to specialize in a narrowly defined area and become an expert. The second strategy is combining pharmacy and another discipline, such as business, information management, physician assistant training, law, publishing, sales, or education.

Career planning is also about coming to grips with balancing a career and a family. It can mean trying to deal with job issues when you wish or feel you should be home with your family.[50] This creates stress and guilt. Pharmacists working under these circumstances should develop coping mechanisms and have an adequate support system to be successful at both their jobs and their personal lives.

Another career planning issue involves two-pharmacist marriages. This situation can involve lifestyle issues, potential conflicts, and stress beyond what the average married couple experiences.[51] Time and home management need to be carefully worked out. What happens when both pharmacists have good careers and one wants to make a career change or move to a new city? Stress occurs. Pharmacists thinking about marriage to another pharmacist should know what lies ahead and talk with pharmacists married to other pharmacists before getting married to one. More information on career planning is provided in Chapter 20, "Career Development."

JOB OUTLOOK

The job outlook for pharmacists during the next 10–20 years is promising. The U.S. population is growing and aging. The first baby boomers reached 65 in 2011. This large population segment and healthcare reform will result in more prescriptions to dispense and patients to counsel. It is predicted that by 2020, the health system in the United States will need, at most, 417,000 pharmacists.[52] In 2016 there were 291,000 pharmacists, thus we are now short by about 126,000 pharmacists. A lot more automation and technician help may be needed to make sure pharmacy takes good care of patients in the future.

SUMMARY

Pharmacists are healthcare practitioners who help patients make the best use of their medication. They work in a variety of settings, and the patient is their number one concern. Pharmacists receive rigorous education and training and are licensed to protect the patient from harm. Pharmacists are vigilant about providing quality drug therapy and are caregivers, clinicians, listeners, advisors, teachers, and lifelong learners. Good pharmacists dispense more than medication—they are empathetic and concerned about the patient. Pharmacists are proud members of a trusted profession.

DISCUSSION QUESTIONS AND EXERCISES

1. The mission of pharmacy is for pharmacists to help patients make the best use of their medication. What is the best way to do this?
2. Some pharmacists complete a pharmacy residency. What do you see as the advantages of doing this? What do you see as the disadvantages of doing this?
3. Do the advantages of doing a residency outweigh the disadvantages of not doing a residency?
4. Some pharmacists achieve board certification in a specialty area of practice. Is this something that interests you? Why? Why not?
5. As a pharmacist, what characteristics do you feel will be prominent in your dealing with patients?
6. When you receive a doctor of pharmacy (PharmD) degree, you will be entitled to be called "doctor." How do you feel about this?
7. We may need 126,000 more pharmacists between 2016 and 2020. What ways, other than adding pharmacists, will help dispense the gap?
8. Being a pharmacist means being a lifelong learner. What does the term *lifelong learning* mean to you? What will be your strategy for being a lifelong learner?
9. Part of being a pharmacist is teaching others one on one. How do you feel about this?
10. What does it mean to be a "professional"?

CHALLENGES

1. One estimate is that there may be a shortage of pharmacists in the United States in the year 2020. For extra credit and with the approval of your professor, prepare a concise report concerning the possible options for meeting the prescription and medication needs of patients in 2020, state conclusions, and state what you think is the best option for solving this problem.
2. Based on increased education and training and perceived needs, pharmacists are expanding their scope of practice into new responsibilities and are providing cognitive services. However, routine payment for these services has been slow. For extra credit and with the permission of your professor, prepare a concise report providing convincing arguments on why payers should pay pharmacists for their cognitive services.

WEBSITES OF INTEREST

If you are a high school student and are thinking about becoming a pharmacist, it is recommended that you go to the following sites for further information about pharmacy and pharmacists:

Board of Pharmacy Specialties: http://www.bpsweb.org
Certification in geriatrics: http://www.ccgp.org
Directory of Residencies, fellowships, and graduate programs: https://www.accp.com/resandfel
The Good Pharmacist: http://www.thegoodpharmacist.com
National Association of Boards of Pharmacy: https://nabp.net
Pharmacy Workforce Center: http://www.aacp.org/resources/research/pharmacymanpower/Pages/default.aspx
ASHP Online Residency Directory: https://accred.ashp.org/aps/pages/directory/residencyprogramsearch.aspx
Residency Accreditation: https://www.ashp.org/Professional-Development/Residency-Information/Residency-Program-Directors/Residency-Accreditation
Residency Matching Program: https://www.natmatch.com/ashprmp
U.S. Bureau of Labor Statistics: http://www.bls.gov/oes/current/oes291051.htm
USPHS pharmacy: https://www.usphs.gov/profession/pharmacist

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3 Pharmacists and the Healthcare System

INTRODUCTION

Pharmacists do not practice in isolation, but practice as part of a healthcare team functioning within a healthcare system. The healthcare system in the United States is complex—so complex that no one can adequately describe it in all of its detail. With healthcare reform, care is becoming more accountable.

This chapter is about the pharmacist and the parts of the healthcare system where there is an interface between the two. The chapter presents an overview of disease; the healthcare system, and its evolution, expenditures and financing; the delivery of care; the health professions; and the place of drugs. It will end with a timeline of the history of pharmacy in the United States, and a discussion of how pharmacists play an important part in the healthcare system and healthcare reform.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- State the five leading diseases that cause death in the United States.
- Briefly explain how the healthcare system in the United States is structured and how it is changing.
- Provide a brief explanation of how medical care is delivered in the United States.
- Explain the terms "accountable care," the "patient-centered medical home," "transitions in care," "quality measures," and what they mean for pharmacists.
- Name two major sets of quality healthcare measures used in the United States.
- Compare and contrast Medicare and Medicaid.
- Explain the place of drugs in the healthcare system.
- Explain the term "medication therapy management" (MTM).
- Explain and contrast the four parts (A–D) of Medicare.
- Explain the primary role and emerging opportunities for pharmacists in the U.S. healthcare system.
- Discuss HIPAA (Health Insurance Portability and Accountability Act) and what it means for pharmacists.

DISEASE BURDEN

Disease burden is the effect on society of both disease-related mortality and disease-related morbidity.[1] For example, the major causes of death and disease burden in the world are: heart disease, chronic obstructive pulmonary disease (COPD), lower respiratory infection, trachea-bronchus-lung cancer, and HIV/AIDS.[2] The leading underlying risk factors are: high blood pressure, tobacco use, high blood glucose, physical inactivity, and being overweight or obese.

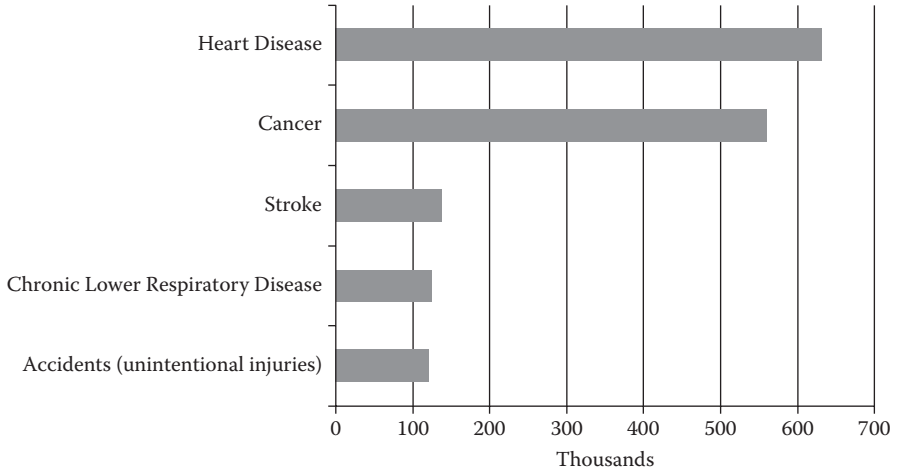

FIGURE 3.1 Number of deaths for leading causes of death in 2013 in the United States. (From Centers for Disease Control and Prevention, *National Vital Statistics Reports, Deaths: Final Data for 2013*, 64(2) February 12, 2016.)

Figure 3.1 shows the leading causes of death by disease in the United States in 2015.[3] Heart disease, cancer, and stroke represent almost 70% of all deaths. The contrast of disease burden between the United States and the rest of the world is striking.

Despite great improvements in the overall health of the nation, compelling evidence indicates that Americans who are members of racial and ethnic minority groups and those who are poor are more likely than whites to have poor health and die prematurely. The major attributable causes of death by risk factor are: tobacco, poor diet, and physical inactivity.

OVERVIEW OF THE HEALTHCARE SYSTEM IN THE UNITED STATES

The healthcare system in the United States is complex—so much so that no one can adequately describe it in all of its detail. Furthermore, it seems to be getting even more complex with healthcare reform.

Healthcare systems can be compared using five basic parameters: access, quality, cost, financing, and how providers are paid.

Access to Care

The United States is probably best in the world for its quantity and quality of health practitioners and medical facilities and our access to them, but it probably is the worst for the proportion of the population that has limited access to care because of having no health insurance or being uninsured. The United States is the only country in the developed world, except for South Africa, that does not provide healthcare for all of its citizens.

The Medicare Part D prescription benefit implemented on January 1, 2006 reduced the cost of medication, but did nothing to provide better access to care. One major impediment to insuring more people in small businesses has been that many small businesses cannot afford to provide insurance coverage for their employees.

Quality of Care

Many U.S. citizens probably think the United States has the highest quality of healthcare in the world, but this is untrue. It depends on how you measure quality. In 2016, Singapore was first among 145 countries, with an overall "health grade" of 89.5 percent. Italy ranked

second healthiest with 89.1 percent, while Australia came third with 88.3 percent, followed by Switzerland, Japan, and Israel. The United States was 37th.[4]

The World Health Organization (WHO) compares a population's health with how effectively its government spends its money on health, how well the public health system prevents illness instead of just treating it, and how fairly the poor, minorities, and other special populations are treated. Table 3.1 compares the life expectancy of some selected countries with their gross domestic product (GDP). What do you conclude from this table?

In another comparison, the United States spends the most on healthcare, but still ranks lower than many other countries.[5] The best countries are Japan, Spain, Switzerland, Italy, and France. The worst ratings for the United States are for low birth weight percentages (13th), neonatal mortality and infant mortality overall (13th), and years of potential life lost (excluding external causes) (also 13th). Note that the U.S. healthcare system is the best in responsiveness—the extent to which caregivers are responsive to patient expectations with regard to areas such as being treated with dignity and respect.

Although the use of tobacco and alcohol in excess is clearly harmful, their use does not explain the relatively poor position of the United States on health indicators. One author has suggested that the poor health ratings of the United States may be the result of three factors: (1) a relatively poor primary care infrastructure; (2) a high number of deaths from unnecessary surgery, medication errors, other medical errors, nosocomial infections, and adverse drug reactions; and (3) a high degree of income inequality.

Cost

Despite the low ranking for healthcare in the United States, the country spends the most per person on healthcare.[4] In 2014, the United States spent a stunning $9,403 per person. Japan spent the equivalent of $3,703 per person on health; France spent $4,959 per person; Canada spent $5,292 per person: and the UK spent $3,935 per person. All of these countries have a one-payer (the government) health system, while in the United States., there are thousands of insurance companies and other intermediaries (like pharmacy benefit companies) that add to cost overlaps and administrative expense.

TABLE 3.1
Life Expectancy versus Health Expenditure as a Percentage of Gross Domestic Product (GDP) for Selected Countries for 2015

Country	Life Expectancy (Years)	GDP (%)
Japan	84	10.2
Spain	82	9.0
Switzerland	83	11.7
Italy	83	9.2
France	82	11.5
Australia	82	9.4
Canada	82	10.4
United Kingdom	81	9.1
United States	79	17.1

Source: The World Bank. http://beta.data.worldbank.org. Accessed January 17, 2017.

The United States is spending more and more of its gross domestic product (GDP) on healthcare and spends the highest of all countries, at 17.1%.[6] In comparison, many countries that have better quality care spend far less of their GDP on healthcare and have longer life expectancies.

There are many reasons why healthcare in the United States is so expensive. One reason for this is the rising costs of medical technology and prescription medication, the latter of which is subsidizing the cost of medication in many other countries. The pharmaceutical companies seem shameless about this and charge what the market bears.

Perhaps the biggest reason for expensive healthcare in the United States is the administrative costs associated with operating a multipayer system, estimated to be between 19.3% and 24.1% of the total dollars spent on healthcare in the United States.[7]

Prior to healthcare reform (started in 2010), the higher proportion of uninsured and underinsured in the United States also contributed to expensive healthcare because conditions that could be treated inexpensively at the early stages of illness can later develop into health crises that are much more expensive.

Another factor is that Americans covered by health insurance have had little incentive to limit their consumption or to look at less-expensive treatment options.[8] Also, American consumers remain relatively uninformed about healthcare, are heavily dependent on their health providers to direct their healthcare purchases, and usually are not provided options concerning their care.

Financing

In 2014, the United States spent $2.6 trillion on healthcare.[9] Table 3.2 shows the money spent on healthcare in the United States from 1960 to 2014. What is the trend between private and public funding? Table 3.3 shows how the money is spent. Note the dramatic rise in prescription expenditures. This will rise even further based on the use of costly *specialty pharmaceuticals.*

Healthcare in the United States has undergone three distinct evolutions. It is currently in the fourth, moving from the era of rugged individualism to more control by the federal government.[10] For example, the proportion of healthcare spending using public funds in 1960 was 23%. In 2014, this proportion was 53% (see Table 3.2). With the advent of healthcare reform legislation passed in 2010, even more healthcare will be financed with public funds.

TABLE 3.2
Healthcare Expenditures in the United States, 1960–2014

Year	1960	1980	2000	2014
Expenditure		*Cost (Billion $)*		
Nationally	23	217	1162	2564
Private insurance	5	62	406	869
Public funds	5	97	557	1365
Out-of-pocket	13	58	199	330
Payer		*Proportion of Cost Paid*		
Private insurance	21%	28%	35%	34%
Public funds	23%	45%	48%	53%
Out-of-pocket	56%	27%	17%	13%

Source: U.S. Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, 2015.

TABLE 3.3
National Health Expenditures in Billion $ (%) by Type, 1990–2014

Expenditure	1990	2000	2010	2014
Hospital care	9 (38.6)	101 (46.3)	416 (40.7)	972 (37.9)
Physician and clinical services	6 (23.9)	48 (22.0)	289 (25.7)	604 (23.5)
Dental services	2 (8.5)	13 (6.1)	62 (5.3)	114 (4.4)
Home health care	0.1 (0.2)	2 (1.1)	32 (2.8)	83 (3.2)
Prescription drugs	***3 (11.5)***	***12 (5.6)***	***121 (6.5)***	***298 (11.6)***
Other nondurable medical products	1 (7.0)	4 (4.5)	25 (2.7)	46 (2.2)
Durable medical equipment	2 (3.2)	10 (1.9)	32 (2.2)	57 (1.8)
Nursing home care	1 (3.5)	15 (7.0)	85 (7.3)	156 (6.1)

Source: U.S. Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, 2015.

Private-Sector Funding

Many employees of large employers in the United States receive or have access to healthcare insurance. Most of these companies use an insurance company to provide healthcare benefits for their employees, and some are self-insured.

In the beginning, all insurance premiums were paid by employers, but today more and more of the cost of premiums is being paid by employees. Some employees struggle to pay their share of the premiums and the copayments and deductibles associated with their health insurance. A *deductible* is the amount the individual pays per year before the insurance payment goes into effect. A *copayment* is a percentage of the charge paid by the individual. For example, the individual may have to pay the first $300 of healthcare costs in a given year before any costs are paid by the insurance company. After the deductible is paid, the individual may have to pay a percentage (e.g., 10% in network, 30% out of network) of the charge.

The employee may be able to choose the type of health plan (e.g., managed care, preferred provider organization, or a point-of-service plan) (see Chapter 10, "Managed Care Pharmacy").

Public-Sector Funding

Public-sector funding for healthcare comes from the federal and state governments.

Medicare

Medicare, Title 18 of the Social Security Act, was enacted in 1965. Medicare is a social insurance program. Eligibility is strictly determined by age (65 and over) and is independent of means tests. Benefits are earned. The scope of benefits is narrow but broader, and financing is through special taxes paid by employees and employers. Programs are administered centrally with uniform rules by the Centers for Medicare and Medicaid.

When patients approach age 65, they may enroll in Medicare, which starts on the first day of the month when they turn 65. There are two choices: Traditional Medicare or Medicare Advantage.

Traditional Medicare provides basic coverage for hospitals (Part A) and doctors and outpatient services (Part B). It does not cover vision, dental, or hearing care. The patient can go to any doctor or hospital nationwide that accepts Medicare.

Medicare Advantage covers everything Traditional Medicare coverage does but may offer lower costs and extra services. Each plan has a different mix of costs and benefits and usually includes prescription coverage.

Medigap Supplementary policies also exist that optionally cover some out-of-pocket expenses not paid by Traditional Medicare and may cover extra services, depending on the individual policy.

Regardless of the type of Medicare plan, the Part A benefit is mandatory and covers hospital services, nursing home services, home health services, and hospice services. The Part B benefit is optional and covers medical and surgical services and entails an annual deductible and coinsurance. Unlike Part A, when payment is paid in full, a charge by a physician may not be fully paid by Medicare.

Congress created the Part C benefit for Medicare under the Balanced Budget Act of 1997 to incorporate the cost-saving measures of managed care into the Medicare program. It covers everything that Part A and Part B cover but offers this coverage in a new manner that may take the form of a health maintenance organization, preferred provider organization, medical savings account, or other new type of health plan.

The Part D benefit (prescription drug plans, PDPs) is a result of the Medicare Modernization Act of 2003. This legislation provides seniors and people with disabilities with the first comprehensive prescription drug benefit ever offered under the Medicare program and the most significant improvement to senior healthcare in nearly 40 years.

Since January 1, 2006, everyone with Medicare, regardless of income, health status, or prescription drug usage, has had access to prescription drug coverage. Medicare prescription drug coverage is insurance that covers both brand name and generic prescription drugs at participating pharmacies. Medicare prescription drug coverage provides protection for people who have high drug costs. There are two ways to get Medicare prescription drug coverage: (1) through a stand-alone Medicare PDP or (2) through a Medicare Advantage Plan or another Medicare health plan that offers medical and drug coverage. Like other insurance, beneficiaries pay a monthly premium, which varies by plan, and a yearly deductible. They also pay part of the cost of their prescriptions, including a copayment or coinsurance. There is additional help for those with limited incomes and resources—some may not have to pay a premium or deductible.

Individuals have the option of having the premium taken from their Social Security check, paying the premium directly, or having the premium taken directly from a bank account. Due to changes adopted in the federal Affordable Care Act, Medicare's Part D prescription drug coverage gap (i.e., the "donut hole") is gradually closing. In 2016, the coverage gap started when an individual and the drug plan they're enrolled in had spent a total of $3,310 on medications. For 2017, the coverage gap started when total spending reached $3,700.

Medicaid

Medicaid, or Title 19 of the Social Security Act, is a federal and state welfare program for insuring the indigent or poor. Eligibility for Medicaid is based on a means test, financing is through general revenues, and the administration is at the state level. Each state administers its own program within federal guidelines. Some services are mandated. These include inpatient and outpatient services, physician services, lab and x-ray services, skilled nursing facility services, family planning, home care services, and several others. Some services are

optional, and a state may or may not cover them (e.g., prescription drugs, intermediate care facilities, and dental services). In general, Medicaid services cover more than Medicare services. With healthcare reform, Medicaid programs are being expanded.

When the Medicare Part D prescription benefit was started on January 1, 2006, many *dual eligible* (people who qualify for both Medicare and Medicaid) were shifted from Medicaid to Medicare.

Paying Providers

Up until recently, there have been two basic methods of payment to providers (hospitals and health practitioners): (1) cost charge-based methods, the most common of which is fee for service, and (2) prospective reimbursement.

Fee-for-service: In the *fee-for-service* model, providers are at no risk and are responsible for providing all needed care. There is no incentive to contain costs; the more service you provide, the more you are paid. Hence, this model has largely been abandoned by payers.

Physicians and other health professionals are paid in one of two ways on a fee-for-service basis: fee schedules or usual-and-customary charges. In the first instance, a *relative value scale* compares procedures with respect to their length and complexity. Usual-and-customary charges are based on the typical amount charged by all physicians in the local area.

Few patients pay for prescriptions themselves (private pay). Most prescriptions are paid for by a third party. Third-party programs involve two administrative entities: the insurance company (which pays on behalf of the employer) and the pharmacy benefits manager, who administers the benefit (working with pharmacies, enrollees, and prescribers; sometimes handling the drug formulary; adjudicating claims; monitoring utilization and cost and undertaking cost containment measures). The most common way of paying pharmacies is to reimburse them on the acquisition cost of the drug plus a dispensing fee.

Prospective reimbursement: In this payment model, providers are paid ahead of time, based on formulas. The provider is at risk—using more services than necessary may cause the provider to lose money. Prospective payment using *diagnosis-related groups* (DRGs) and *capitation* is the way hospitals are paid for government patients—a set amount per diagnosis or the way health maintenance organizations (HMOs) are paid per member per time period. Prospective reimbursement provides incentives to produce care efficiently; if the costs of the hospitals and HMOs are less than the DRG or capitation rates, they get to keep the difference.

New payment methods: There is ongoing concern about providers being paid to do something with no regard for outcome. For example, a cardiologist gets paid to perform a cardiac catheterization, despite whether the patient improves, gets worse, or stays the same. This concept is part of the new thinking called *accountable care.*

Value-based purchasing: Starting in 2012, the Center on Medicare and Medicaid Services (CMS), the largest payer of healthcare, decided to no longer pay for poor outcomes like patients returning to the hospital too soon or acquiring an "in-house" (*nosocomial*) infection. CMS may no longer pay for patients who have prolonged hospital stays like from falling out of bed or experiencing a medication error. CMS penalizes hospitals for negative outcomes by paying them less than the standardized rates.[11]

Other outcomes pharmacists can impact: Pharmacists belong in *accountable care organizations* (ACOs).[12] Pharmacists can impact outcomes by performing interventions that keep patients out of the hospital, emergency room, or physician offices by optimizing therapy and improving medication adherence.

THE AFFORDABLE HEALTHCARE ACT

After many struggles and failed attempts at providing cost-effective healthcare for all citizens, the United States passed highly contested legislation in 2010 to reform healthcare (Affordable Healthcare Act, ACA).[13] The law is not perfect, but is an improvement and may be repealed and replaced, or improved starting in 2017.

The law included a large number of health-related provisions taking effect from 2010–2018. It included expanding Medicaid eligibility, subsidizing insurance premiums, providing incentives for businesses to provide healthcare benefits, prohibiting denial of coverage/claims based on preexisting conditions, establishing health insurance exchanges, and supporting medical research. It was hoped the costs of these provisions were going to be offset by a variety of taxes, fees, and cost-saving measures like new Medicare taxes for high-income brackets, taxes on indoor tanning, cuts to the Medicare Advantage program in favor of traditional Medicare, and fees on medical devices and pharmaceutical companies.

There is also a tax penalty for citizens who do not obtain health insurance (unless they are exempt due to low income or for other reasons). The Congressional Budget Office estimated that the net effect (including the reconciliation act) would reduce the federal deficit by $143 billion over the first decade, but this estimates has not been met.

Healthcare reform provides a unique opportunity for pharmacy to expand its clinical services and medication therapy management (MTM) programs. There are now permanent billing codes for MTM payments to pharmacists.

THE DELIVERY OF CARE

Meeting patient needs means meeting patients at their point of need and where they are in the health care continuum. The *healthcare continuum* starts with self-care and flows through ambulatory care (Chapter 8), acute care (Chapter 9), critical care, home care (Chapter 11), long-term care (Chapter 12), and hospice care. Disconnects can occur when patients transition from one level of care to another.

The process of care in the United States is fairly standardized in the patient–doctor relationship and when care is provided in a hospital. It is also standardized for routine dispensing of medication but less so for the delivery of pharmaceutical care, something that needs attention. Patients generally know what to expect and how to act when dealing with physicians, less so with hospital personnel, and not at all with the pharmacists trying to be more patient centered.

Patient-Centered Care

The patient–provider interface in the United States has generally been paternalistic, and leaders in the health professions are advocating a more patient-centered approach to care, which has not yet reached a tipping point. Table 3.4 lists the tenets of patient-centered care developed in 2003, but still viable today.[14] Patients secretly hope for these promises, but observation reveals a disappointing compliance with these promises in most healthcare settings. Patient-centered care is presented in more detail in Chapter 7.

The Healthcare Team

The healthcare team is comprised of many individuals—doctors, nurses, pharmacists, and other healthcare professionals (such as physician assistants and nurse practitioners)—all available to help the patient. In general, the health professions are empowered by society through

TABLE 3.4
The Attributes of Patient-Centered Care

Attribute	Meaning or Explanation
No needless death	Don't kill me
No needless pain	Don't hurt me
No helplessness	Don't make me feel helpless
No unwanted waiting	Don't make me wait
No waste	Don't waste money

Source: Berwick D.M. *Replacing Don's Right Knee*. Boston, MA: Institute for Health Care Improvement. December 4, 2003. With permission.

a covenant that goes like this: "If you will use all of your abilities and talents to help me and will protect my privacy, I will allow access to my body and provide information that may be confidential."

In general, the health professions in the United States have done a good job of holding up their end of the covenant, but they have not always done it in a patient-friendly way. Patients do die because of what we do or do not do, they have pain that is under-treated, they often feel helpless and wait a lot, and there is a great deal of waste. The problem is that not a lot has changed in the delivery of care from the patient's point of view, and patients feel helpless to change the system. Only the health professions can do that.

However, the health professions seem more concerned with labor issues that need addressing. The medical profession is dominated by specialty practice because of the payment system that favors this group. There are shortages of nurses and pharmacists, and the perfect storm—a growing older population—is nearing the shore.

THE PATIENT-CENTERED MEDICAL HOME

Practice is changing under the umbrella of the *accountable care* initiative by accepting that integrated teams work better than practicing solely. The integrated team approach to care is most evident today in the *patient-centered medical home* (PCMH) which is a "one-stop" care approach for patients where all of the ambulatory and some acute care they will need is in one place.[15] All the primary and specialty care is located there, and some medical homes include a connection to a hospital under the accountable care model. Thus, the patient has everything they need.

The PCMH is a splendid opportunity for ambulatory clinical pharmacists to show how they can improve patient outcomes and quality measures.[16] Pharmacists embedded into a PCMH team, along with physicians, nurse practitioners, and medical aids can make a big difference for patients.

Prescribing Authority

Those allowed by regulation to prescribe prescription drugs are controlled by state law. In general, in the United States, those who may prescribe drugs include doctors (medical doctors [MDs] and doctors of osteopathy [DOs]) and dentists, veterinarians, some physician assistants, and some nurse practitioners within their scopes of practice. The irony is that most

of these prescribers have less education in pharmacology and therapeutics than pharmacists with the doctor of pharmacy degree. The educational weakness of pharmacists to prescribe medication is in the area of diagnosis. That is why the best therapeutics may result from the collaborative practice of doctors (expert at diagnosis) and pharmacists (expert at drugs). This is the model used in the clinics of Veterans Affairs and in some innovative healthcare organizations.

Patient Confidentiality

Protecting the confidentiality of patient information is an ethical standard found in all health professions. In 1996, HIPAA was passed by Congress.[17] The act establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, healthcare clearinghouses, and those healthcare providers who conduct certain healthcare transactions electronically.

The law requires appropriate safeguards to protect the privacy of personal health information and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The law also gives patients the right to their health information, including the rights to examine and obtain a copy of their health records and to request corrections.

The regulations under the act applies to what are called "covered entities": healthcare providers, health plans, and healthcare clearinghouses that transmit any health information in electronic form in connection with a transaction covered under HIPAA. The regulations are made up of three distinct parts:

Transaction standards: The transaction standards call for use of common electronic claims standards, common code sets, and unique identifiers for all healthcare payers and providers.

Privacy regulations: The privacy rules govern the release of individually identifiable health information, specifying how health providers must provide notice of privacy policies and procedures to patients, obtain consent and authorization for use of information, and tell how information is generally shared and how patients can access, inspect, copy, and amend their own medical records.

Security regulations: The security regulations dictate the kind of administrative procedures and physical safeguards covered entities must have in place to ensure the confidentiality and integrity of *protected health information* (PHI).

Needless to say, all pharmacists need to be careful and only share patient information with those who have the need to know and have the authorization of the patient to know. PHI includes any information in which the patient is identified by name, social security number, or other system used to find patient information. Pharmacists need to be careful about storing such information on laptop computers or other portable electronic devices.

THE PLACE OF DRUGS IN THE HEALTHCARE SYSTEM

The Positives: Prescription drugs serve as complements to medical procedures, act as substitutes for surgery and other medical procedures (e.g., lipid-lowering drugs that lessen the need for bypass surgery), and provide new treatments where there previously were none. Some of the major advances in public health—the near eradication of polio and measles and

the decline in infectious diseases—are largely the result of vaccines and antibiotics. As the understanding of genetics increases, the possibility for pharmaceutical and biotechnology interventions will increase.

The elderly and people with disabilities are particularly reliant on prescription drugs. Not only do these people experience greater health problems, but their problems also tend to include conditions that respond to drug therapy.

Prescription drugs are the primary modality used to improve patients' health and to get them out of the hospital sooner. They mostly prevent or control ailments and diseases, but rarely cure.

Over-the-counter medications are used by most of the public to help with self-limiting health problems, and these agents serve a useful role in self-care. The roles of alternative therapies (herbs, folk medicine, megavitamins, and homeopathic remedies), although widely used, in most cases are yet to be validated scientifically.

The Negatives: Although drugs can be wonderful in providing relief and occasionally cure some ailments, they also can be dangerous. That is why society sanctions pharmacists—to keep drugs as safe as possible by making sure medication is prescribed and used correctly. Drugs can cause harm to patients in four ways: (1) error, (2) drug–drug interactions, (3) allergic reactions, and (4) adverse drug reactions. The potential harm from drugs ranges from an annoying side-effect (like drowsiness) to death. The other downside of drugs is that they can be used inappropriately resulting in failed treatment, unneeded hospitalization, emergency, and physician visits, which are costly.

THE ROLE OF PHARMACISTS IN THE U.S. HEALTHCARE SYSTEM

Pharmacists have always been a part of the healthcare system (see Figure 3.2) in the United States, but that role has changed and continues to change with time.[18] Society sanctions each health profession from the standpoint of need. If there was no need for pharmacy, the profession would not exist.[19]

The role of the pharmacist is much the same as when the profession started—to supply the medication. But through the years, there have been additions such as making sure: (1) the drug is prescribed correctly; (2) the patient understands their medication and how to take it; (3) the nurse administers the medication correctly (in the hospital); and (4) they have the drugs in their location under control.

Societal Purpose of Pharmacy

To discover what pharmacy is and what it is to become, one must start with its societal purpose. In 1985, the pharmacy profession took a hard look at itself and critically evaluated its societal purpose at an invited conference of 150 thought leaders in pharmacy. This consensus conference concluded that "pharmacy is *the* healthcare profession most concerned with drugs and their clinical application,"[20] and that the fundamental purpose of the profession is to serve as a force in society for safe and appropriate use of drugs.

Note that the purpose of the profession is not to dispense drugs. In the broadest sense, pharmacy should promote health by promoting the optimal use of drugs. The profession seeks to advocate rational drug therapy rather than merely react to treatment decisions made by others. A broader role for pharmacists as public health advisors is yet to be explored.

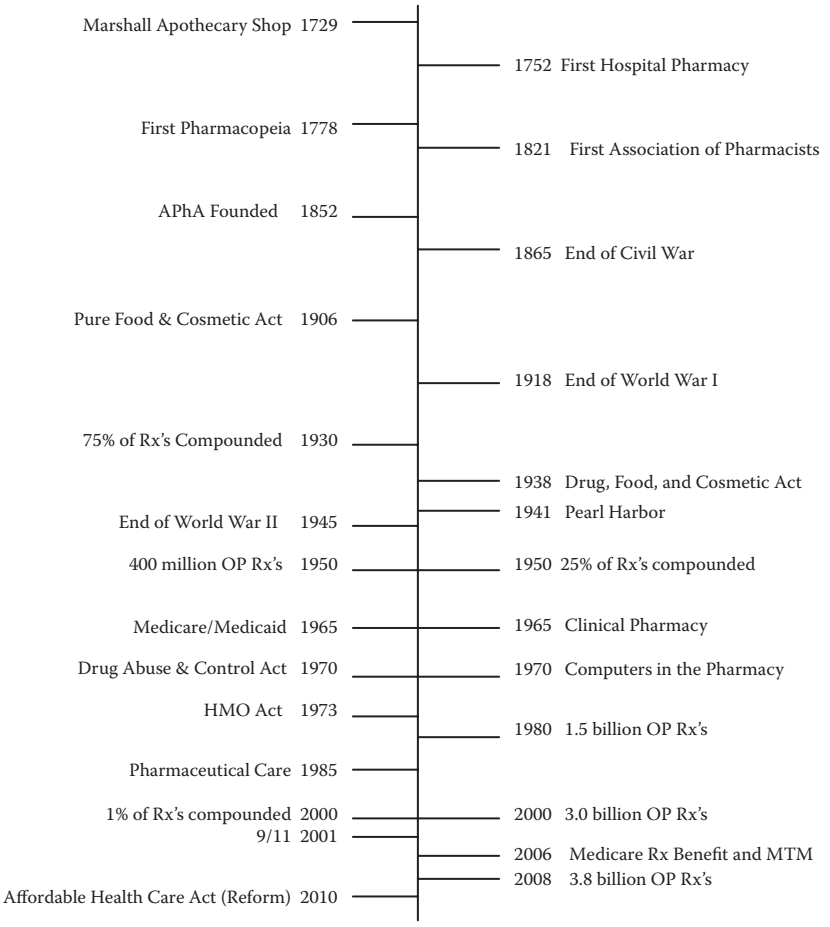

FIGURE 3.2 Timeline of the history of pharmacy in the United States.

Pharmacy's Destiny

How the profession evolves is highly dependent on how pharmacists see themselves. If most pharmacists see themselves as dispensers of medication, this is largely how others (the public, the media, and other health professionals) will view them. If most pharmacists see themselves as clinical practitioners, the profession will likely reach a tipping point and go in that direction, especially if there is a thoughtful plan in place to achieve this goal. When the country truly gets serious about healthcare reform, pharmacists need to be at the forefront with evidence of what they can and will do for patients and the healthcare system.

However, forces are at play that may prevent pharmacy from meeting its desired destiny. One of those is the unexpected growth in medication use that is outpacing the supply of pharmacists.[21] Increased workload has deterred many pharmacists from being more patient centered and from practicing pharmaceutical care.[21] The answers to meeting prescription workload demand and achieving the goals of pharmaceutical care are the use of additional supportive personnel, loosening restrictive barriers on the use of supportive personnel, and using much more pharmacy technology and automation.

ACCOUNTABLE CARE ORGANIZATIONS AND THE MEDICAL HOME

Opportunity

There are several new opportunities for pharmacist to show how they can improve patient care in the ACOs.

Cognitive Services: Pharmacy has an excellent opportunity to move toward its goal of being viewed (by the public, other health professions, and the media) as a clinical profession. Under healthcare reform, the MTM program of every health plan may be expanded. In addition, billing codes have been developed to bill for a pharmacist's cognitive services. Healthcare reform is expected to expand this clinical role for pharmacists.

Helping with Transitions of Care: It has recently come to light that gaps in care occur when there is a *transition in care.*[22] One major gap in transiting care is that the patient's medication occasionally gets fouled up. For example, important medication prescribed in the emergency room for a patient is not continued when they are admitted to the hospital. Or, when a patient is transferred from the hospital to a nursing home, the medications prescribed at discharge are not picked up by the nursing home staff and the patient is left uncovered.

Pharmacists can help by optimizing *medication reconciliation* which is a process of making sure the medications are correct when the patient transfers to a different level of care.[23]

Impacting Medication Adherence: Improving medication adherence above 80% correlates with a decrease in healthcare utilization and cost.[24] It is a role that can be an exclusive for pharmacists, and a role that healthcare payers may be interested in providing financial incentive.

Improving Quality Measures: Health plans, and in turn, PCMHs' are being provided attractive financial incentives by achieving high scores on quality measures.[25] For Medicare Advantage, there are STAR ratings, and for commercial health plans there are HEDIS measures. Even Obamacare has quality measures. Of importance is that about half of the measures involve medication, which presents a superb opportunity for pharmacists. More detail on these measures will be provided in Chapter 10, "Managed Care Pharmacy."

The keys for pharmacists to expand their role are: (a) having a strong desire and the time, (b) having the skills, (c) getting a health plan that allows them to do so, (d) having a process in place to document interventions and outcomes, and (e) having a billing mechanism in place. MTM tools are available for pharmacists.[26–27]

SUMMARY

The healthcare system in the United States is complex, responsive, and wasteful. Millions of people in the United States still do not have health insurance, and minorities and the poor are still receiving disparate care. The quality of care in the United States is not as good as 36 other countries, yet its care is by far the most expensive. Critics feel the healthcare system in the United States is broken and needs reform.

Pharmacists are a part of a healthcare team, functioning within the healthcare system. Pharmacy's societal roles are to serve as a force for safe and appropriate use of drugs and to help patients make the best use of their medication.

Healthcare reform presents exciting opportunities for pharmacists to expand their role in patient-centered care by providing value-added service that will help achieve pharmacy's long-term goals of being viewed as a clinical profession.

DISCUSSION QUESTIONS AND EXERCISES

1. Contrast and compare the disease burden of the United States with that of the rest of the world. Explain the differences.
2. Of the five leading disease causes of death in the United States, in which disease are we making the most progress? The least progress?
3. What primary method should pharmacists use to help improve the quality of healthcare in the United States?
4. Make a convincing argument regarding what the United States should do to decrease the cost of care without decreasing quality.
5. What primary method should pharmacists use to help decrease the cost of care in the United States?
6. Under HIPAA, can a pharmacist discuss a patient's drug therapy with the patient's spouse without the patient's written permission?
7. What is medication therapy management (MTM), and how does it differ from disease management?
8. What effect do you think healthcare reform will have on clinical services provided by pharmacists?
9. Select, investigate, and discuss one of the pharmacy events on the history of pharmacy timeline (Figure 3.2).
10. How will accountable care and the patient-centered medical home change drug therapy? Pharmacy practice?

CHALLENGES

1. Pharmacy is trying to be viewed as a clinical profession. For extra credit, and with the permission of your professor, prepare a concise report listing and explaining the steps the profession should go through to achieve this goal.
2. Under Medicare's Part D prescription regulations, each health plan providing the Part D benefit must have a medication therapy management program (MTMP). Investigate and visit a pharmacy performing MTM for a health plan and prepare a concise report on what you saw and discovered about MTP being performed by pharmacists.

WEBSITES OF INTEREST

Centers for Medicare & Medicaid Services: http://www.cms.gov/
Healthcare Reform: http://www.healthcare.gov/
HIPAA: http://www.hhs.gov/ocr/hipaa/

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4 The Drug Use Process

INTRODUCTION

There is a process of how drugs are distributed and used once they are approved for use in the United States. This process is complex, but organized and controlled, and is called the *drug use process*. Pharmacists are accountable for controlling much of the drug use process so drugs are used safely and effectively and not diverted into the wrong hands.

This chapter focuses on how drugs make their way to the patient after being manufactured. The chapter is divided into three sections: drug products and distribution, medication use, and patients. Drug pricing, quality drug therapy, and patient outcomes from taking medication are also discussed with emphasis on how pharmacists affect the process.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- List five general categories of drugs.
- Discuss how drugs are distributed, prescribed, and administered in the United States.
- Discuss how drugs are priced.
- Explain how the use of drugs is increasing and why.
- Discuss how pharmacists help control the drug use process.
- Discuss the concept of self-care as it relates to the use of medication.
- Define the terms *quality drug therapy, investigational drug*, and *drug order.*
- Explain the terms *patient outcome, transition-in-care,* and *specialty pharmaceuticals.*
- Explain what the following acronyms mean: OTC, CAM, MCM, PBM, DRG, DUE, and DEA.

WHAT IS THE DRUG USE PROCESS?

The drug use process is complex, so much so that a whole book could be written about it. At a minimum, it involves the process of manufacturing, storing, distributing, prescribing, pricing, dispensing, administering, using, controlling, and monitoring drugs and their effects and outcomes. This chapter presents an overview of the process.

PART I—DRUG PRODUCTS AND DISTRIBUTION

The United States has the most complex, yet the most efficient, drug distribution system in the world. Automation, such as bar coding, computerized inventories, robots, and automated information systems, keeps the products flowing. As drugs flow through the distribution system, they increase in value.[1]

Drug manufacturers, wholesalers, and retailers are the major firms responsible for the supply and distribution of medication in the United States. *Drug manufacturers* develop and produce the pharmaceutical products. Sometimes pharmacists prepare, from scratch, custom-made drug products that are not available from pharmaceutical companies. *Drug wholesalers*

distribute medication, medical devices and appliances, health and beauty aids, and other products to pharmacies and all of these, except prescription drugs, to other retailers. *Retailers* (such as pharmacies) distribute these products to patients.

The Drugs

It is estimated that there are no less than 30,000 drug products (prescription [Rx] and over the counter [OTC] drugs) in the United States. In general, there are five types of medication: (1) prescription drugs, (2) controlled substances, (3) OTC drugs, (4) investigational drugs, and (5) complementary alternative medicines (CAMs) that may be purchased with a prescription or OTC without a prescription.

A prescription medication is only available when the pharmacist receives a legal prescription or drug order from a licensed prescriber. Prescription medication used to be called *legend medication*, as it was labeled with the following required legend of the U.S. Food and Drug Administration (FDA): "Caution: Federal law prohibits using this medication without a prescription." However, the FDA now requires the phrase "Rx only." This has freed space on the label for other important information that may help decrease errors in use by the patient.

Specialty pharmaceuticals: Within the category of prescription medication, a new entity has emerged call *specialty pharmaceuticals*, which are defined as products used to treat chronic, high-cost, or rare diseases and can be injectable, infusible, oral, or inhaled medications.[2] Specialty pharmaceuticals tend to be more complex to maintain, administer, and monitor than traditional drugs; therefore they require closer supervision and monitoring of a patient's overall therapy, something pharmacists can do. Specialty pharmaceuticals have several characteristics:

- Frequent dosage adjustment
- Dosage administration of injectable and infusible
- More severe side effects than traditional drugs
- Special storage, handling, and/or administration
- Narrow therapeutic range
- Periodic laboratory or diagnostic testing
- Higher costs than "traditional" products ($10,000–$100,000 annually)
- Targets a smaller number of patients (5,000–100,000)
- Patient registration
- Patient training and clinical call center
- Compliance management
- Clinical data reporting and analysis

The nature of these agents has spurred a new domain within pharmacy's *scope of practice* called *specialty pharmacy*.[2]

Specialty pharmacy is defined as the service created to manage the handling and service requirements of specialty pharmaceuticals, including dispensing, distribution, reimbursement, case management, and other services specific to patients with rare and/or chronic diseases. Specialty pharmacy provides two key deliverables: (1) a mechanism to manage the cost of specialty pharmaceuticals for the patient; and (2) an opportunity to save money for the benefit sponsor as compared to traditional models in which products are delivered through less efficient means, primarily hospitals or physicians' offices. As a side note, *specialty pharmacies* need separate licensing to be called a *specialty pharmacy.*

Controlled substances, which are also prescription-only products, are drugs classified by the U.S. Drug Enforcement Administration (DEA) as addicting or misused. These drugs have varying levels of control on their distribution and use based on the addiction liability and potential for abuse of the drug. The Comprehensive Drug Abuse Prevention and Control Act of 1970 placed controlled substances into five schedules:

Schedule I: The drug or substance has a high potential for abuse and no currently accepted medical use in treatment in the United States. There is a lack of safety for use of the drug or other substance under medical supervision. Examples of drugs in Federal Schedule I are marijuana, heroin, and lysergic acid (LSD). *Note:* Some states allow the use of marijuana for medical conditions. However, the drug is illegal according to Federal law. At this point (2017), the DEA was not actively pursuing this illegal use.

Schedule II: The drug or other substance has a high potential for abuse, is currently accepted for medical use in treatment in the United States, or has a currently accepted medical use with severe restrictions. Abuse of the drug or other substance may lead to severe psychological or physical dependence. Examples of drugs in Schedule II are morphine, cocaine, and methadone (opioids).

Schedule III: The drug or other substance has a potential for abuse less than the drugs or other substances in Schedules I and II and has a currently accepted medical use in treatment in the United States. Abuse of the drug or other substance may lead to moderate to low physical dependence. Examples of drugs in Schedule III are barbiturates, amphetamines, and codeine.

Schedule IV: The drug or other substance has a low potential for abuse relative to the drugs and other substances in Schedule III and has a currently accepted medical use in treatment in the United States. Abuse of the drug or other substance may lead to limited physical dependence relative to the drugs or other substances in Schedule III. Examples of drugs in Schedule IV are stimulants other than amphetamine and tranquilizers such as chlordiazepoxide (Librium) and diazepam (Valium).

Schedule V: The drug or other substance has a low potential for abuse relative to the drugs and other substances in Schedule IV and has a currently accepted medical use in treatment in the United States. Abuse of the drug or other substance may lead to limited physical or psychological dependence relative to the drugs and other substances in Schedule IV. Examples of drugs in Schedule V include codeine when mixed with other ingredients to make a cough syrup and small amounts of opium when mixed with other medicinal ingredients.

A comprehensive, up-to-date list of which drugs are controlled substances and which schedule they are in is maintained by the DEA (https://www.dea.gov/druginfo/ds.shtml).

An *epidemic of prescription drug abuse* in the United States continues unabated. Opioid analgesics (such as Vicodin) are effective for severe pain, but also come with a high potential danger of overuse and addiction. The CDC estimates that the United States consumes these drugs at a greater rate (about 259 million prescriptions) than any other country in the world, and twice as much as Canada, the number two country. What is the role of the pharmacist during this epidemic? It is to help educate, monitor use, advise on proper medication security and disposal, and to work with drug enforcement agents.

Over-the-counter (OTC) drugs may be sold without a prescription. Some of these drugs may have started out as prescription drugs, but were converted to OTC status after being

found to be safe. Patients seeking an OTC medication for a health problem present a good opportunity for pharmacists to guide and help patients. Most vitamins, minerals, and nutrients are also OTC.

Investigational drugs are drugs that are being investigated and are not yet approved by the FDA for marketing. They are also defined as drugs labeled with the legend "Caution: New drug, limited by Federal Law to investigational use."

Drugs must make their way safely and efficiently from the manufacturer to the physician (all drugs), the doctor (all drugs), nonpharmacy retailer (OTCs), or the investigator (prescription and investigational drugs).

Complementary alternative medications (CAMs) are prescribed or OTC medications that are out of the mainstream of treatment options. They are considered unproven and not accepted by most medical practitioners as generally safe and effective, or as safe and effective as FDA-approved medication.

Distribution of Drugs from Pharmaceutical Manufacturers

Most of the pharmaceutical products made by manufacturers go directly to drug wholesalers and to other major distribution centers, rather than the end user. This can be tricky—production needs to meet demand. If production of a drug is high and demand is low, too much is available. This represents cost and storage problems for the manufacturer. If demand is high and production is low, there will be a shortage of the drug.

Unlike in the past, community pharmacies are rarely able to order drugs directly from the manufacturer, and if they can, the required minimum dollar amount to be ordered is high.

Pharmaceutical companies also distribute their products to distribution centers set up by chain pharmacies (such as CVS, Rite Aid, and Walgreens); mass merchandisers (such as Kmart, Target, and Walmart); and grocery store chains that have pharmacies (such as Kroger and Publix).

Although some hospitals can buy directly from the manufacturer, most buy their medication through an arrangement called *group purchasing*. Most hospitals are part of a group of hospitals. Pharmaceutical companies will ship large quantities of drugs to the buying group warehouses of these hospital groups or to wholesalers. The distribution can be similar for most managed care organizations (MCOs) such as Aetna, Cigna, Kaiser Permanente, and Prudential.

Distribution from Drug Wholesalers

The basic function of the *drug wholesaler* is to ensure a smooth, safe, and efficient distribution of products to retailers, such as community pharmacies (independent, chain, and grocery stores); mass merchandisers; and mail-order pharmacies. At the wholesaler, large pallets of drugs delivered from the manufacturer are broken down into smaller units for distribution to pharmacies, other distribution centers, and drug *repackagers*.

Drug wholesalers (such as Amerisource Bergen Brunswig, Cardinal Health Inc., and the McKesson Corporation) store manufactured goods in strategic geographical locations so they can quickly send the products to hospitals, managed care facilities, clinics, and community pharmacies. The Healthcare Distribution Management Association estimates there are about 60 wholesale corporations that run about 225 distribution centers throughout the United States. They distribute drugs to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and other healthcare providers across the country.[3]

Drug wholesalers are licensed in the state in which they are located and in the states in which they do business. As most handle controlled substances, they must also have a DEA license. They are required to adhere to strict storage and handling requirements. Drug wholesalers also must ensure the integrity of the medications they distribute. Thus, temperature and humidity must be controlled. They must protect against medications getting into the wrong hands. The latest development is to be able to trace drugs when they move from one place to another.

In addition to dispensing orders for customers, drug wholesalers provide other services such as supplying important order and inventory information for their customers, helping with claims processing, and providing computer support. Some drug wholesalers will help clients count their inventory once a year.

Distribution from Distribution Centers and Repackagers

The distribution centers of chain drugstores, mass merchandisers, food store pharmacy chains, hospital groups, and groups of independent pharmacies break down the products shipped to them from the manufacturer and ship needed supplies to their pharmacies.

There are also service centers called *repackagers*. After receiving the drugs from the pharmaceutical company or drug wholesaler, the repackager packages the drug exactly the way the customer (the pharmacy) wants it. For example, the product may be put into individual, single-dose packages with labeling and bar coding so the hospital or nursing home pharmacy does not need to do this. Another example of repackaging is *prepackaging* the drug in a container for a 30-day supply. However, the label information on the repackaged medication must be identical to the label information on the original container, as approved by the FDA, or it will be considered "misbranded" and a violation of the Federal Drug Law.

Most repackaging is done by pharmacy chains for their pharmacies. However, now that automation is available, some repackaging and the addition of bar coding to the products are being done in the hospital. The repackager needs to have a pharmacy license and must follow laws carefully so the product is not misbranded (mislabeled) or adulterated (changed the nature of).

Counterfeit Drugs

The problem of stolen and counterfeit drugs surfaced in 2004 when it was reported that the United States ranked first in worldwide incidents.[4] Counterfeit drugs can have harmful effects on patients, no effect at all, or can kill them. They can frustrate efforts to deal with the high burden of disease and undermine healthcare systems.

The World Health Organization (WHO) estimates that $200 million a year in prescriptions are counterfeit or tainted and that counterfeit drugs are a $32-million-a-year business.[5]

Counterfeit drugs can range from random mixtures of harmful substances to inactive, useless preparations. In all cases, they are unreliable, their source is unknown, and they are always illegal.

As the largest market for pharmaceuticals, the United States will continue to be a target for the distribution of contraband. The Internet has made it easier for consumers to obtain—sometimes without a prescription or a doctor's approval—prescription medication illegally. In over 50% of the cases, medications purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit.[6]

Self-Care and the Role of OTC Medication

It is important for pharmacists and pharmacy technicians to understand illness and the patient's reaction to it. Seldom do people go to a physician when they first become ill. Most wait to see if the illness abates or progresses. Some will deny that they are ill. Some will seek the advice of family or friends. Still others will take control and seek out as much information as they can about their problems.

Self-Care

There is solid agreement among health providers that patients need more involvement in their health and care. The partnership between these types of patients and healthcare providers is termed *lifestyle medicine*.[7] Documentation of increased interest in self-care is witnessed by the many self-help books, TV programs, newspaper articles, and talk shows covering the topic.

It is difficult to discover what spawned this self-care revolution. However, one thing is obvious: consumers are increasingly self-medicating with nonprescription drugs. The Nonprescription Drug Manufacturers Association has surveyed many consumers to learn about their attitudes about this practice:[8]

- Almost 7 of 10 consumers prefer to fight symptoms without taking medication, if possible.
- Among consumers, 85% believe it is important to have access to nonprescription medication.
- About 9 of 10 consumers realize they should take medication only when necessary.
- Of consumers who ended the use of their nonprescription medication, 90% did so because their medical problem or symptoms resolved.
- Even though a medication may be available without a prescription, almost 95% of consumers agreed that care should be taken when using it.
- Nearly 93% of consumers report that they read instructions before taking a nonprescription medication for the first time.

Over-the-Counter Medication

Some people who experience a health problem will go to a pharmacy to browse the over-the-counter (OTC) medication aisle for a cure. Many will try reading the labels of various OTC medications to see if the medication will cure what ails them.

Three-fifths (59%) of Americans have taken an OTC in the past 6 months.[9] This is slightly higher than taking a prescription drug in the past 6 months (54%). Three-quarters (78%) of Americans taking an OTC in the past 6 months have done so to relieve pain. Other use includes medicine for a cough, cold, flu, or sore throat (52%); allergy or sinus relief (45%); heartburn, indigestion, or other stomach problems (37%); constipation, diarrhea, or gas (21%); infections such as athlete's foot or yeast infection (12%); skin problems (10%); and other (3%).

Unfortunately, self-medicating is incomplete and imperfect. How do people seeking OTC remedies know their true diagnoses? How do they know if the problem is self-limiting, or if they need to see a physician, or even if they need to go directly to an emergency room? How do they discover if the product they are about to buy will work for the problem they are experiencing or if there is something better?

The system of self-medication works better if the patient seeks the advice of a pharmacist in the search for relief of the problem. A *good pharmacist* would be continually vigilant and notice patients walking down the OTC medication aisles of the store looking for a product. Pharmacists would be wise to do the following for these patients:

- Try to identify the real problem.
- Determine the seriousness of the problem. If serious, refer the patient to his or her physician or an emergency room or call 911.
- If the condition is self-limiting, recommend the best OTC product or other treatment.
- Recommend how the product should be used to have the best results.
- Offer to be available for follow-up.

Unfortunately, many pharmacists are too busy dispensing prescriptions to be available for OTC medication counseling. Thus, they lose a wonderful opportunity to make a difference for these patients who are in need of help. In addition, OTC medications are sold in places other than pharmacies. For these purchases, the consumer has no place to turn to for proper counsel.

It is fortunate that there is a system of self-medication in the United States and that OTC medication can be found in drugstores, convenience stores, supermarkets, and mass merchandisers. If this were not so, we would need many more physicians and healthcare facilities. A survey on patient satisfaction with pharmacy services found that patients' highest awareness of OTC medications was for cold remedies, vitamins, and dental products, and that satisfaction was high with these products.[10]

Complementary and Alternative Medications

It is estimated that 30%–50% of Americans use complementary alternative medicines (CAMs) such as herbs, acupuncture, or chiropractic care.[10] Some of the reasons people use CAMs is belief that the combination with conventional medicine would help (54.9%), belief that it would be interesting to try (50.1%), suggestion from a medical professional (25.8%), and because conventional medicine was too expensive (13.2%).

A survey asked some U.S. pharmacists about their beliefs and attitudes about CAM.[11] The percentages of pharmacists completely agreeing or somewhat agreeing with the following statements were as follows: alternative medicines are safe (33%), alternative medications are effective, 48%; I consider myself knowledgeable about alternative medicines, 47%; and I am comfortable providing information about alternative medicines, 47%. Pharmacy schools should take note of these results.

Dietary Supplements

The use of dietary products continues to grow despite knowledge of problems surrounding their use: safety, effectiveness, interactions with drugs and foods, and high cost.[11] Motivation for using these products may be (a) that they are safe because many of the products are derived from "natural sources," (b) easy access, (c) lack of motivation to use exercise and diet, and (d) hope for a quick fix to a weight problem. Many do not work and are pure shams. Counseling opportunities in this area abound for the patient-centered pharmacist.[12]

Tips for Consumers

Pharmacists advising consumers on how to use medication wisely should consider using the following tips:

- Talk to your doctor and pharmacist about your medication.
- Know what you are taking, why, and how much and how often you should take it.
- Know for how long you should take your medicine.
- Know the most important side effects of the medication you are taking.
- Avoid alcohol when taking drugs affecting the central nervous system.
- Read prescription labels.
- Keep medicines in their original containers.
- Know the names of drugs you are allergic to and tell your doctor and pharmacist, even if they do not ask.
- Know if you need to be routinely monitored for the drugs you are taking.
- Know if your drug interacts with other drugs or foods.
- Use the same pharmacy for all of your medication. Why?

Prescribing Drugs

An important part of the drug use process is how drugs are prescribed. This involves a process that is more complex than most people realize. It starts with a patient's need and the prescriber's willingness to help. In some states, the prescriber might be a physician assistant or nurse practitioner. However, these categories of healthcare workers have limited prescribing privileges and, in most cases, less drug knowledge than the pharmacist. Veterinarians may also prescribe, but only for animals, and certain drugs can be prescribed only by veterinarians and dispensed on the order of a veterinarian.

Once the physician establishes the *doctor–patient relationship*, the physician asks about the patient's *chief complaint*—the main reason the patient is seeking the physician's advice. Next are questions about the history of the present illness, followed by questions about the patient's past medical history. Once this is accomplished, the physician performs a physical examination of the patient (historically called the *laying on of hands*).

While working through this process, the physician is trying to rule out what the problem is not. The physician then may order laboratory tests to help confirm the patient's diagnosis. When all the information is complete, the patient will be told the physician's opinion of the health problem. Sometimes it may be necessary to discuss severity and prognosis (prediction of probable outcome). Treatment alternatives are discussed next. Nonmedical treatment such as exercise or rest or medication, radiation, or surgery may be advised. In any case, the role of the pharmacist assumes drug therapy is the therapy of choice.

The Prescription

If the condition warrants a prescribed medication, the drug is ordered using a prescription (ambulatory patient) or drug order (hospital/nursing home patients). A *prescription*—the slang term is *script*—is an order by a prescriber requesting the pharmacist to *dispense* (prepare, package, and label) specific medication for a patient at a particular time.[13] Before the 1960s, most prescriptions were written using Latin phrases and symbols. Thus, physicians

and pharmacists needed to know Latin. Although some Latin terms are still used today, most prescriptions are written in English.

The prescription may be written on a prescription blank, which is a piece of paper, usually 4 by 6 inches, preprinted with terms, lines, and space to write information. However, there is no legal requirement that the information be on such a form. It may be on any piece of paper, even a restaurant napkin. There is no requirement that the prescription be in writing. Most prescriptions can be provided to the pharmacist verbally. It should be documented in the prescriber's records that the medication was ordered for the patient. The pharmacist, on receiving an oral prescription from a prescriber, must, under legal requirement, immediately record the prescription in writing or in electronic format.

Parts of a Prescription

A model prescription is shown in Figure 4.1. The legal requirements for a prescription vary from state to state. However, prescriptions have eight essential features.[14]

Date: The prescription should be dated the same day it is written or ordered by the physician. It should be presented to the pharmacist within a reasonable time of seeing the physician.

Name, address, and birth date of the patient: It is important to identify the patient correctly. Names instead of initials should be used to keep from confusing a patient with someone else. All names should be spelled correctly. An address and telephone number are important in case it becomes necessary to contact the patient at a later time.

Superscription: The "Rx" symbol is the superscription that heads the introduction to the prescribed medication. *Rx* in Latin means "recipe."

Inscription: This part of the prescription contains the name, strength, and quantity of medication to be prepared.

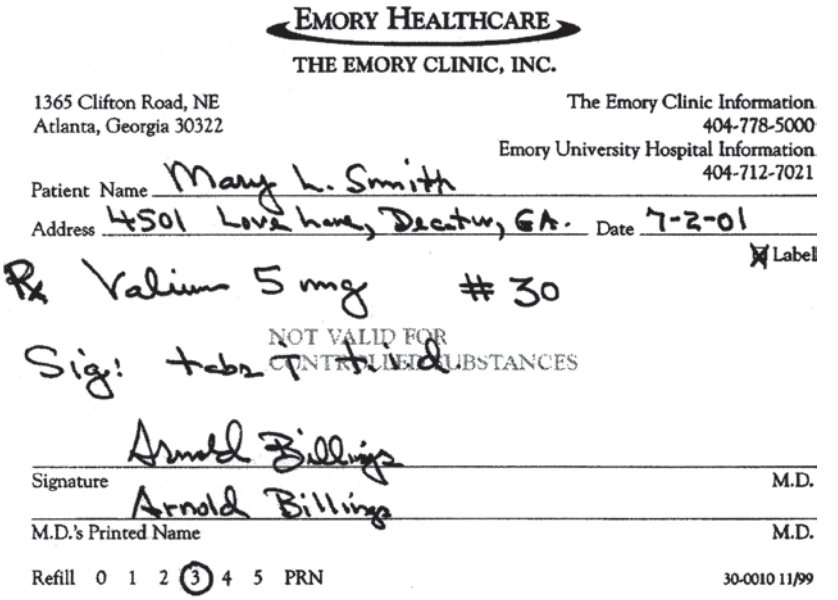
Subscription: This section may include any special instructions or directions to the pharmacist about the method of preparation and dispensing.

Signatura: This section of the prescription is usually shortened "sig." In Latin, *signatura* means "take." The signatura is the directions to be typed on the label of the prescription container. If safe, the pharmacist must put the amount of medication to be taken at one time and the number of times per day on the prescription label, as prescribed by the prescriber. However, the pharmacist may add directions to the label that help in taking the medication correctly. Other information added to the label may be the lot number and expiration date of the medication.

Refill information: It is important for patients to know if their medication can be refilled without returning to the prescriber. If there is no refill, it is better to put this on the label than to put nothing.

Signature, address, and registry number of the prescriber: The prescription must be signed by the prescriber. The signature and address of the prescriber authenticate the prescription. If the prescription is a narcotic or controlled substance, the physician's DEA registry number needs to be added.

Discussion of other requirements for narcotic and other controlled substance prescriptions is beyond the scope of this book.


EMORY HEALTHCARE

THE EMORY CLINIC, INC.

1365 Clifton Road, NE
Atlanta, Georgia 30322

The Emory Clinic Information
404-778-5000
Emory University Hospital Information
404-712-7021

Patient Name Mary L. Smith

Address 4501 Love Lane, Decatur, GA. Date 7-2-01

Label

℞ Valium 5 mg #30

Sig: tabs tid

NOT VALID FOR CONTROLLED SUBSTANCES

Arnold Billings

Signature M.D.

Arnold Billings

M.D.'s Printed Name M.D.

Refill 0 1 2 (3) 4 5 PRN

30-0010 11/99

FIGURE 4.1 An example of a prescription.

Types of Prescriptions

There are all types of prescriptions: new ones, refills, trade name, generic, narcotics, controlled substances, and compounded ones (ones made from scratch by the pharmacist).

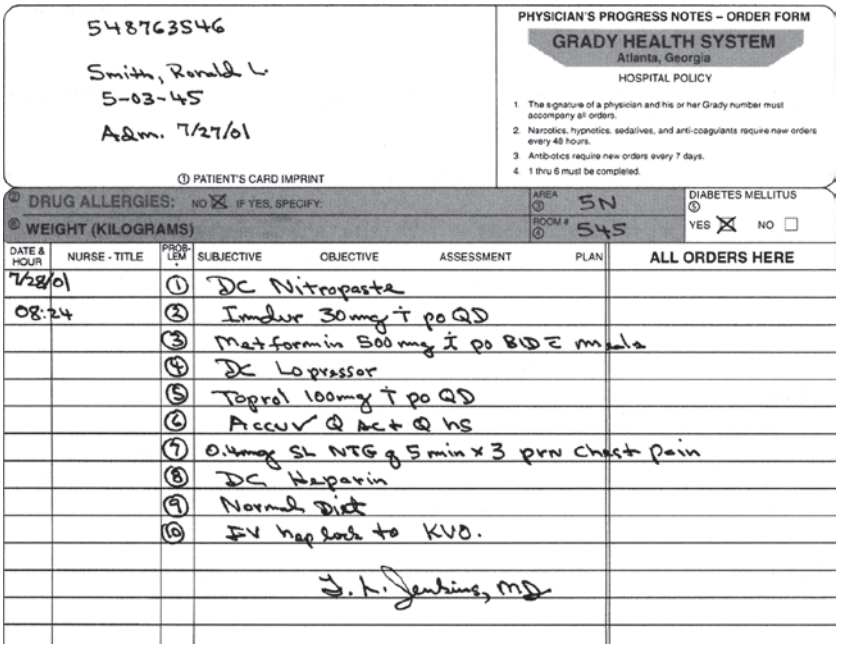
Writing the Prescription

The writing of the inscription, subscription, and *signatura* is dispensed with specific terminology and often uses Latin terms and abbreviations and apothecary, avoirdupois, or the more standard metric units of measurement. This is why most patients cannot read or understand them—or maybe it is because of poor handwriting, which pharmacists become masters at reading. However, when in doubt, the pharmacist must always call the doctor for clarification.

Drug Orders

It is important to recognize that physicians write *drug orders* for patients in organized healthcare settings—such as hospitals, managed care organizations (MCOs), and nursing homes—rather than prescriptions. The differences between a drug order and a prescription are in definition, legal status, and how they are written.

A drug order is a medication order written to a pharmacist (on paper or electronically) by a legal prescriber for an inpatient—a patient confined to a bed—of an institution. A drug order has legal requirements that exempt it from having all the information needed on a prescription, but it needs to have information beyond a prescription, such as the patient's location (room number). An example of a written drug order is shown in Figure 4.2. Most orders are now transmitted electronically. Figure 4.3 shows patient medications are listed in a patient's



548763546

Smith, Ronald L.
5-03-45
Adm. 7/27/01

① PATIENT'S CARD IMPRINT

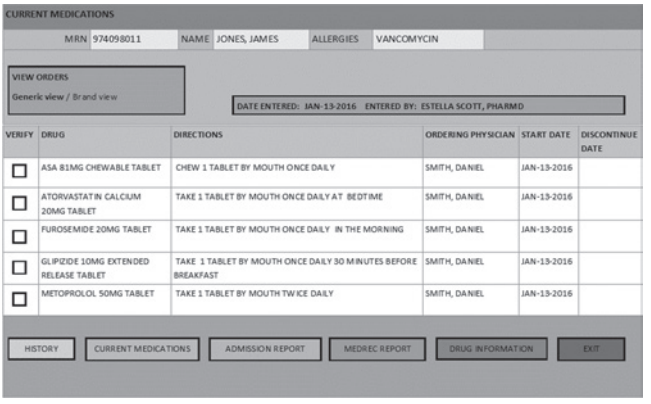
PHYSICIAN'S PROGRESS NOTES – ORDER FORM
GRADY HEALTH SYSTEM
Atlanta, Georgia
HOSPITAL POLICY

1. The signature of a physician and his or her Grady number must accompany all orders.
2. Narcotics, hypnotics, sedatives, and anti-coagulants require new orders every 48 hours.
3. Antibiotics require new orders every 7 days.
4. 1 thru 6 must be completed.

② DRUG ALLERGIES: NO ☒ IF YES, SPECIFY:
③ WEIGHT (KILOGRAMS)
AREA ① 5N
ROOM # ④ 545
DIABETES MELLITUS ⑤ YES ☒ NO ☐

DATE & HOUR	NURSE - TITLE	PROBLEM	SUBJECTIVE	OBJECTIVE	ASSESSMENT	PLAN	ALL ORDERS HERE
7/28/01		①	DC Nitropaste				
08:24		②	Imdur 30 mg T po QD				
		③	Metformin 500 mg I po BID ☰ meals				
		④	DC Lopressor				
		⑤	Toprol 100 mg T po QD				
		⑥	Accuv Q Act + Q hs				
		⑦	0.4 mg SL NTG q 5 min x 3 prn Chest pain				
		⑧	DC Heparin				
		⑨	Normal Diet				
		⑩	IV hep lock to KVO.				
			J. A. Jenkins, MD				

FIGURE 4.2 An example of a manual drug order.



CURRENT MEDICATIONS

MRN 974098011 NAME JONES, JAMES ALLERGIES VANCOMYCIN

VIEW ORDERS
Generik view / Brand view

DATE ENTERED: JAN-13-2016 ENTERED BY: ESTELLA SCOTT, PHARMD

VERIFY	DRUG	DIRECTIONS	ORDERING PHYSICIAN	START DATE	DISCONTINUE DATE
☐	ASA 81MG CHEWABLE TABLET	CHEW 1 TABLET BY MOUTH ONCE DAILY	SMITH, DANIEL	JAN-13-2016	
☐	ATORVASTATIN CALCIUM 20MG TABLET	TAKE 1 TABLET BY MOUTH ONCE DAILY AT BEDTIME	SMITH, DANIEL	JAN-13-2016	
☐	FUROSEMIDE 20MG TABLET	TAKE 1 TABLET BY MOUTH ONCE DAILY IN THE MORNING	SMITH, DANIEL	JAN-13-2016	
☐	GLIPIZIDE 10MG EXTENDED RELEASE TABLET	TAKE 1 TABLET BY MOUTH ONCE DAILY 30 MINUTES BEFORE BREAKFAST	SMITH, DANIEL	JAN-13-2016	
☐	METOPROLOL 50MG TABLET	TAKE 1 TABLET BY MOUTH TWICE DAILY	SMITH, DANIEL	JAN-13-2016	

HISTORY | CURRENT MEDICATIONS | ADMISSION REPORT | MEDREC REPORT | DRUG INFORMATION | EXIT

FIGURE 4.3 An example of a patient's medication profile for pharmacist review.

medication profile for the pharmacist once a written prescription or drug order is entered or by a pharmacy technician or when it is transmitted electronically from a physician's office.

When prescribing drugs in an organized healthcare setting, the physician normally must prescribe only those drugs found in the organization's *formulary*. A formulary is a listing of *drugs of choice*—as determined by relative drug product safety, efficacy, and effectiveness—along with information about each drug approved by the medical staff of that organization for use within the organization. More information on drug formularies is provided in Chapter 9, "Health System Pharmacy."

Drug Samples

Sometimes a patient may receive just a sample of the medication, or a sample plus a prescription for the medication. These drug samples are small quantities of the drugs supplied to the physician, usually by sales representatives of drug companies. The idea behind samples is for the patient to try the medication to see if it works and is tolerated before having his or her prescription *filled* (slang for dispensed) at a pharmacy. This might save patients money.

Pharmacists, and some regulators, such as state boards of pharmacy, health departments, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), frown on sample giveaways because of lack of control over samples, and even though they are dated, they sometimes become out of date before they are given to patients. In addition, some physicians feel they may become biased toward a certain drug or may start prescribing the most expensive drugs if they are provided samples. Therefore, some physicians refuse to accept samples.[15]

Dispensing

Prescriptions can be sent electronically to the pharmacy, but which pharmacy? There are considerations in making a decision on which pharmacy to use, which will be discussed in Chapter 8, "Ambulatory (Community) Pharmacy." The patient will decide whether to take the prescription to a pharmacist to be dispensed or whether they will pick up the prescription that was sent electronically from the prescriber's office. Surprisingly, some patients decide not to dispense or to pick up their prescriptions.[15,16]

Types of Retail Pharmacies

Patients have a variety of choices for dispensing their prescriptions: independent community pharmacies, chain store pharmacies, mass merchandiser pharmacies, food store pharmacies, mail-order pharmacies, outpatient pharmacies in hospitals, and Internet pharmacies.

Independent Community Pharmacies

Independent community pharmacies are owned and operated by a pharmacist (a sole proprietorship) or a pharmacist with other pharmacists or nonpharmacists (a partnership). Independent community pharmacies were the first pharmacies in the United States, and for many years, they were the only pharmacies.

Chain Store Pharmacies

Chain store pharmacies are usually owned and operated by large companies. However, there are a few, small, usually family-owned local chains. Chain pharmacies are run according to corporate policy, and most of the people in upper management who oversee the pharmacies in the company are not pharmacists. Examples of chain store pharmacies are CVS, Rite Aid, and Walgreens.

Mass Merchandiser Pharmacies

Mass merchandiser pharmacies are also owned by large corporations and run according to the procedures of the corporations. Like chain pharmacies, most of the people in upper management who oversee the pharmacies in the corporation are not pharmacists. Examples of mass merchandiser pharmacies are Kmart, Target, and Walmart.

Food Store Pharmacies

Food store pharmacies are located within stores in grocery store chains. They fit into the concept of "one stop shop." Like chain and mass merchandiser pharmacies, large corporations own these pharmacies. The people within the corporation who have control over the pharmacies at the corporate level may not be pharmacists. Examples of food store pharmacies are Kroger, Publix, and Albertsons.

Mail-Order Pharmacies

Mail-order pharmacies can be divided into two categories: (1) those affiliated with large *pharmacy benefits management* (PBM) companies and (2) smaller, independent operations. PBMs are used by employers, or the insurers of employers, to manage and handle pharmacy claims.

Mail-order pharmacies accept new prescriptions from patients through the mail, dispense the prescriptions, and send them back through the mail to the patients. Refills for medication are requested by telephone, electronic mail, or a postcard.

Controversy continues to surround the concept of mail-order pharmacy. A survey by J. D. Powers and Associates announced that "mail order customers are, on average, happy with service—scoring an 844 on a 1000-point satisfaction scale."[16] The next day, the National Community Pharmacists Association (NCPA) announced their survey found "48 percent of respondents who were mail-order customers had to go without medication because of late delivery."

Sometimes, the mail-order pharmacy is in a state other than the state where the patient lives. The lack of one-on-one contact with a pharmacist and the delay in receiving medication are the main reasons people do not use mail-order pharmacies. Examples of mail-order pharmacies are those associated with the American Association of Retired Persons (AARP), Express Scripts, Medco, and Caremark/CVS.

Outpatient Pharmacies in Hospitals

Some larger hospitals have outpatient pharmacies within the hospital, usually close to the entrance, the clinics, or the emergency room. These pharmacies dispense medication to *ambulatory patients*, those who are not hospitalized (outpatients). These pharmacies dispense prescriptions written by physicians on the hospital staff. They also dispense the first dispensing of a new prescription for a patient being discharged from the hospital and prescriptions for employees of the hospital.

Internet Pharmacies

Some *cyberpharmacies* have emerged. The first question about these is usually—are they legal? They are if they are licensed by the Board of Pharmacy in the state in which they are located and in the states where they are doing business. These pharmacies run much like mail-order pharmacies but with a few wrinkles. Some Internet pharmacies establish personal contact between pharmacists and patients via e-mail, using patient profiles, offering OTC sales, and providing a wide choice of delivery options, including mail, express delivery, or pick up at an affiliated retail pharmacy. Planetrx.com is an example of an Internet pharmacy.

The Dispensing Process

The dispensing of medication, a prescription, is more comprehensive than most patients realize. Most patients have never been behind a prescription counter to see what takes place. It is much more than "count and pour" (the medication) and "lick and stick" (the label). Here are the standard procedures in dispensing a prescription:

- Accepting the prescription and establishing the pharmacist–patient relationship
- Reviewing the prescription and patient information
- Reviewing the patient's medication profile
- Checking for drug interactions and proper dosage
- Reviewing the insurance coverage
- Retrieving the drug or ingredients
- Preparing or compounding (making) the medication
- Labeling the prepared medication
- Checking and dispensing the medication
- Counseling the patients about their medication

Each of these steps is discussed in more detail in Chapter 8, "Ambulatory (Community) Pharmacy."

OBRA

The act, passed in 1990, placed expectations on the pharmacist regarding how to collect important patient information, review patient therapy, and counsel patients about their medication. The act initially affected only Medicaid patients, but the states adopted the act for all patients.

Collecting Important Patient Information: Information that would be included in documented information is listed as follows:

1. Name, address, and telephone number
2. Age and gender
3. Disease state(s) (if significant)
4. Known allergies and/or drug reactions
5. Comprehensive list of medications and relevant devices
6. Pharmacist's comments about the individual's drug therapy

Reviewing Patient Therapy: The following are areas for drug therapy problems that the pharmacist must screen:

- Therapeutic duplication
- Drug–disease contraindications
- Drug–drug interactions
- Incorrect drug dosage
- Incorrect duration of treatment
- Drug–allergy interactions
- Clinical abuse/misuse of medication

Counseling Patients About Their Medication: OBRA-90 also required states to establish standards governing patient counseling. In particular, pharmacists must offer to discuss the unique drug therapy regimen of each patient when dispensing prescriptions for them.

Such discussions must include matters that are significant in the professional judgment of the pharmacist. The information that a pharmacist may discuss with a patient is as follows:

1. Name and description of the medication
2. Dosage form, dosage, route of administration, and duration of drug therapy
3. Special directions and precautions for preparation, administration, and use by the patient
4. Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered
5. Techniques for self-monitoring of drug therapy
6. Proper storage
7. Refills information
8. Action to be taken in the event of a missed dose

Drug Distribution in Organized Healthcare Settings

Although some organized healthcare settings, such as hospitals, have outpatient pharmacies that dispense medication on the order of a prescription for their ambulatory patients, most of the medication dispensed is for *inpatients*—patients confined to beds.

Inpatients receive their medication by refined, organized drug distribution systems such as *unit dose* and *centralized intravenous (IV) admixture services*. Thus, pharmacy in organized healthcare settings is practiced much differently from the way pharmacy is practiced in a community pharmacy. Besides medication distribution, which is becoming more automated, the clinical services provided by pharmacists in organized healthcare settings are more extensive and more specialized.

Further information on how medications are prepared and distributed within organized healthcare settings is presented in Chapter 9, "Health System Pharmacy."

Drug Sales

Drugs are Big Business

Today, drugs are big business—for the drug manufacturers, their investors, drug wholesalers, and corporate drugstore chains. How big is the legitimate drug business? As shown in Table 4.1, prescription medication (almost 4 billion prescriptions) is approaching a $400-billion industry in the United States, and it is getting larger.[17] As shown in Table 4.2, the proportion for *specialty pharmaceuticals* is rising.

Why Costs for Drug Prescriptions are Rising

The following are reasons for the increase in the cost of prescriptions:[18]

Spending growth in a few heavily advertised drug categories: Most of the increases in total drug spending have been among a few therapeutic categories that are heavily advertised by the drug companies. Four drug categories are increasing dramatically: oral antihistamines, antidepressants, cholesterol reducers, and antiulcer medication.

TABLE 4.1
Retail Expenditures and Prescriptions, 2009–2015

Year	Expenditures (Billion $)	Prescriptions (Billions $)
2009[a]	255.3	3.54
2010	261.2	3.54
2011	276.6	3.57
2012	280.9	3.71
2013	297.1	3.81
2014	329.9	3.92
2015[a]	356.7	3.95

Source: ASPE analysis of IMS Health NPA data from October 2009 to September 2015. Expenditure data are not available for Mail Service of Specialty Mail Service channels.

[a] Estimates for 2009 and 2015 are re-weighted to reflect annual figure.

TABLE 4.2
Retail Expenditures and Specialty Drug Expenditures, 2009–2015

Year	All Retail Drugs (Billion $)	CVS/Caremark Specialty Drugs (Billions $)	Share of Retail
2009	255.3	14.52	5.7%
2010	261.2	15.01	5.7%
2011	276.6	16.72	6.0%
2012	280.9	17.30	6.2%
2013	297.1	18.67	6.3%
2014	329.9	22.95	7.0%
2015	356.7	27.13	7.6%

Source: ASPE analysis of IMS Health NPA data from October 2009 to September 2015.

Generic drugs have a small market share despite lower prices: Although the proportion of generic drug use has been rising, the proportion of total drug sales for generic drugs has been dropping.

Spending is up because of higher prices and increased use: The proportionate increase for drugs because of rising prices is 64%, whereas the percentage because of increased use is 36%.[17] A reason for the higher prices is the introduction and widespread use of costlier new drugs. Two reasons for increased use are (1) new drugs for diseases previously unable to be treated and (2) the aging population.

Employers and health plans have increased the coverage for prescription drugs: Coverage for prescription medication has increased. Also, patients having all or a portion of their prescription drugs covered by an employer insurance plan use more medication. This is because they are insulated from knowing the true cost of their medication.

An increase of elderly individuals with treatable chronic conditions: The population in the United States is aging. Chronic healthcare conditions rise with age, many of which can be treated or controlled with prescription medication.

Direct marketing by pharmaceutical companies to consumers: The FDA allows drug companies to advertise directly to the consumer on television and through popular magazines. Advocates claim this increases awareness and sends more patients to their physicians for treatment. Critics argue that direct-to-consumer advertising results in patients pressuring physicians for the latest, most expensive drugs even when older, less-costly, and equally or more effective drugs can be used.

Economic and foreign trade relations: These often allow countries outside the United States to buy drugs at lower prices than consumers pay in the United States.

Increased cost of conducting clinical trials: The cost of clinical trials has been rising rapidly, which means only companies with hopes of producing a "blockbuster" drug will eventually be able to afford to do clinical research. This may lessen competition and increase prices further.

PART II—MEDICATION USE

How often is medication used? How is it administered? Do people always take it as prescribed? How should medication be monitored?

Medication Use in the United States

According to a national survey, over half (51%) of American adults take two or more medications each day.[19] Additionally, almost half (46%) of Americans take at least one prescription medication each day, whereas more than a quarter (28%) take multiple prescription medications daily.

The rate of prescription use is highest among older Americans. Of those 65 years old or older, 79% reported taking one prescription medication each day compared with respondents aged 55–64 (63%), 45–54 (52%), and 44 years or younger (28%). For Americans aged 65 years or older taking medication daily, the average number of drugs taken daily is four.

Among respondents who reported the use of a prescription medication within the past week, the majority (61%) indicated that the medication was for a long-term health condition. Twenty-four percent said they were treating a recurring health problem, whereas 10% indicated that they were treating a short-term, acute health condition.

Besides increased OTC sales in the United States, the use of alternative medicine (e.g., herbal supplements, megavitamins, and other nontraditional remedies) is increasing dramatically. Overall, 4 of 10 Americans are trying alternative health treatments. In the American Society of Hospital Pharmacists survey, more than one-third (39%) of respondents reported taking an average of four herbal supplements and vitamins in the past week.[18] Forty percent reported taking an average of two herbal supplements or vitamins each day.

As well as more medication being taken, there has been a shift in where patients are buying their medication. Although every community pharmacy is dispensing more prescriptions, the fastest growing are mail-order and food store pharmacies, and the slowest growing are independent community pharmacies. There is some concern that the independent community pharmacy may not be able to survive much longer.

Drug Pricing

In the early days of pharmacy, pharmacists merely set a price for the medicine they prepared. The basis for the charge was the cost of the ingredients used—mostly plant materials and

some vehicles (oils, tinctures, ointments)—the pharmacist's time, and a little extra for living expenses. Today, it is more complex.

Manufacturers

No one knows for sure how drug companies price their drugs. Every drug company does it differently, although they all probably consider some of the same issues. Because drug companies producing new drugs spend so much money in development, they are allowed to trademark their product and drug name and receive patent protection for 20 years from the time of filing. This allows the company to sell its brand-name product without competition for 20 years to help recoup the research-and-development costs for the drug and for drugs that did not make it.

Interestingly, making the drug product is usually not expensive. Therefore, this is not usually a reason for setting the price of the drug. Besides recouping development costs for new drugs, manufacturers also need money for development and for advertising, which is a major expense. Over the period 2003–2015, pharmaceutical manufacturers spent 30% of their total revenues on marketing, yet only 17% on research.[16] A large portion of the marketing cost is spent for direct-to-consumer advertising and the balance for promoting products to prescribers. The profit during this time was 20%.

Multitier Pricing

Historically, pharmaceutical manufacturers have set up different drug prices for different buyers, and this has been allowed. Drug companies charged low prices to hospitals, other large buyers like chain drug stores, and the government, the largest buyer of drugs. Independent community pharmacies and others were charged the most. Today, drug manufacturers are granting large discounts to institutional buyers, such as health maintenance organizations (HMOs), nursing homes, and hospitals.[19] Drug manufacturers are even ignoring large drugstore chains despite volume buys. Independent pharmacies, even the ones in large buying groups, are also being ignored. The National Community Pharmacists Association (NCPA) contends that community pharmacies are paying three to five times more than institutional buyers for the same brand-name drug.[20]

The drug manufacturers contend that community pharmacies do not do what institutional buyers do—move market share, use formularies, and educate physicians—which have value to the manufacturers. They say community pharmacies simply dispense prescriptions as written by physicians.

Meanwhile, independent community pharmacists are asking for a level playing field. Several years ago, thousands of pharmacies and drugstore chains launched a class action price-fixing suit against the drug manufacturers and wholesalers for discriminative pricing. Shortly thereafter, 15 drug companies settled the lawsuit for $693 million. Although these companies do not admit to any wrongdoing, they are prevented from further use of two-tier pricing.

Prices for U.S.-Made Drugs in Other Countries

One controversy, and one that upsets many patients, is that some U.S. drug manufacturers are selling their drugs outside the United States for substantially lower prices than they charge within the United States. For example, a government report found that prices on average are 72% higher in Maine than in Canada and 102% higher than in Mexico.[21,22] Some countries have government price controls on drug products, or the government purchases all of the medications and therefore can negotiate lower prices for drugs based on their buying power.

Buyers and Sellers of Prescription Drugs

Although drug manufacturers are the only pure sellers of prescription drugs, many others both buy and sell prescription drugs, for example, drug wholesalers, community pharmacists, hospitals, MCOs, and the government.

Drug Wholesalers

Drug wholesalers, such as AmerisourceBergen, Cardinal, and McKesson, purchase their drugs directly from the drug manufacturers at a price called the *wholesale average cost* (WAC). Distribution through drug wholesalers has increased beyond 80%.[23] Drug wholesalers do not make much money on the sale of an individual item (about 1%–2%).[22] Although profit margins have been dropping, drug wholesalers run efficient operations and make money by selling large amounts of many items.

Community Pharmacy

Community pharmacy includes all retail pharmacies in the community: independent, chain drugstore, food store, and mass merchandiser.

Buying

All drug pricing is based primarily on a figure called *average wholesale price* (AWP). This is the cost assigned to the product by the manufacturer and listed in a regularly published source such as the *Drug Topics Red Book* or *American Druggist Blue Book*.[24] AWP is typically *not* the average price at which wholesalers sell the drug. A common joke among pharmacists is that AWP stands for "ain't what's paid." Despite its inaccuracy, the AWP is what *third-party payers*—insurance companies and PBMs—historically have used to calculate their reimbursement for the ingredient cost of a prescription, but AWP may no longer be useful and will probably disappear from use.

Based on discussion with community pharmacists, the actual acquisition cost of a product is typically 10%–15% less than the AWP. The *actual acquisition cost* is dependent on two things: volume and loyalty. The more drugs the pharmacy buys, and the more they buy from one source (a drug wholesaler or buying group), the less the drugs will cost.

In trying to develop a more accurate figure for what pharmacists pay for drugs, third-party payers have developed the *estimated acquisition cost*. This is usually defined as AWP less some percentage discount (e.g., AWP less 10%). A recent innovation is for drug wholesalers to sell their products to the buyer at WAC plus 2% or 3%. WAC is generally about AWP minus 16.66%. Therefore, AWP is disappearing.

Selling

The only flexibility pharmacists have in pricing medication is for *private-pay patients*—those who pay for their medication out of their own pocket. Historically, community pharmacists have used three methods for pricing medication: (1) a percentage markup on the cost of the drug (cost plus 25% of cost), (2) cost of the drug plus a professional fee (cost plus $3.00), or (3) a sliding scale (cost of the drug plus a sliding fee based on the cost of the drug).

Each method has pros and cons; however, today most community pharmacists use the sliding scale method of pricing prescriptions for private-pay patients. For generic prescriptions,

many community pharmacies price these at 60% of the charge for the comparable trade name product.

Third-Party Contracts

Most of the prescriptions in the United States are paid by someone other than the patient. With healthcare reform, this proportion is rising. Insurance companies and PBMs (such as Express Scripts, Merck Medco, and PCS) that handle prescription claims processing for the health plans of various employers set up prices they will pay pharmacies for prescriptions dispensed to their clients. Community pharmacies are paid much less for dispensing third-party prescriptions than they are for dispensing prescriptions to private-pay patients. For example, a repayment for dispensing third-party prescriptions is AWP minus 12% plus $3.00. Community pharmacy owners decide on a plan based on whether it is worthwhile to take part.

Medicaid Patients

Prescriptions of patients paid by the government under the Medicaid program are reimbursed differently. Each state sets reimbursement.[25] For example, a while back, the Medicaid reimbursement to pharmacies in one state was AWP minus 10% plus $4.63, and the patient paid a $0.50 copay for each prescription. In New York, the reimbursement rate was AWP minus 10% plus $3.50 for a brand-name drug and AWP minus 10% plus $4.50 for a generic drug. Patient copays were $0.50 for a generic drug and $2.00 for a brand-name drug. In California, the reimbursement rate was AWP minus 5% plus $4.05. The copay was $1.00 for each prescription.

Medicare Patients

Patients receive Medicare after they retire, usually at 65 years of age or older. This age group uses more medications than any other age group, and retirees are usually on fixed incomes.[26] The Medicare Modernization Act, authorizing payment for outpatient prescriptions for Medicare beneficiaries, is covered in Chapter 3, "Pharmacists and the Healthcare System."

Gross Margin, Reimbursement, and Making a Profit

It is increasingly difficult for community pharmacies to stay in business. Over the past several years, many community pharmacies in the United States have closed.[27] Profitable community pharmacies have declined because third-party reimbursement programs have increased, and these programs pay less than cash-paying customers. Because of this, the private-pay patient is paying a subsidy to compensate the pharmacy for costs involved in serving third-party customers.[28]

To stay in business, pharmacies need to make a profit. Therefore, the price paid for a prescription needs to cover three elements: (1) the price the pharmacy pays for the product, (2) the cost of dispensing the prescription, and (3) net profit.

A study was conducted to estimate the reimbursement necessary to provide community pharmacies in Georgia with a reasonable profit on third-party prescription programs.[28] It was discovered that pharmacies in Georgia bought single-source prescription drugs (brand-name drugs with no competing product) for AWP minus 17.2% and multi-source drugs (drugs produced by more than one company) for AWP minus 45.1%.

The difference between the purchase price and the selling price of a drug is its *gross margin*. To compute profit, the cost of dispensing must be subtracted from the gross margin. The cost of dispensing includes salaries, supplies, and overhead (costs such as electricity, heat, and taxes). It was discovered that the median cost of dispensing a prescription was $6.41. The range was $5.18 (for mass merchandisers) to $7.19 (for traditional chain drugstores). A reasonable profit was set at 12%. This translated into making $0.54 per prescription.

The study concluded that for pharmacies in Georgia to earn a reasonable profit on third-party prescriptions, the repayment needed to be AWP minus 15% plus $6.95 for single-source drugs and minimum acquisition cost (MAC) plus $6.95 for multisource drugs. This is much higher than the reimbursements currently provided in most third-party programs.

As this shows, there is much more opportunity for pharmacies to make up some of the pricing disparity on multisource drugs, most of which are generics. Most community pharmacies price prescriptions for generic drugs at 60% of the price of the brand-name equivalent. This provides patients with cost savings while increasing the gross margin of the pharmacy.

Hospitals

In 2017, there were 5564 hospitals in the United States (down 4% from 5815 in 2010), and they all buy, dispense, and charge for many drugs.

Buying

As already mentioned, hospitals receive discounts when buying large quantities of drugs. Today, almost all hospitals have joined large buying groups to gain the lowest prices on drugs. Hospitals receive large discounts when buying drugs because they have favored status with the drug companies. This annoys many community pharmacists. A drug bought by private and nonprofit hospitals through group buying may cost only a fraction of what a community pharmacist pays for a drug, and a city or county government hospital will pay less.

The federal government is the largest single buyer of drugs. It buys drugs for Veterans Affairs Hospitals, the Department of Defense (DOD), and the U.S. Public Health Service. The government buys drugs using the Federal Supply Schedule. The Federal Supply Schedule catalog prices are interpreted as prices to "most-favored customers," such as large insurance companies and HMOs.[22] Federal Drug Supply prices are considered to be the lowest available. The patients in Veterans Affairs hospitals usually do not pay for their medication.

Drug Formularies

A *drug formulary* is a list of prescription *drugs*, both generic and brand name, used by practitioners to identify *drugs* that offer the greatest overall value. A committee of physicians, nurse practitioners, and pharmacists maintain the *formulary*.

Hospital drug formularies not only promote rational prescribing, but also reduce the cost of drugs by lowering therapeutic overlap. For example, rather than having every benzodiazepine (e.g., Valium), there is only one. This raises the amount of the one drug ordered, lowers inventory cost, and decreases the cost of the medication. This is because of the price reduction manufacturers are willing to give if their product is the only one on the formulary within a particularly therapeutic class. If every hospital in the buying group commits to using the same drug in a drug class, and only that drug, the price goes even lower.

Projecting Drug Costs

Projecting drug costs for the budget for the next year in hospitals has become a major problem as costs are rising in hospitals at unprecedented rates.[29] Rate increases happen because of the following:

1. Many new drugs are much more expensive than the drugs they are replacing.
2. New drugs have been developed for conditions previously untreated (e.g., HIV).
3. There is increasing drug use because of an increasing intensity of illness and an older patient population.
4. There is drug pricing inflation.

Selling

Hospitals establish drug charges based on what they expect private-pay patients to pay. This charge is sometimes referred to as the *usual-and-customary charge*. Each hospital has its own basis for setting the charge, and the pricing strategy usually varies by category of drug: oral solids, injections, intravenous solutions. Many of the drugs used in a hospital are not found in community pharmacies (many are injectable), but for the ones that are, the hospital charge is many times higher than is charged in the community. This, hospitals say, is to offset the necessary parts of the hospital, such as the personnel department, hospital administration, and the maintenance department, that do not directly charge for their services.

Reimbursement

Less than 10% of hospital patients are private pay. The balance of hospital patients have their bills paid by private insurance, Medicaid, or Medicare. Private insurance (such as Blue Cross/Blue Shield) negotiates prices for its patients. Medicaid sets the prices it pays for inpatient medication, just like it does for patients receiving prescriptions from a community pharmacy. The big difference is for Medicare patients.

Medicare pays for the drugs Medicare patients receive while they are in the hospital but does so indirectly through a hospital reimbursement program called *prospective reimbursement*.[30] A single national reimbursement rate has been set for this form of payment for approximately 500 *diagnosis-related groups* (DRGs). Each DRG is weighted for the extent of care needed. For each weight, there is a reimbursement figure that is reset each year. Hospitals bear the financial risk of exceeding the cost of care for each DRG. If the cost exceeds the DRG rate, they lose money. However, if they provide care at a lower cost than the DRG rate, they are rewarded with the difference. The cost of drugs is part of the overall cost of care. Thus, Medicare does not pay for each drug provided to the patient. It pays one rate for treating a patient with a specific diagnosis regardless of how many drugs or how expensive the drugs are that are used for that case.

Since the implementation of prospective reimbursement by Medicare in 1983, the DRG system of reimbursement has been adopted by other payers, including some insurance companies and many state governments. The reimbursements by third parties, such as insurance companies, and federal and state governments, have been making many hospitals struggle for survival. Because of low third-party reimbursement, there is a cost shift to private-pay patients, who pay more for the care they receive.

Managed Care

The 1990s saw explosive growth in managed care. Opponents of managed care call it "managed cost," stating that MCOs care more about cost than care. Rising drug costs are a major concern of MCOs. Although drugs comprise less than 14% of total healthcare costs, they are rising at a much faster rate than medical expenses. More on this is discussed in Chapter 10, "Managed Care Pharmacy."

Buying

MCOs purchase their drugs for use for inpatients at preferential rates based on volume and the ability to control how drugs are used within their organization. MCOs also pay for the prescriptions their members receive as outpatients through their own pharmacies, mail-order pharmacies, or community pharmacies. MCOs are able to arrange prescription discounts with community pharmacies based on the number of clients they have who may have their prescriptions dispensed. The pharmacy receives payment on a *fee-for-service basis*, which pays for the ingredient cost plus a professional fee, or on a *capitation basis*, which pays a set amount per patient every month, plus a copay for each prescription dispensed.[31] The latter method is risky for pharmacists, and most do not elect to do it.

Because managed care programs are complex and require a large prescription volume to be conducted efficiently, MCOs usually have prescription claims managed by PBMs. Reimbursement by PBMs is usually substantially lower than private-pay prescription prices.

Selling

Technically, MCOs do not make money selling drugs. MCOs put themselves at risk by contracting with employer groups to provide medical care for employees of various companies for an annual, negotiated employee fee called *capitation*. The employees become members of the MCO. At the end of the year, it is hoped—and carefully calculated—that the MCO will spend less for the healthcare of its members than it collected in capitation fees from employers. The MCOs sell these plans to employers by touting their ability to manage costs. Thus, it is usually in the best interest of the MCOs and their investors not to spend money. Thus, they are always looking for ways to spend less for drugs.

PART III—PATIENTS

Patients often have many choices of where to go to have their prescriptions dispensed. The cost of the prescription is only one factor to consider. Most patients have to have their prescriptions dispensed at a pharmacy that will accept their insurance program. However, most community pharmacies accept most insurance programs. Thus, the decision should be based on something other than price or insurance. For many, it will be convenience. Beyond this, it comes down to where the patient feels the most comfortable. Patients feel comfortable when they feel welcomed and when they know the pharmacist is competent and cares.

Economic Value of Pharmaceuticals

Despite the high and rising cost of pharmaceuticals, drugs may represent the best way to erase or control disease. They also may be the most cost-effective. Researchers discovered that the total cost of treating depression in the United States fell by 25% from the early 1990s to the mid-1990s. In addition, outcomes improved because of advances in medical treatment

and antidepressant drugs.[32] A leading selective serotonin reuptake inhibitor (SSRI) is safer and more tolerable than older drugs. Despite its higher cost, the total treatment cost for the SSRI was equal to or lower than the treatment cost of using the older agents.[33]

In another study, patients suffering from migraines benefited from taking a pain medication. Taking this medication resulted in fewer migraine-related disabilities, fewer severe migraines, and fewer hospital stays, emergency room visits, physician office visits, and disability days associated with migraine headaches. Despite the medication cost of $44 a month, overall treatment costs dropped $391 per employee per month.[34]

Medication Administration

Patients usually receive medication one of three ways: (1) self-administration, (2) administration from a friend or relative, or (3) administration from a nurse.

Self-administration is the way most medication is taken. It also may be the most dangerous. Unless the doctor, nurse, or pharmacist counsels the patient on taking the medication, the chances of the patient taking it correctly diminish. The patient should understand the name of the medication, what it is for, and what to expect from it. Most important, the patient needs to understand how to take the medication correctly.

Does taking one tablet three times a day mean three times during the waking hours or spread out every 8 hours? Does it need to be taken with water, or can it be taken with fruit juice or milk? Can patients stop taking the medication when they feel better, or do they need to take it until it is all gone? If they miss a dose, should they take twice as much next time? How should the medication be stored? What about side effects?

Medication administered by a friend or relative is needed when the patient is sick and at home. This method of medication administration may be safer than self-administration. Most people are more careful when responsible for others. They also tend to ask more questions and be careful to administer medication correctly. Friends and relatives are better at giving the medication on a schedule or reminding the patient when the medication is due to be taken.

Nurse-administered medication is the most accurate method of administering medications. Nurses know medications and how to give them, and if they do not, they have been trained to find out. Nurses pride themselves on this important function. They also have developed ways to get the most ornery patient or youngest child to ingest the medication.

No matter who administers the medication, it is easy to make an error, such as forgetting to give it, giving the wrong drug, giving too much or too little, or giving it at the wrong time. This is unfortunate, as so much effort went into seeing the physician, getting a diagnosis and a prescription, and getting the prescription dispensed. Not taking the medication properly can result in an extended illness, going back to the physician, having an adverse reaction, or possibly having to go to the emergency room or hospital. All of this results in more time and expense.

Unclaimed Prescriptions and Taking Medication

The Problem

Unclaimed Prescription: Some people never have their prescription dispensed, or if it is called in or electronically sent into the pharmacist, the medication is never picked up. How big of a problem is this? About 3.27% of people never pick up their dispensed prescriptions from community pharmacies.[35] The unclaimed prescription rate does not appear to be dependent on how the prescription arrives at the pharmacy. This unclaimed prescription

problem translates into 146 million prescriptions not being picked up and $219 million in lost sales. Reasons cited by patients for this problem were recovery from their illness, having a similar drug at home, not feeling they needed it, and not liking to take medication.

The problem of unclaimed prescriptions is also a problem for outpatient pharmacies in hospitals. A study showed that 1.6% of patients did not pick up their medication.[36] One proposed solution to this problem is to call the patients to remind them their medication is ready for pick up.

Medication Adherence: Even if a person has a prescription dispensed, it does not mean he or she will take it as prescribed. Forgetting or purposely not taking medication as prescribed is called *nonadherence*. Nonadherence (formerly called noncompliance) is a big problem. Overall, only 58% of patients take their medications as prescribed. There are various means of discovery rates of medication adherence, such as urine tests, serum tests, pill counts, patient interviews, and record reviews.[37,38] As reported in the literature, rates of nonadherence with prescribed therapy vary between 15% and 93%. The variance is explained by different patient populations, the category of drugs, how often the medication is prescribed per day, and by differences in study design.

The underlying problems associated with medication nonadherence are patient actions (decisions and behaviors).[39,40] Patients decide whether to take a medication and how often. Reasons for patients not taking their medication or not taking it as prescribed include cost, feeling better, side effects, not realizing the importance, and forgetting.

Cost

The cost of not taking medication as prescribed is high for lives lost, time lost, and added care needed. It has been estimated that 125,000 Americans die each year, simply because they fail to take their medication as prescribed.[41] The resultant effect is hundreds of thousands of extra hospital admissions (10% of the total). In one study, 36 of 89 medication-related admissions were related to medication nonadherence.[42] Of these, 54% were because of intentional nonadherence.

Another study examined the records of seven patients not taking their medication as prescribed.[43] More than $14,000 was spent on outpatient visits, hospital days, and emergency room visits over one year as a direct result of medication nonadherence.

There is also the cost of time, such as having to stay home or leave work or school to seek medical attention. The estimated cost is a loss of 20 million workdays a year or about $1.5 billion in lost earnings.[41] The annual cost of medication nonadherence in the United States is estimated to be more than $100 billion dollars.[44] Some think it may cost as much as $100–300 billion.

Recent information suggests that the more medications a person takes, the less compliant he or she becomes. Also, reducing the copays for the medication improves adherence.

Improving medication adherence should be a daily function of every pharmacist and a significant component of the profession's scope of practice.

Solutions

Once it has been determined that there is a nonadherence problem, the pharmacist should try to find out why. The most common issues are (a) cost, (b) need, (c) fear of the medication not working or causing adverse effects, and (d) forgetfulness.

Cost: The pharmacist can sometimes help with this by arranging for a generic equivalent drug or arranging with the doctor to prescribe a drug as effective as the more expensive drug but at less cost.

Need: If the patient does not feel he or she needs the drug, the pharmacist, by understanding the diagnosis and severity of illness, should be able to help convince the patient to take the drug. If not, the patient should be referred to the physician.

Fear of the medication not working or causing adverse effects: Again, the pharmacist understands the drug well—its benefits and its potential side and adverse effects—and therefore should be able to help reassure the patient.

Forgetfulness: The pharmacist can also help with this problem. Pharmacy computer systems can now be programmed to calculate when a refill is needed and to print a list of patients due for prescription refills. Postcards, telephone calls, or e-mail reminders can be sent to patients. In addition, adherence charts can be printed for patients to put on their refrigerators or bathroom mirrors. There is also reminder packaging available to show if a medication has been taken.

One of the most effective methods of improving medication adherence is for the pharmacist to shift from treating patients as passive pill takers to treating them as active participants in making decisions about their health. Patients should be asked if they know why they are taking their medication and what may happen to them if they do not take it or do not take it as prescribed.

The most effective way to improve medication adherence is by understanding why the patient is not taking the medication as prescribed and then using a combination of methods specifically designed to address the patient's reasons for not being compliant. This is not only in the patient's best interest but also in the pharmacist's best interest both clinically and economically.

Quality Drug Therapy

There is much more to being a pharmacist than making sure patients receive the drugs prescribed and doing what you can do to make sure they take the drugs as prescribed. Today, pharmacists are trained to help each patient receive *quality drug therapy*, which is safe, effective, timely, and cost-effective drug therapy delivered with care.

Pharmacists used to dispense prescriptions written by physicians and were not allowed to question whether the drug prescribed was the best drug for the patient. This has changed for various reasons. First, the drugs are becoming more complex and more potent, and there are more of them. Second, physicians cannot know everything about every drug. Third, the clinical education of the pharmacist has expanded, and fourth, the scope of practice and legal duty of the pharmacist to help and protect the patient has expanded.

Physicians prescribe drugs based on what they know and feel is best. Pharmacists see the patient from a different viewpoint, may know things the physician does not know about the drug or patient, or know about other drugs that may benefit the patient. Thus, if the pharmacist thinks the patient may benefit from changing the prescribed drug—its dose, route of administration, or dosage form or changing to another drug—there is an obligation to call the physician and discuss it. After all, healthcare is a team effort. How problems are discussed with the physician is often as important as what is discussed to effect a successful change.

This new pharmacy practice started in the early 1960s and was first called *clinical pharmacy.* Clinical pharmacy has evolved into an even higher level of practice called *pharmaceutical care*. See Chapter 7, "Pharmaceutical Care."

How Drug Therapy is Monitored and Reviewed

A major emphasis in healthcare is providing quality care. Part of this care is the drug therapy the patient receives. The quality of drug therapy can be measured. Accreditation bodies, such as the JCAHO, require the medical staff of healthcare organizations to review the quality of their drug therapy routinely and take measures to improve it. The accreditation policies usually say the director of the pharmacy will help the medical staff perform these quality reviews.

The method of reviewing the quality of drug therapy is called *drug usage evaluation* (DUE). These programs are formal, structured, ongoing comparisons of drug therapy versus locally developed criteria representing best drug therapy and making recommendations for improvement. DUE programs have evolved over the years and continue to undergo changes. Currently, most DUE programs are measures of the structure and process of prescribing drugs. More sophisticated programs also measure patient outcomes.

The original intent of DUE programs was to review the use of drugs for appropriate use within an organization such as a hospital. Drug classes were selected for review—usually quarterly—based on the opinion of the medical staff that there could be an opportunity for improvement. The director of pharmacy, working with staff pharmacists, would draft criteria for the appropriate use of the drug class under review and submit it to the *Pharmacy and Therapeutics* (P&T) Committee of the medical staff for its review, editing, and approval. The director of pharmacy is usually the secretary of this important committee.

DUE criteria can be as simple or as complex as the medical staff want. The criteria can be positive (how the drug should be used) or negative (how the drug should not be used). Criteria can include when the drug should be used, for what types of patients (such as age and gender), appropriate dosage, length of therapy, and proper monitoring procedures. Some of the items for review may have some exceptions.

Once the DUE criteria are approved, the P&T committee usually appoints the pharmacy service to perform the DUE. The P&T committee will select the review, either prospective or retrospective. In *prospective* DUEs, a random sample of patients is followed forward in time as a cohort. Prospective reviews are usually more accurate but take time and labor. *Retrospective* DUEs go backward in time and take less time and effort. This DUE is performed by selecting a random sample of medical records of patients known to have received the drug under review.

Once data are collected on how the drug was used in the sample of patients reviewed, the pharmacy service compares the use of the drug versus the preferred way of using the drug *vis-à-vis* the approved criteria. These results are then presented to the P&T committee for its review, input, and recommendations.

The JCAHO, during its accreditation visits, is interested in these recommendations. They want to know if the recommendations were carried out and if follow-up audits were completed to see if the recommendations improved therapy.

The JCAHO is interested in targeted reviews for specific problem areas, data collected prospectively, and the analysis of data with the potential to intervene more immediately in drug prescribing and to continue the process for extended periods of time. It is also pushing for including the measurement of patient outcomes in the DUE criteria. There are some excellent references for further study of the DUE process.[45–47]

Patient Outcomes

The major drawback of traditional DUE programs has been the focus on the process of drug therapy rather than the outcome of drug therapy. Focusing on the outcomes of drug therapy

provides insight into the value of the drug use process. In general, there are four categories of health outcomes:

Clinical outcomes: Clinical outcomes are the traditional outcomes measured in patients. Examples are less pain or no pain, better amount and quality of sleep, reduced anxiety, and fewer seizures. In effect, it is treatment success.

Behavior, functional, and humanistic outcomes: These *outcomes* have to do with feeling and relating to others better and the ability to do more. Examples are improved school or job attendance, better range of motion, walking further, and perceived therapeutic benefit, health status, and quality of life.

Economic outcomes: These outcomes measure the cost of the various aspects of care, and some measures try to determine the cost of improvement or benefit.

Satisfaction with care: Another improvement measure is the patient's satisfaction with the care received. To measure satisfaction with care (and for quality of life), well-built and validated questionnaires need to be used.

As a side note, just because a pharmacist intervention improves a laboratory level, this does not mean there will be an improved outcome. A better laboratory value is an intermediary or *process indicator*, and it may not result in the curtailing of diseases or achieve another positive outcome.

How pharmacists are trying to achieve better patient outcomes is covered in Chapter 7, "Pharmaceutical Care."

Medication Safety

Although medication can cure an illness or help a patient feel better, it also has the potential for harm.[48,49]

Side Effects

All drugs have *side effects* that may occur in all patients. These are known, usually minor, annoying effects of the drug experienced by most people taking the drug. An example is drowsiness associated with some antihistamine drugs used for treating hay fever symptoms.

Adverse Drug Reactions

Some drugs can cause more dangerous conditions called *adverse drug reactions*. These are unwanted, more serious, adverse effects of the drug that are not experienced by every patient taking the drug.

Allergic Drug Reactions

Patients allergic to a drug or an ingredient in the medication, even a color dye, can experience drug reactions that can vary from a minor annoyance to a threat to life. It is critical that every pharmacy, patient profile, and computer system contain information on each patient's allergies.

TABLE 4.3
Summary of Cost of Illness—Drug-Related Morbidity and Mortality

Resource	No. of Events	Approximate Cost/Event	Total Cost (%)
Physician visits	126,846,567	$109	$13,826,275,829 (7.8)
Total hospital admissions	9,609,722	$12,646	$121,524,547,864 (68.5)
Total ED visits	18,703,833	$308	$5,760,780,460 (18.5)
Total LTC facility admissions	3,454,460	$9,489	$32,779,372,199 (18.5)
Total additional prescriptions	83,735,556	$42	$3,516,893,339 (2.0)
Total deaths	218,113		
Total			$177,407,869,681 (100)

Source: Ernst FR and Grizzle AJ, JAPhA, 41, 2, 2001.
[a] Rounded to the nearest dollar ED = emergency department; LTC = long-term care.

Drug–Drug Interactions

Some drugs interact with other drugs or interact with food or drink the patient is taking. One drug can make another drug inactive or overactive. The outcome of a drug interaction can range from a minor inconvenience to death. Pharmacists must be vigilant about detecting and stopping these interactions from occurring.

Medication Errors

Medication errors rarely occur, considering the millions of prescriptions and doses of medication patients receive yearly. The incidence is a fraction of a percentage. However, this is meaningless if the error occurs to you or someone you love. Therefore, the public has zero tolerance for medication errors. That means pharmacists and pharmacy technicians have to be perfect, and there is no room for errors. Is this fair? No, because to err is human. But, its reality.

Pharmacists have built good check-and-balance systems—a safety net—for detecting medication errors before they harm patients. However, medication errors occasionally occur within the drug use process. These errors usually are the result of a medication system failure rather than the failure of one person.

Adverse drug reactions, allergic drug reactions, drug–drug interactions, and medication errors as a group are called *drug misadventures* or *adverse drug events*. These are discussed in further detail in Chapter 7, "Pharmaceutical Care."

Adverse drug events (ADEs), like those discussed above are costly. In 2001, the cost of illness from ADEs was estimated to be $177.4 billion per year.[49] Table 4.3 provides the details of this estimate. Although this study has not been updated, it provides a striking picture of the problem, and a wonderful opportunity for pharmacists.

Home Medication

As of this writing (2017), there is a major ongoing societal problem—adults and children abusing legitimately prescribed medication, primarily Schedule II and III opiates (such as Oxycontin) and tranquilizers (such as Xanax). Pharmacists need to be vigilant for the over-prescribing and overuse of these agents for a patient's welfare, but also to not be considered part of the problem. It is imperative that pharmacists stress the importance of securing such prescriptions in the home.

Control of the Drug Use Process

The drug use process is extensive and complex. It is also designed with many checks and balances to keep patients from experiencing a preventable drug misadventure.[50] At the center of this control is the pharmacist. Laws, rules and regulations, accreditation policies, and pharmacy tradition have given the pharmacist this important responsibility. Although pharmacists have accepted this responsibility, and they are up to the task, they cannot do it alone. They need the help of pharmacy technicians, other health professionals, automation, and patients who will take responsibility for their own health. They also need infrastructure support.[51]

Current Issues in the Drug Use Process

Some current issues in the drug use process deserve discussion: nutraceuticals and herbal medicines, direct-to-consumer advertising of prescription-only drugs, importing of drugs from other countries, the rising number of prescriptions, and compounding of sterile products.

Nutraceuticals and Herbal Medicines

Nutraceuticals (nutrient, vitamin, and mineral products), which are often sold in health food stores, represent a challenge to the FDA, U.S. Pharmacopeia (USP), and health professionals. Although some of these products may be helpful to patients, many are not standardized, and none are regulated. Thus, unsubstantiated claims can, and are, being made for these products without doing any controlled, scientific studies to back up the claims. In addition, several of these products have caused adverse events. Will standards be set for these products (by the USP) and will they be regulated (by the FDA)? How should physicians and pharmacists advise patients about these products?

Direct-to-Consumer Advertising of Prescription-Only Drugs

The FDA has recently allowed drug companies to advertise directly to patients via television commercials and magazine and newspaper advertisements. This has not been viewed by some healthcare professionals as wise. Based on seeing one of these ads, some patients come into physicians' offices demanding a certain drug. This puts added pressure on physicians. Even if the drug requested may not be helpful, physicians may succumb to patient pressure and prescribe a drug they know may not help and might even cause some problems for the patient. Even if the physician talks the patient out of using the drug, there may be lingering mistrust of the physician by the patient. Should the FDA continue to allow direct-to-consumer advertising of prescription-only products?

Importing of Drugs from Other Countries

The recent escalation of drug prices for patients in the United States and cheaper prices for the same drugs in other countries has caused patients, and some Internet-based businesses of questionable legal status, to obtain drugs from foreign sources.

Currently, this is an illegal practice. However, the U.S. Congress is thinking about changing laws to allow the reentry of drugs approved for use in the United States. The basis for this is that some drugs made and approved for use in the United States are shipped for use to Mexico, Canada, and other countries. The prices for these drugs are much lower than what patients pay for the same drug in the United States.

Rising Number and Cost of Prescriptions

The number of prescriptions dispensed each year is rising at an unprecedented rate. This rise is the result of increased demand and better drugs. The first individuals in the large baby boom generation turned 65 in 2011 and they will probably need more medication as they get older. It will take another 20 years before the population at age 65 and older starts to drop. The affordability of medication will continue to be a problem for many people. The proportion of expensive medication (such as *specialty pharmaceuticals*) will continue to rise, and this may put patient and government pressure on pharmaceutical companies to reduce cost.

Pharmacist Compounding of Sterile Products

Making prescription from scratch, called *compounding,* has its roots in the very beginning of pharmacy. Pharmacists have a longstanding history of making needed medications not available from pharmaceutical manufacturers. State pharmacy acts classify compounding as part of *the practice of pharmacy*. The FDA says compounding is not manufacturing (which would need batch records, lot numbers, and testing for purity, potential infection, and contents) as long as the compounded products have a prescription or drug order, and are produced on a per patient basis. Everything was fine until September 2012.

At that time, "the Centers for Disease Control and Prevention, in collaboration with state and local health departments and the Food and Drug Administration (FDA), began investigating a multistate outbreak of fungal meningitis and other infections among patients who had received contaminated steroid injections from the New England Compounding Center (NECC) in Framingham, Massachusetts. The NECC was classified as a compounding pharmacy".[52] An investigation revealed the company had been in violation of its state license because it had been functioning as a drug manufacturer, producing drugs for broad use rather than dispensing individual prescriptions.

This incident has forced the *United States Pharmacopeia* (USP) and the pharmacy profession to sharpen their standards on the extemporaneous compounding of sterile products.

SUMMARY

The drug use process is a complex, structured process involving the manufacture, distribution, prescribing, preparation, storing, dispensing, administrating, monitoring, and review of drugs and their use. The process is controlled, and at the center of this control are various checks and balances, regulations, and the pharmacist. Even with control, the system is not perfect and thus needs constant attention and improvement.[52,53]

DISCUSSION QUESTIONS AND EXERCISES

1. If you live near a pharmaceutical company, make an appointment to visit and observe how drugs are manufactured and distributed to drug wholesalers.
2. If you live near a drug wholesale company, make an appointment to visit and observe how drugs are distributed to pharmacies.
3. Make an appointment to visit a hospital pharmacy. Watch how drugs are prepared and distributed to nurses and patients.

4. Make an appointment to talk with the risk manager in a hospital about medication errors. Review at least one medication incident report.
5. A patient hands you (the pharmacist) a prescription. You note that it is a 10-fold overdose and potentially lethal.
   a. How would you handle this?
   b. If you talk to the physician, how would you handle this?
   c. If you talk to the patient, how would you handle this?
6. Go to the FDA's website (http://www.fda.gov) and go to the MedWatch program of the FDA to learn how serious adverse drug reactions are reported.
7. How do serious adverse reactions to vaccines get reported? Who can report?
8. If pharmacists are responsible for the drug use process in organized healthcare settings, and the administration of medication is a part of this process, how can pharmacists assist nurses to administer drugs safely?
9. You are the owner of a small, independent pharmacy and are the only pharmacist. A 55-year-old female patient presents you with a prescription medication used to treat multiple sclerosis. The medication is for one month and costs the patient $250. The patient says she can only afford $100. What would you do?
10. For question 9, this time you are a part-time pharmacist dispensing while the owner is off for the day. What would you do?

CHALLENGES

1. Patients not taking their medication as prescribed is a major public health problem. For extra credit, and with the permission of your professor, investigate and prepare a concise report about the problem and develop three new strategies to help combat this problem.
2. The problem of polypharmacy is real. For extra credit, and with the permission of your professor and the help of a pharmacist, identify a patient in whom polypharmacy is likely. Write a concise report about this patient's medications (not naming the patient or pharmacy) and recommend how you would reduce the polypharmacy.

WEBSITES OF INTEREST

Controlled substances: http://www.justice.gov/dea/pubs/csa.html

Counterfeit medications World Health Organization: http://www.WHO.int/mediacentre/factsheets/fs275/en/index.html

National Council on Patient Information and Education: http://www.talkaboutrx.org/index.jsp

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5 Pharmacy Supportive Personnel

This chapter is mostly about pharmacy technicians. It begins with defining supportive personnel and explaining where pharmacy technicians work and why they are needed. Next is information on what work pharmacy technicians perform, what they know, how they become certified, how they are supervised, and what it means to be professional. Finally, the chapter covers earnings, working conditions, satisfaction, advancement, and job outlook.

INTRODUCTION

Being a healthcare professional means being part of a team focused on one goal: helping the patient achieve better health. Pharmacists are a part of this healthcare team, and their duty is to help patients make the best use of their medication. This is a big job, one that pharmacists cannot do alone. Thus, the pharmacy profession developed other categories of pharmacy assistants to accomplish the work more efficiently, and to free pharmacists to spend more time with patients.

Some of the categories of supportive personnel within the pharmacy profession are couriers (delivery personnel), clerks (sales, purchasing, and billing), and data entry personnel (enter patient and drug information into the computer). In some states, these workers are called pharmacy extenders.

The most skilled supportive personnel in pharmacy are called *certified pharmacy technicians*. Pharmacy technicians work alongside pharmacists and are essential in providing comprehensive, quality, and cost-effective pharmacy services for patients.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Explain the categories of pharmacy supportive personnel.
- Define the terms pharmacy technician, certified pharmacy technician, and a pharmacist's professional judgment.
- Explain the legal limits of pharmacy technicians.
- Explain how pharmacy technicians are trained and certified.
- Discuss which functions pharmacy technicians can and cannot perform in most states.

THE PHARMACY TECHNICIAN

A *pharmacy technician* is an individual working in a pharmacy who, under the direct supervision of a licensed pharmacist, aids in the highest-level pharmacy tasks that do not require the *professional judgment* of the pharmacist. Pharmacy technicians may assist in routine activities in the pharmacy, such as unpacking goods, stocking shelves, and delivering medications, however these may also be carried out by other pharmacy extenders.

The role of the pharmacy technician is expanding because of an emerging consensus on what knowledge, skills, and abilities are needed to be a pharmacy technician and what role pharmacists should play in overall pharmacy practice, including direct patient care. Consensus is also being reached on the functions, educational training requirements, proper supervision, and recognition of pharmacy technicians by state boards of pharmacy.[1] Recognition of pharmacy technicians and their status within pharmacy has increased because of the recent creation of a national certification process.

EMPLOYMENT

In 2015, there were 379,430 pharmacy technician jobs in the United States.[2] About 7 of 10 jobs were in retail pharmacies, either independently owned or part of a drugstore chain, grocery store, department store, or mass retailer. About 2 of 10 jobs were in hospitals, and a small percentage are working in mail-order or Internet pharmacies, clinics, pharmaceutical wholesalers, and the federal government. There are now more pharmacy technicians than licensed pharmacists in the United States, and based on current workload and employment projections, more are needed.

WHY PHARMACY TECHNICIANS ARE IMPORTANT

The rising workload of prescriptions and drug orders could not be met without the services and help of pharmacy technicians and automation. This increase in workload is expected to continue for the next several decades as the "baby boomers"—those born after World War II—go through their retirement years during the next few years.

Besides meeting the prescription and drug order demand, the contribution to patient care when pharmacy technicians are used to their fullest extent cannot be overemphasized. The pharmacist and pharmacy technician working together as a team can provide higher-quality patient care. For example, there is a positive association between the use of pharmacy technicians and the extent of clinical pharmacy services provided to patients.[3] Using pharmacy technicians probably enables pharmacists to spend more time with patients, which is a goal of the profession.

Just within dispensing and drug distribution roles, a pharmacist, using proper delegation and supervision, can consistently improve both the quality and the quantity of the work. The key is to have skilled pharmacy technicians, pharmacists who recognize and know how to delegate and supervise technicians, along with a pharmacy supervisor who is diligent about overseeing the process, and recognizes their teamwork.

To work efficiently and smoothly, there should be a covenant between the pharmacist and technician. Pharmacy technicians should seek to achieve more work, free pharmacists to spend more time with patients, and keep pharmacists from making errors. The pharmacist should help pharmacy technicians learn, encourage them to do more, and provide positive feedback and appreciation when pharmacy technicians succeed in their role. All of this advances teamwork, goodwill, and morale, and enriches the workplace for everyone.

WHAT PHARMACY TECHNICIANS DO

Pharmacy technicians perform many duties, but the duties may vary by practice site. For example, what pharmacy technicians do in hospital pharmacies is somewhat different from what they do in community pharmacies. What pharmacy technicians do in mail-order pharmacies

is slightly different from what they do in community pharmacies. What pharmacy technicians do in home care pharmacies is slightly different from what is done in hospital pharmacies. What pharmacy technicians do in pharmacies serving nursing homes is somewhat different from what they do in either hospital or community pharmacies.

What a pharmacy technician is allowed to do in one state may not be allowed in another state because of differences in state pharmacy laws and regulations. What a pharmacy technician is allowed to do in one pharmacy may not be allowed in another pharmacy because of the policies and procedures of the owner or corporation, the institution, or the pharmacist under whom the pharmacy technician is working. All pharmacists are trained differently, and each pharmacist has biases about how the job should be done. Thus, pharmacy technicians need to be flexible and learn how each pharmacist wants things done. No matter what, a pharmacy technician should not be asked or allowed to do anything that would violate legal requirements.

Pharmacy technicians, if properly trained, can perform any of the dispensing and drug distribution functions of a pharmacist as long as it does not involve professional judgment or are not restricted by law. The pharmacist must check all prescriptions and drug orders dispensed before they leave the pharmacy's control (i.e., are given to a patient, caregiver, physician, nurse, etc.). It is anticipated that automation may eliminate this requirement in the future.

All pharmacy technicians may not be asked to do the same things. This will vary according to the ability and experience of the technician and whether the pharmacy is specialized or divides the work into specialized areas.

Functions of Pharmacy Supportive Personnel

Some specific functions performed by pharmacy supportive personnel are shown in Table 5.1, which lists functions by supportive personnel and what is typically performed in a community or hospital pharmacy. These functions will vary according to the state pharmacy laws, the size of the pharmacy, the number of people employed, and the direction of the pharmacist in charge.

The functions performed by hospital pharmacy technicians take a different skill set than the skill set needed in retail pharmacy. For example, after receiving training, some pharmacy technicians are allowed to compound some medications and add drugs to intravenous solutions using aseptic techniques to ensure that the solution remains sterile (not contaminated with bacteria or other infectious agents). This does not mean hospital pharmacy technicians are better than community pharmacy technicians, they just have different skillsets. At the same time, some compounding and the mixing of sterile products in community pharmacies is taking place, but lately this has been under closer scrutiny.

Pharmacy supportive personnel, especially pharmacy technicians, perform slightly different functions in specialty, home healthcare, nuclear, and consultant (extended care) pharmacies. Pharmacy technicians in home healthcare pharmacies mostly prepare special intravenous additive solutions (for pain, infection, and nutrition) and medication for patients at home. These patients receive care from visiting nurses and family as well as other health professionals—including pharmacists.

Pharmacy technicians working in *nuclear medicine pharmacies* mainly prepare low-level radioactive compounds that are injected into patients for use as diagnostic agents in nuclear medicine and radiology departments of hospitals. Pharmacy technicians working for *consultant pharmacists* prepare medications, according to a prescription, for patients in *extended care facilities* such as nursing homes, assisted-living centers, and similar specialized nursing units.

TABLE 5.1
Typical Functions of Supportive Personnel in Pharmacy[a]

Supportive Personnel	Community Pharmacy	Hospital Pharmacy
Technicians	Review the prescription	Interpret drug orders
	Verify patient information	If no computerized prescriber order entry system (CPOE), enter patient information and drug orders into computer system
	Read the prescription	Fill unit dose orders
	Enter information into computer and process through insurance	Prepare intravenous additive solutions and sometimes total parenteral nutrition (TPN) and chemotherapy solutions
	Retrieve and return medication to stock	Prepackage drugs
	Count and pour medication	Order and inventory drugs
	Label the container	Compound medication
	Present medication to a pharmacist for a final check	Present medication to a pharmacist for a final check
		Perform medication reconciliation
Clerks and assistants (and sometimes technicians)	Wait on customers	Unpack medication
	Use of point of sale software for prescription payment	Restock medication carousels
	Unpack merchandise	Deliver medication refill automated dispensing cabinets
	Stock shelves	Perform clerical functions
	Prepare insurance forms	
	Other clerical duties	

[a]Functions vary by state law and may vary from pharmacy to pharmacy.

The important role of pharmacy technicians in pharmacy practice cannot be stressed enough. At the same time, pharmacy technicians and student pharmacists need to understand how careful they need to be in their daily activities and not become complacent. Mistakes can kill patients.

WHAT PHARMACY TECHNICIANS NEED TO KNOW

Pharmacy technicians need a variety of knowledge, skills, and abilities to help pharmacists and patients.[4] These skills include the following:

- Communicating pleasantly and effectively with patients, prescriber offices, and coworkers
- Having good spelling and reading skills
- Having good math and pharmacy calculation skills
- Reading and understanding medical terminology, pharmacy jargon, and abbreviations
- Understanding and remembering generic and trade names of drugs
- Reading and interpreting prescriptions and drug orders

- Having good computer skills
- Selecting the correct drug
- Performing pharmaceutical calculations
- Counting and measuring medication
- Compounding drugs
- Labeling medication containers
- Using aseptic techniques

Successful pharmacy technicians need to be alert, organized, tidy, dedicated, good at communicating, responsible, and detail oriented. Although they should be able to work alone, they should also be willing and able to take directions from, and have their work checked by, pharmacists and *pharmacy interns* (who are pharmacy students in training and are registered by most state boards of pharmacy). They must appreciate the importance of always being precise and accurate. Candidates interested in becoming pharmacy technicians cannot have a prior record of drug or substance abuse. An exceptionally good pharmacy technician would be continually vigilant to help the pharmacist by performing some of the technical tasks that prevent the pharmacist from working directly with patients.

HOW PHARMACY SUPPORTIVE PERSONNEL ARE TRAINED

In the beginning, most pharmacy supportive personnel were trained informally and on the job. Most of the on-the-job training was done by observing another worker. This is still true for pharmacy clerks and assistants, but is less true for pharmacy technicians. Therefore, many pharmacy technicians have received some formal training where they work in an educational program, or both. Pharmacy employers prefer pharmacy technician applicants who have been formally trained, are certified, have experience as a pharmacy technician, and have strong customer service and communication skills.

Currently, there are some state requirements, but no federal ones for training pharmacy supportive personnel. For example, in Washington state, the pharmacy technician must complete a state board of pharmacy-approved training program which usually lasts 16 weeks.[5] On completing a training program, the technician must pass a final test and complete 500 hours of training to receive a certificate.

Because there are still no legal requirements in some states to train pharmacy technicians, some employers elect to train pharmacy technicians informally and on the job. Seeing the need to train community pharmacy technicians better, the National Association of Chain Drugstores and the National Community Pharmacy Association (representing independent retail pharmacies), developed *The Community Retail Pharmacy Technician Training Manual*.[6]

In 2016, there were more than 698 pharmacy technician programs in 1114 locations.[7] Programs varied widely in terms of class sizes, faculty credentials, and admission criteria. As of 2013, 258 pharmacy technician programs were accredited by the American Society for Health-System Pharmacy (ASHP).[8]

A model curriculum for formal pharmacy technician programs has been developed by the ASHP.[8] The model curriculum has 46 goals with many objectives for each goal.

Pharmacy technician training programs can receive *accreditation*—assurance that the program meets minimum standards as an acceptable program to most pharmacists—from the ASHP. The main objectives of accreditation are to (1) upgrade and standardize the formal training that pharmacy technicians receive; (2) guide, assist, and recognize those healthcare facilities and academic institutions that wish to support the profession by operating such programs;

(3) provide criteria for the prospective technician trainee in the selection of a program by identifying those institutions conducting accredited pharmacy technician programs; and (4) provide prospective employees a basis for determining the competency of pharmacy technicians by identifying technicians who have successfully completed accreditation.

In an article "Has the Time Come for National Standards on Technician Training?" the issue arose regarding whether the *Accreditation Council for Pharmacy Education* (ACPE) should establish uniform national requirements for technician training.[9] This issue was spurred by the ASHP setting pharmacy technician training standards in eight areas:

1. Administrative responsibility for the program
2. Qualifications of the training site
3. Qualifications of the pharmacy service
4. Qualifications of the program director and preceptors
5. Qualifications and selection of the applicant
6. The technician training program
7. Experimentation and innovation
8. Granting a certificate

To meet current ASHP standards, technician training programs should provide a minimum of 600 hours of training over 15 weeks or more. A list of ASHP-accredited pharmacy technician programs is available from the ASHP or is available on the Internet.[10]

The issue of national standards for pharmacy technician training was also spurred by the "White Paper on Pharmacy Technicians: Needed Changes Can No Longer Wait," which was endorsed by many pharmacy and pharmacy technician organizations.[11]

In 2014, the American College of Pharmacy Education authored a report titled "Advancing the Pharmacy Profession Together through Pharmacy Technician and Pharmacy Education Partnerships."[12] This document is considered a key blue print for the profession to move forward over the next 10 years.

TECHNICIAN CERTIFICATION AND COMPETENCY

Certification

In 1995, the pharmacy profession developed a voluntary, national *certification* process for pharmacy technicians. *Certification* is a process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association.[13] The *Pharmacy Technician Certification Board* (PTCB) was established to create one consolidated, national technician examination and certification process. In May 2009, the *National Association of Boards of Pharmacy* (NABP) requested each state to make pharmacy technician certification mandatory. In 2016, 23 states and the District of Columbia required pharmacy technicians to be certified.[14]

Certification helps pharmacy technicians formalize and elevate their careers and feel they are truly part of a healthcare team. Employers know individuals who pass the examination have a standardized body of knowledge. Passing the test increases the technician's confidence, which likely improves the technician's job performance in the pharmacy.

Some pharmacists view the pharmacy certification process as comparable to completion of an associate's degree. Certification also sets these technicians apart from uncertified technicians. Many pharmacies, such as the Veterans Affairs (VA), are now requiring PTCB

certification as a condition of employment. Such requirements will help elevate the level of pharmacy practice.

The advantages of pharmacy certification to employers are a decrease in the training time and cost of on-the-job training. Most of all, it indicates that the pharmacy technician has a certain knowledge about pharmacy practice. Eligible candidates include those that have (1) a high school diploma or GED (general equivalency diploma), (2) no felony convictions, (3) no drug- or pharmacy-related convictions, and (4) no denial, suspension, or restriction of registration by a state board of pharmacy.

The Pharmacy Technician Certification Examination (PTCE) was based on the results of the 1991–1994 Scope of Pharmacy Project and was designed in collaboration with testing experts.[15] The examination is a valid measure of the technician's knowledge and skill base for activities that are most commonly performed by a pharmacy technician, as determined by a national task analysis. The multiple-choice exam contains 90 multiple-choice questions (80 scored questions and 10 unscored questions) and is taken over a 2-hour period. Official score reports are available online approximately three weeks following the exam. The content of the examination covers tasks pharmacy technicians perform in various practice settings, including community and institutional ones.

The PTCE is offered continuously throughout the year at more than 120 sites across the nation and online. As of December 31, 2015, PTCB had granted 587,536 pharmacy technician certifications to those who passed the examination through the examination and transfer process.[16] In 2015, the mean passing rate was 73%.

Renewal of certification is required every 2 years. A total of 20 hours of continuing education in pharmacy-related topics is required within the 2-year period. At least 1 hour is in the area of pharmacy law. A maximum of 10 hours may be carried out in practice sites (in-service projects) under the supervision of the pharmacist for whom the certified pharmacy technician works. Certification will be removed if the pharmacy technician does not take steps to recertify. A state board of pharmacy can also suspend a pharmacy technician from working for breaking the law or for behavior not appropriate for pharmacy personnel.[16]

Pharmacy technicians who would like to apply for certification can contact the PTCB at 2215 Constitution Avenue, NW, Washington, D.C. 20037-2985. The cost of the PTCE in 2015 was $129. A survey revealed that 33% of chain pharmacies, 40% of hospitals, and 50% of independent pharmacies pay for their technicians to take the PTCE.

Books and other study guides are available to help in preparing to take the PTCE. A practice exam is also available online from the PTCB. Some of these resources are listed at the end of this chapter.

PHARMACY TECHNICIAN ORGANIZATIONS

It is important for pharmacy technicians to network with other pharmacy technicians and to belong to a membership organization that will represent them. Some pharmacist organizations, especially local and state, have membership categories for pharmacy technicians and provide specific continuing education and newsletter articles. Among the national organizations that have special member affiliation for pharmacy technicians are the American Pharmacists Association (APhA), the American Society of Health-System Pharmacists (ASHP), and the National Community Pharmacy Association (NCPA).

Pharmacy technicians also have their own professional organizations. The National Pharmacy Technician Association (NPTA) and the American Association of Pharmacy Technicians (AAPT) are the two national organizations for pharmacy technicians, and both

have state chapters and growing memberships. Each has an annual convention, continuing education programs, and other services.

SUPERVISION OF PHARMACY TECHNICIANS

Good sense and the law require that a pharmacist ensure that the medicine prepared and dispensed from the pharmacy is correct for the patient. The pharmacist must make sure all drug products prepared by pharmacy technicians are correct. For public safety, some state boards of pharmacy have regulations about the number of pharmacy technicians a pharmacist can supervise.

A survey of state pharmacy rules concerning the supervision of pharmacy technicians in hospitals revealed that nine states required a technician-to-pharmacist ratio of 1:1, six required 2:1, three required 3:1, nine did not specify a ratio (but required a sufficient number of pharmacists and supportive personnel as thought necessary by the pharmacy director), and 24 did not mention a ratio. Note that exceptions may be submitted to a state board of pharmacies to extend these ratios (along with proper justification). A list of ratios, by state, is available.[14]

Another survey developed a technician-restriction score (TRS) as a way to decide which states were the most and least restrictive.[3] Technician-to-pharmacist ratios and the extent of supervision were considered when composing the TRS for each state. A pharmacy regulation requiring "immediate and direct" supervision of a pharmacy technician, meaning the technician has to be within the sight or sound of a pharmacist, would contribute to a higher TRS than if the pharmacist were merely required to be within the same building but responsible for the technician. A low technician-to-pharmacist ratio would contribute to a lower TRS than a high technician-to-pharmacist ratio. Based on TRS scores, 26 states were classified as less restrictive, and 25 states were classified as more restrictive.

A national survey of hospital pharmacy services found that the technician-to-pharmacist ratio on pharmacy department payrolls was consistently 1:1, even for states that had a higher ratio allowed by law.[17] This finding suggests that the employment of more pharmacy technicians may be limited more by pharmacists or for cost reasons than by state rules and regulations.

The number of technicians a pharmacist can directly supervise is set by state regulation. This ratio usually varies form 1:2 (one pharmacist for every two technicians) to 1:6. Some states vary the ratio depending on the practice setting. Other states do not even have a set ratio at all, instead allowing each pharmacy practice to determine an appropriate number of technicians to be supervised by a pharmacist. In 2008, the technician-to-pharmacist ratio at Walgreens was 1:6 while at CVS it was 2:1.[18] No information could be found on what these ratios are today.

Some pharmacists believe there should not be any technician-to-pharmacist ratio restrictions. Since the pharmacist is ultimately responsible for everything that happens in a pharmacy, they should control what is safe, how many pharmacy technicians should be used, and how the technicians are supervised. However, other pharmacists and some state boards of pharmacy are wary of not having mandated technician-to-pharmacist ratios because it may make it easier for a profit goal to supersede a safety goal.

Another safety feature being used in some states is the *registration* of pharmacy technicians, similar to the way pharmacists are registered (they are also licensed). Registration is being officially enrolled on an existing list.[13] Registration is a mechanism through which

states can monitor the individuals employed as technicians. State boards of pharmacy will be able to keep a record of any complaints or remedial actions about a pharmacy technician, which will help protect the public. Some states require technicians to be certified, and some states differentiate between certified and noncertified technicians in permissible tasks.

Registration is intended to help safeguard the public through interstate and intrastate tracking of the technician work force and preventing individuals with documented problems from serving as pharmacy technicians. *Licensure* is the process by which an agency of government grants permission to an individual to engage in a given occupation upon recognizing that the applicant has attained the minimum competency necessary to ensure that the public health, safety, and welfare will be well protected. As of April 2015, 45 states registered or licensed pharmacy technicians.[16]

BEING A PROFESSIONAL PHARMACY TECHNICIAN

Being a pharmacy technician can be a rewarding career. For those who seek such a career and would like fulfillment and job satisfaction, it takes more than just knowledge, skills, and abilities to do the job. It takes commitment, hard work, and professionalism.

A *professional* is someone qualified to perform the activities of a profession who has character, sensitivity to others, and the desire to fulfill ethical and professional standards. Pharmacy technicians must realize that they represent the time-honored profession of pharmacy. They also must respect the profession by their dress, their personal hygiene, their character, and how they serve and treat others.

All patients, pharmacists, and coworkers must be treated with respect. The pharmacy technician should be courteous, polite, and able to listen and communicate well. The pharmacy technician must also respect confidentiality, whether it involves a patient, a coworker, or the business for which the technician is working.

Pharmacy technicians should understand the impact—positive or negative, minor or major—they can have on the pharmacy service. Being patient-centered is key. Valuable technicians will make the pharmacy practice and business more successful in the areas of quality of care and economics. Part of the job of pharmacists and pharmacy technicians is to make the pharmacy service better and more successful. It is true that the more successful the pharmacy service is, the more successful the pharmacists and pharmacy technicians who work there are.

Having a good attendance record, getting to work on time, dressing appropriately, being well groomed, getting along well with coworkers, and volunteering to do extra work are the attributes of a good pharmacy technician.

Technician Earnings

In 2015, the median hourly pay for pharmacy technicians was $15.23, and the annual median income was $31,680.[2]

Working Conditions

Pharmacy technicians work in clean, organized, well-lit, and well-ventilated areas conducive to doing professional work. They spend most of their day standing. There may be some heavy lifting during daily activities.

Pharmacy technicians work the same hours as pharmacists. In organized healthcare settings, there are usually three shifts—days (7 a.m. to 3 p.m.), evenings (3 p.m. to 11 p.m.), and nights (11 p.m. to 7 a.m.). Most pharmacy technicians work 35–40 hours a week. There are many opportunities for part-time work in retail and hospital settings as well as some opportunities for overtime work.

Some pharmacies are busier than others. In fact, some are fast paced, and some experience a high level of distractions and stress. In these settings, pharmacists and pharmacy technicians need to be vigilant and cautious about committing errors of commission and omission and employ double-check systems.

Workflows vary from site to site, and pharmacy technicians need to adjust to changing conditions. This can be stressful.

Satisfaction

There have only been a few studies completed on pharmacy technician satisfaction. There is greater satisfaction when pharmacy technicians feel that they are a part of a care team or work in decentralized pharmacies in hospitals.[19,20] Other factors that improve satisfaction are positive relationships with coworkers, job variety, and training. Factors contributing to dissatisfaction are work procedures, workload, staffing, and lack of recognition.[21]

Advancement and Expanded Roles

Starting Out: Most pharmacy technicians start in an entry-level position and are supervised carefully even when doing the most basic functions. Once the pharmacist employer or supervisor has had an opportunity to observe and work with the pharmacy technician, the pharmacy technician may be given more leeway and less direct supervision.

Career Ladder Programs: Some pharmacies have career ladder programs. These programs allow the pharmacy technician to advance to higher-level functions and receive more pay.[22] Some pharmacy technicians may become specialized, such as those working in special types of pharmacies (consultant pharmacies, nuclear pharmacies, etc.), or they may perform specific functions (i.e., inventory control, purchasing). Others may supervise other technicians as head or lead technicians.

Expanded Roles: In general, many pharmacy leaders and pharmacists are hoping that as more pharmacy technicians are certified, technician roles will be expanded so pharmacists can delegate most dispensing functions and spend more time with patients. In some pharmacies, technicians are allowed to prepare medication with the pharmacist checking the computer entry versus the prescription or drug order and the medication to be dispensed against the prescription or drug order.

In some hospital pharmacies, technicians are allowed to check other technicians for preparation of intravenous solutions and certain categories of drugs within the unit dose system. This reduces the number of pharmacists needed in dispensing, specifically computer entry, drug selection, and labeling.

In dispensing, the ideal would be for pharmacists to take oral prescription orders, oversee the controlled substances, check the final product (including the prescription, drug labeling, and computer entry), and allow certified pharmacy technicians to handle all other dispensing activities.

Being Successful: A recognized, highly successful pharmacy technician has offered advice for aspiring pharmacist technicians: (1) try to be an accuracy checking technician

(a UK term similar to U.S. certification), (2) use your initiative, (3) keep up-to-date with pharmacy training, (4) never stop learning, and (5) look to the future.[23]

Job Outlook

The job outlook for pharmacy technicians is bright. The number of prescriptions dispensed yearly is expected to rise dramatically. This is mostly due to the rising number of senior citizens as well as changes in Medicare and other programs and the universality of prescription coverage in health insurance plans. In addition, a survey has shown that pharmacists spend two-thirds of their time in technical and nonjudgmental tasks, whereas they prefer to spend time making sure the drugs are prescribed and used correctly.[24] Technical and nonjudgmental functions can be performed by pharmacy technicians or by using automation.

The recruitment of competent pharmacy technicians is already getting more difficult. Most chain store pharmacies are having a harder time recruiting pharmacy technicians, as are independent pharmacists and hospitals. Perhaps because recruiting has gotten so difficult, many employers do not advertise specifically for certified pharmacy technicians. However, the most sought-after pharmacy technicians will be those with certification, formal training, experience, knowledge of automation, and those that are patient-centered.

SUMMARY

Pharmacy technicians play an important role in providing efficient and quality pharmacy products and services for patients. The more education, training, and experience pharmacy technicians have, the more qualified they become. Coupled with national certification, a good work attitude and record can make for a successful career. For some people, starting as pharmacy technicians can ultimately enhance their careers as pharmacists should they decide to continue their professional education.

The job market for pharmacy technicians is expected to grow with the increase in the number of prescriptions as the U.S. population grows older. In addition, the role of technicians is expected to expand as pharmacists expand their clinical role with patients. Well-trained pharmacy technicians who act professionally and seek a career as a pharmacy technician have a bright future.[25]

DISCUSSION QUESTIONS AND EXERCISES

1. Some state boards of pharmacy have technician-to-pharmacist ratios (e.g., 2:1 or 3:1) that set the number of technicians one pharmacist can supervise. Are these ratios a good or bad thing? Why? Why not?
2. Make an appointment to interview a certified pharmacy technician and a technician who is not certified. Ask both technicians the same questions and record your answers and compare your results.
3. Make an appointment with one community and one hospital pharmacist to find out how they feel about using certified pharmacy technicians versus uncertified pharmacy technicians. What are their opinions about mandatory technician-to-pharmacist ratios? Compare your results.
4. Which do you feel is more efficient: using three pharmacists and no pharmacy technicians or using two pharmacists and three certified technicians? Why?
5. Name three functions pharmacy technicians cannot perform in pharmacy.

6. Name three functions pharmacy technicians can perform in most states that will free pharmacists to spend more time with patients.
7. A patient receives the wrong medication. A pharmacy technician comes to you (the pharmacist) and says that he or she made the error, but that you checked it and said it was okay. Who is responsible for this error?
8. Should pharmacy technicians be allowed to check each other's drug preparations so the pharmacist can spend more time with patients? Why or why not? What if it was legally permitted?
9. Who should greet and take the prescription from the patient: the pharmacy clerk, the pharmacy technician, or the pharmacist? Who should give the medication to the patient?
10. In the scenario in question 9:
    a. Which is most cost-efficient?
    b. Which will free the pharmacist to spend the most time with patients?

CHALLENGES

1. For the pharmacy student: It is important for pharmacists and pharmacy technicians to be "on the same page" to maximize benefits to patients and to have a harmonious working environment. For extra credit, and with the permission of your professor, prepare a concise report on working with pharmacy technicians. In doing this, interview a seasoned pharmacy technician about the pros and cons of being a pharmacy technician.
2. For the pharmacy technician student: Working in a community pharmacy and hospital pharmacy are very different. For extra credit, and with the permission of your instructor, prepare a concise report on these contrasting environments from the point of view of a pharmacy technician. In doing this, you should make on-site observations in both settings.

WEBSITES OF INTEREST

American Association of Pharmacy Technicians: http://www.pharmacytechnician.com
National Pharmacy Technician Association: http://www.pharmacytechnician.org/
Pharmacy Technician Certification Board: http://www.ptcb.org/
Pharmacy Technician Educators Council: http://www.pharmacy.org/pharmtech.html

ADDITIONAL PHARMACY TECHNICIAN TEXTS AND RESOURCES

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6 Pharmacy Informatics and Automation

Technology has changed many industries such as aviation, the NFL, and the way we fight wars. It is now transforming healthcare and pharmacy. The computer, like no other single instrument, has changed the way healthcare is practiced. Information technology and automation have also changed the way pharmacy is practiced, and they will continue to do so for some time.

Information technology and automation, collectively called *informatics*, improve the medication use process and can help advance pharmacy practice and pharmaceutical care. It is important for the use of technology and automation in pharmacy practice to be well thought out and used correctly.

This chapter discusses pharmacy informatics and its importance and history. The types of automation used in pharmacy will be presented. Steps in moving to a more automated approach to pharmacy and why information technology and automation are so important to pharmacy will be discussed.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Define information technology.
- Define pharmacy informatics.
- State six benefits of using information technology and automation in pharmacy.
- List three challenges of implementing and using pharmacy informatics.
- Name three specific types of automated dispensing devices used in the pharmacy.
- Discuss the pros and cons of using pharmacy automation to improve safety.
- Discuss the role of clinical decision support in pharmacy practice.
- Describe at least three unique skill sets required for a career in pharmacy informatics.

INFORMATION TECHNOLOGY, AUTOMATION, AND INFORMATICS

Medical informatics is defined by the National Library of Medicine as the "field of information science concerned with the analysis, use and dissemination of medical data and information through the application of computers to various aspects of healthcare and medicine."[1]

Pharmacy informatics is "the use and integration of data, information, knowledge, technology, and automation in the medication use process for the purpose of improving health outcomes."[2] Pharmacy informatics encompasses the use of information technology and automation.

Automation is not an endpoint in itself, but is a tool. It can help pharmacists better achieve optimal medication use. Such tools include systems that can (1) maintain patient profiles, automate the review of new prescriptions or orders for drug interactions and allergies; (2) guide pharmacists and pharmacy technicians through workflows to standardize and optimize dispensing functions; (3) verify the identity and propriety of medications selected for

TABLE 6.1
Informatics in the Medication Use Process

Step in the Medication Use Process	Pharmacy Informatic Examples
Prescribing	Electronic prescribing with drug information and decision support
Perfection[a]	Pharmacist verification, product selection, monitoring parameters, ranking of orders for review and assignment of dispensable units.
Dispensing	Robotics and automation to produce dispensable units, barcode scanning to verify proper product selection, and track/delivery software to manage and monitor the delivery of medication dispensed.
Administration	Electronic medication administration record, barcode administration records, drug information delivery. Smart infusion devices that monitor infusion rates and dosing against set safety limits.
Monitoring	Tracking population trends and individual assessment of therapy. Monitoring changes in patient condition and suggesting pharmaceutical care interventions.
Education	Drug information to patients and health professionals in unique ways with technology. There are a number of reliable sources for patients to self-educate on medications on the Internet.

[a] In the pre-informatics environment, this step was referred to as "*transcribing*." Pharmacists are involved in informatics for several reasons—to improve: (a) medication safety, (b) patient care, (c) efficiency of the medication process, and (d) documenting care.

dispensing, perform complex calculations (such as pharmacokinetic dosing); (4) completely automate portions of the dispensing function (through robotics and other automation); and (5) monitor patient clinical data against rule sets to help pharmacists identify those patients most in need of pharmaceutical care.

The selection, implementation, and management of automation has become so significant a role in pharmacy practice that it is now considered its own specialty (pharmacy informatics) with its own advanced training and unique skill sets.[3,4]

The *medication use process* is broken down into six steps. Informatics can be applied to each step with the goal of improved safety, patient care, and efficiency. When informatics is used in all steps of the medication use process it is referred to as a *closed loop medication delivery system*. The six steps in the medication use process and a brief example of pharmacy informatics of each are shown in Table 6.1.[5]

IMPROVED SAFETY

Pharmacy informatics improves patient safety by building into the medication process a system of checks and balances that would be humanly impossible to know, remember, and perform. Studies from high-reliability industries demonstrate that well-educated and trained humans have a known error rate that ranges from 0.5% to nearly 90%, depending on conditions and tasks to be performed. Given appropriate criteria, automated systems reliably identify potential errors that could result in patient harm, and stop processes for those to be evaluated and resolved.[6] The adoption of *computerized prescriber order entry* (CPOE) in hospitals and *ePrescribing* in ambulatory practice sites has all but eliminated the need for transcription (manually copying) of medication orders and the resulting transcription error.

IMPROVED PATIENT CARE

By incorporating standards of practice and care plans, the computer system can track all orders, check patient results, and track actual performance versus desired performance. The computer can also provide reminders to the users of how to improve performance and identify potentially preferable alternative therapies based on changes in a patient's condition.

IMPROVED EFFICIENCY

Computers work much faster and are more accurate than humans. When properly programmed, computers can process medication orders, provide documents and information about patients, and help prepare medication for patients. Medication orders can be processed faster, and patients can receive their medication sooner and more accurately. In an acute care environment (such as hospitals), immediate efficiency gains are seen by reducing or eliminating a process that was delayed because paper documents had to be physically sent to the pharmacy or having to transcribe information from those documents into a pharmacy system.

IMPROVED DOCUMENTATION OF CARE

Information technology and automation are collectively called *informatics*. The use of informatics can provide details on what has taken place in the drug-use process—the ordering, perfecting, preparing, dispensing, administering, monitoring, and education of the use of medications. Properly designed, software systems can record, store and analyze information about the medication use process that would be impossible for a human to accomplish.

PHARMACY INFORMATICS IN THE DRUG USE PROCESS

Prescribing

Electronic prescribing is used in the ambulatory environment. CPOE is the term used in the hospital environment. Integrating *clinical decision-support systems* (CDSS) with prescribing systems is the key ingredient to improving prescribing practices and safety. CDSS is software that includes rule sets, and when these rules are triggered, the prescriber sees a message or alert that something may be wrong (too much drug, a drug interaction, or a contraindication for the drug) or actions that should be considered (ordering of a lab test before prescribing).

There is much work to be done in improving CDSS. Checking allergy and drug interactions still produces too many false positives to prescribers. Even with some false positive alerts physicians and pharmacists believe that CDSS is very beneficial for safe prescribing. The analogy has been made that prescribing without CDSS is like jumping out of an airplane without a parachute.[3]

In the age of genomic medicine, it will be more difficult to prescribe the correct medicine without the support of CDSS and the help of a skilled clinical pharmacist. The number of variables and factors will exceed the ability of the mind to select the best medication and dose for a particular patient.

Once certain medications are prescribed, it is common in some health systems for physicians to indicate that "dosing per pharmacy protocol." Informatic dosing calculators, using pharmacokinetic principles that take into account multiple patient parameters, are used by pharmacists to determine the optimum dose and monitoring parameters.

E-Prescribing

E-prescribing (electronic prescribing) is the use of an automated data entry system to generate and send a prescription to the pharmacist, rather than writing it on paper and giving it to the patient. Automation of the outpatient prescribing process has many potential benefits, the most important is increased safety.

With the advent of the *Affordable Care Act* and the requirement for both hospitals and physician practices to "meaningfully use" electronic medical records, e-prescribing is very nearly ubiquitous. The last hurdle, the ability to e-prescribe controlled substances, was recently overcome when the DEA created regulations permitting such use.

To further enable e-prescribing there is a service that enables secure transmission of prescriptions from providers to pharmacies. This service is called *Surescripts* and presents the prescriber with the set of prescriptions that have been dispensed in the past at pharmacies of a patient. This service enables the prescriber to understand what the patient has been prescribed, and more importantly, what has been dispensed by a pharmacist. Patient compliance with therapy can be determined and course corrections can be made. This service is still evolving with much improvement so far.[7]

With the advent of the opioid crisis as identified by the *Centers for Disease Control and Prevention* (CDC), most states now also operate a Prescription Drug Monitoring Program that permits physicians to identify patients who may be "doctor shopping" to obtain controlled drugs.

Computerized Prescriber Order Entry

In hospitals, the movement toward CPOE systems is happening rapidly due to incentives included in the HITECH Act. These are systems used by prescribers to order their medication, laboratory tests, and diets by entering them directly into a computer.[8] CPOE allows prescribers to enter their orders directly into the hospital information system by using a terminal in the hospital, a handheld device, or their office computer. The extensive use of CDSS in the hospital environment helps improve safety although current systems lack awareness of patient context, and therefore are known to produce alert fatigue.[9]

The passage of the American Recovery and Reinvestment Act of 2009 (ARRA) has a provision that has been a boom to e-prescribing, CPOE, and many other electronic medical record implementations. It outlines incentives for physicians and health systems to implement these systems. Penalties for not moving in this direction started in 2014 through reduced Medicare payments. This initiative is managed through the Office of the National Coordinator for Health Information Technology. It has driven significant changes both in hospital practice and in physician office practice. In both locations, electronic medical records are now commonplace; the Office of the National Coordinator indicating that over 90% of non-federal acute care hospitals were adopting CPOE as of 2015.[10]

Experience with driving "meaningful use" of electronic medical records systems has demonstrated both benefit and harm from these systems. Indeed, the term "*e-iatrogenesis*" has been coined to describe the new types of medication errors that have been introduced by the advent of CPOE systems.[11]

Perfection

When reviewing a medication order or a prescription, a pharmacist checks for the appropriateness of the drug, dose, frequency, and route of administration. Pharmacists should also

check for (1) therapeutic duplication; (2) real or potential allergies or sensitivities; (3) real or potential interactions among medications, food, and laboratory test values; (4) other contraindications; variation from organizational criteria for use; (5) other relevant medication-related issues or concerns; and (6) clarification of all concerns, issues, or questions with the individual prescriber before dispensing the medication.[12] Pharmacists then *transform* the prescribed order to a form that can be safely dispensed by assigning appropriate physical medications to the order.

Transformation of a prescription of a medication order or a prescription occurs when the prescription or order lacks sufficient definition to allow dispensing to occur, and so the pharmacist must further interpret, or transform, the physician's prescription into something that can actually be dispensed. In the world of medication orders (acute care—CPOE), the act of ordering a medication often intentionally lacks the identification of an off-the-shelf medical product. Early CPOE products just put what had been pharmacy order entry (actually, a product forecast in the old Pharmacy Systems) before physicians with disastrous results. Physicians were intimidated by the sheer volume of possible things to order and often chose the wrong things (an example of *e-iatrogenesis*). Therefore, part of the pharmacist review process is the transformation (change) of orders received from a CPOE system into something that can be dispensed. Here are some examples:

- In oral medications, physicians will often specify a drug at a dose and a route (without form) that the pharmacist may transform into a dispensable order by specifying a dosage form and a unit-strength.
- In IVs, a pharmacist may receive an order for (for example) Dextrose 5% in 0.45% 1000 mL with 20 mEq/L of Potassium Chloride, which the pharmacist may transform into a dispensable order by associating it with a pre-mixed IV or with a combination of a plain IV (Dextrose 5% in 0.45% Sodium Chloride 1000 mL) plus 20 mEq (10 mL of Potassium Chloride 2 mEq/mL).
- Chemotherapy doses are often given in terms of amounts per kg of body weight yielding doses that require transformation into a specified amount of specified forms of injection or oral dosing.
- TPN (intravenous feeding) is probably the most elaborate transformation in that the order is often specified in clinical terms (total calories broken into carbohydrate, fat, and protein calories) or amounts per kg of body weight or in terms of final concentration, which the pharmacist must render into a formula that describes volumes of specific off-the-shelf ingredients which, when mixed together, yield the requested nutrition.

Just as CDSS can be applied to e-prescribing and CPOE, it can be applied to the perfection process (see Table 6.1, Step 2) to increase safety and efficiency. While some patient checks can be applied at ordering, others from a pharmaceutical care perspective may be applied at the perfection step in the *medication use process*. For example, prioritization of orders can be applied. This can present the pharmacist with the most important items for perfection in order of priority to review.

Dispensing

Pharmacy technology and automation are relatively new in pharmacy practice. The first national survey to discover the use of pharmacy automation in the United States

took place in 1996.[13] This survey was published when not much information technology and automation were being used in a pharmacy, except for packaging and counting medication.

A 2014 ASHP national survey notes the following about the use of automation[14]:

- 97% of hospitals used automated dispensing cabinets either as primary distribution or in combination with cart fill.
- ~45% of hospitals use machine-readable coding to verify dispensing accuracy.
- Pharmacists use automation to review and approve medication orders before the first dose was given in 81.2% of hospitals.
- Electronic medical records, computerized prescriber order entry, barcode medication administration, and smart infusion devices were reported as "widespread."

Not to be outdone, community pharmacies now widely accept electronic prescriptions, and provide both web pages and smart phone applications so patients can request prescription refills. Some offer centralized mail-order pharmacy options that significantly reduce cost and improve convenience, especially for medications used to manage chronic disease states. National chain pharmacies maintain a network of pharmacy systems that permit customers to obtain refills at one of their stores wherever the patient may be in the United States.

Administration

Helping patients remember their medications through informatics is gaining interest. There are "*smart containers*" that can remind patients when to take their medication.[15] Also, the use of text messaging, email, and social media is increasingly used to help patients adhere to medication schedules.[16] Technology exists that can send a text message or email when a patient swallows a capsule.[17] These technologies are not in general use today, but increasingly, studies are being undertaken to show their value to patients in special populations.[18]

The first barcode scan for commercial use was on a pack of Wrigley's Juicy Fruit Gum in 1974. In hospitals, using this technology for scanning a patient and then the medication to insure the right medication in the right dose is given to the right patient is being used. Over 90% of hospitals now use this technology for medication administration.[19]

Barriers to Bar Coding

There are some barriers to adoption of barcode medication administration (BCMA). For pharmacy practice, the most significant of these is the lack of current and comprehensive data regarding the barcodes that can be found on medications in the supply chain. This problem requires the pharmacy to update and maintain their systems' data constantly so bar code scanning correctly and reliably identifies each scanned item and properly determines whether or not it should be given to the patient.

Most hospitals now use "*smart infusion devices*" that contain drug error reduction software libraries that fire "soft" or "hard" stops on infusion rates set into these pumps that can help avoid infusion pump programming errors. More recently, these devices have implemented interoperability with electronic medical records (EMR), permitting the pump to query the EMR and program itself, requiring only that the user review and accept the programming before starting infusion.[14,20,21]

Monitoring

New information and patient monitoring technology is becoming available regularly. One example of a device that pharmacists can use to monitor patients is DynaPulse (PulseMetric Inc., San Diego, CA). DynaPulse is a noninvasive device that can be used to monitor blood pressure and 16 hemodynamic values in patients in less than a minute. These results can be stored in a computer for documentation and future reference and can be sent over the Internet to the patient's physician and pharmacist.

Monitoring for adverse events in the hospital, through rules-based systems of patient parameters, medications and lab values has proven to be better than manual review.[22] Algorithms to alert providers when things are not going well with a patient's condition are being used to detect adverse reactions.[23] These rules-based systems are now being used to identify and prioritize patients for clinical pharmacy intervention, managing clinical work queues, and have nearly eliminated the gathering of patient clinical information that once dominated clinical pharmacy practice.

In a first ever declaration, a clinical professional society indicated that controlling and monitoring infections simply cannot be done effectively without informatic support. Well-designed software can collect, analyze, report, and trend more data than dozens of practitioners. The statement from the Association of Professionals in Infection and Epidemiology Control (APIEC) says "use of automated surveillance technologies is an essential part of infection prevention and control activities."[24] Antimicrobial surveillance systems are now commonplace elements of *antibiotic stewardship programs*.

Education

Pharmacies and patients now have information at their fingertips at lightning speed via the Internet. Access to information about new drugs, old drugs, drug therapy, and diseases are available with only a few clicks of the computer mouse. Pharmacists can read articles, answer quizzes, and gain continuing education credit without leaving their pharmacies or their homes. All of this was impossible just a few years ago.

An example of new information technology is the *National Institutes of Health's* (NIH) new alternative and complementary medicine database, *PubMed*.[25] The vast majority of peer-reviewed journal are now available online, and their contents can be readily searched using Internet search engines.

Reference books that once occupied linear feet of shelf space can now be accessed as applications on smart phones or on the Internet and are continuously updated, rather than waiting for publication updates. One purveyor of such references is Omnio. They provide both reference books and clinical computational tools.

There is a proliferation of drug information going on with healthcare providers and patients. Information once limited to the healthcare professional community is now readily available to patients on-line. This glut of information contains both reliable and questionable information, and more than ever, pharmacists need to help patients discern which of the information is reliable, and which should be ignored.

Telepharmacy

Pharmacies are starting to use the computer in creative ways to increase market share. They have taken the lead from physicians, who have developed *telemedicine*. One telemedicine

company helps improve patient care by bringing intensive care unit patients to intensivists, critical care physicians who are scarce and who are remotely located.[26] Patient information, on-time real-time transmission of electronic monitoring of the patient, and two-way pictures and conversations with patients, nurses, and physicians on the scene can take place.

Another example of *telemedicine* is how patients can buy on-line consultations with physicians over the Internet. Although this will never replace a physical examination by the physician, it can provide much needed information and advice on whether the patient should see a physician, go to the emergency room, or not worry about the problem.[27] Telemedicine is particularly valuable in rural settings where there may not be any medical specialists such as endocrinologists, pediatricians, and cardiologists.

Pharmacy has now started down the road of *telepharmacy*,[28] which includes the dispensing of medications and information and the provision of pharmaceutical care to patients from a distance.[29] Some community pharmacies, especially some chain store pharmacies, are starting to use the computer to accept orders for prescription refills and to send prescription refill reminders to patients.[30] Hospital pharmacies are using it for remote *perfection* of orders entered via CPOE and, more recently, remote dispensing, either through dispensing technology or through remote pharmacist checking, where permitted by state law.

Some online (Internet) pharmacies accept new prescriptions from patients. However, some of these may not be licensed pharmacies, and patients need to be cautious about these deceptive or bogus pharmacies.[29] In addition, a recent survey of 300 adult online consumers revealed that most people would rather patronize their local pharmacy than a *virtual pharmacy*.[26] The reasons provided for not liking an online pharmacy included less comfort level with the pharmacist, insurance not accepted, physician not being able to enter the prescription online, and the service being more expensive.

Summary

Informatics is improving pharmacy practice by improving efficiency, providing more and faster access to information, and helping free up pharmacists to do pharmaceutical care. This, in turn, is helping improve pharmacists' morale and professionalism.[30]

AUTOMATION

A Brief History

Pharmacy automation started in the late 1960s with the use of tablet-counting machines-units that held medication and had a dial for setting the number to be counted. The medication container was placed below an opening in the device that delivered the tablets into a container. During the 1980s, the first device to automate preparing *total parenteral nutrition* (TPN) solutions became available. The first automated unit-dose filling machine was available in the early 1990s. Many automated medication use products are now available.

Since the first national survey on pharmacy automation in the United States in 1996, the use of automation has slowly increased and should dramatically increase over the next 10 years.[13] With the growth projections for retail prescriptions showing no signs of slowing down, the current shortage of pharmacists, and the cost cutting going on in hospitals, automation in pharmacy may increase dramatically. Such growth should also reduce one of the barriers to using automation—cost.

Benefits of Pharmacy Automation

The benefits of using pharmacy automation are improved speed, accuracy, documentation, and efficiency and the ability to analyze, compare, and provide new information.

Improved speed: Not only do computerized systems process information at unimaginable speed, but their ability to transmit information over large distances nearly instantaneously has substantially reduced latencies in the drug distribution processes both in terms of waiting for documents for dispensing and in removing the need to transcribe them into other systems.

Improved accuracy: Unless there is a human programming or intervention error, computers are flawless at computing and processing information. This is needed in the medication process to remove errors. When set up properly, computer-driven automated processes should substantially reduce medication errors. The FDA requirement that all medications were to be barcoded with the national drug code by 2004 (effective 2006) has resulted in virtually all medications being labeled with their national drug code (NDC) in a barcode which permits barcode scanning to ensure that the correct medication was selected during dispensing and during administration.[31,32]

Improved documentation: Properly designed systems have demonstrated their ability to quickly, transparently, and reliably capture volumes of processed information useful both in continuous quality improvement and in the forensic processes that become necessary when errors occur.

Improved efficiency: Automated systems have been shown to actually eliminate manual processes, permitting reassignment of staff to more useful purposes.

Ability to analyze, compare, and provide new information: Analytics is becoming increasingly important both in its ability to analyze and recommend process change, to more quickly identify patients for whom pharmacist intervention is required, and to provide early warning when processes are not working properly. An increasingly important example of this latter purpose involves using information from automated dispensing cabinets to identify individuals who may be diverting controlled substances especially in light of recent multi-million dollar Drug Enforcement Administration (DEA) fines for failing to properly manage controlled substances inventories.[33–35]

Challenges of Pharmacy Automation

Some of the challenges of automation include the cost, space, fear of being replaced, and one error becoming many errors.

Cost: Pharmacy automation remains a significant source of both capital and ongoing operational costs. Cost accrues from purchase and maintenance of hardware, software licensing and updating, ongoing data governance, technical support, and additional supporting processes and personnel.

Space: Modern network infrastructure has removed the need to maintain computers and servers in pharmacies, but older facilities still present challenges in placement and connection of workstations to these networks.

Fear of being replaced: Fear of being replaced has been reduced with the increasing volume of work and the shortage of pharmacists.[36] For every job that might be eliminated, new jobs arise.

One error can become many errors: Pharmacy automation can either decrease errors or make them worse (M. Neuenschwander, The Neuenschwander Company, Personal communication).[37] If an automated preparation and dispensing device is not set up correctly, the same error can be repeated many times until the error is discovered. Soon after automated compounding devices that made *total parenteral nutrition* (TPN) solutions became available, it was discovered that these devices, when set up incorrectly, can make repeated and potentially lethal errors.

Selecting Pharmacy Automation

Buying an automated dispensing system can be a daunting task. One can become easily overwhelmed by all the different types of equipment. The ASHP recently published some basic steps to help make the job easier in selecting an automated dispensing system.[38] First, identify the issues that need to be resolved by the equipment or system. Second, decide the system features you want. Third, compare your findings with what the current technology offers.

THE MARKET FOR PHARMACY AUTOMATION

There are estimations that the market for pharmacy automation in 2007 was $2.3 billion and that the annual growth would be 9.4% to reach nearly $8.99 billion in 2020.[39] With the advent of modern technologies, those estimates have turned out to be quite low.

Types of Pharmacy Automation

Pharmacy automation has grown to include a variety of automated devices such as:

Tablet Counters

These devices count oral solids (tablets and capsules). The first such device was the Baker Cell. Today there are many other kinds of these devices. These now vary from simple tablet counters to robotic devices that select, count, fill, and label prescriptions automatically. At least one of these systems also comes with a prescription workflow system that standardizes the manual prescription filling process.[40] One community pharmacy is using robotics to dispense 450 prescriptions a day.[41] Because the pharmacists no longer have to spend so much time in the dispensing process, they can spend more time counseling patients on the use of their medication.

IV Compounders

Once limited to fluid pumping devices and TPN compounders, devices that perform sterile dose compounding now extend to robots that completely automate some or all of the intravenous (IV) compounding process. Companies such as Arxium and Aesynt produce such robotics.

Related to this category are IV workflow software systems that apply controls similar to those used in robotics to the manual IV compounding process that improves the efficiency, quality, and transparency of compounding an IV. Such systems are available from Aesynt, Baxter, and BD.[43–45]

Packaging Devices

While most medications for acute care use come packaged from the manufacturer in *unit-dose* form, some are not, despite regulation. There are a variety of devices that package bulk oral solid medications into unit-dose format (strip packaging) from table-top hand-operated systems, to large cassette-driven systems that package small runs on-demand, or even create patient-specific strip packages to support unit-dose cart fill.

Other devices package medications individually or package medications so that all medications to be given at the same time are packaged together on blister-pack cards (sometimes called "bingo cards") for use in long term care and assisted living facilities.

Still other devices can be used to create multiple-dose strip packs where each package in a patient-specific strip contains all the medications that need to be given to patients at one time. These can simplify nurse preparation of medications in long-term care and assisted living facilities, and can be used as alternatives to standard prescription packaging for patients who take large numbers of medications.

Some health system pharmacies and some consultant pharmacists serving nursing homes will have the medication that is not available in unit-dose packaging repackaged by *repackagers*, which are companies that specialize in putting bulk medication into unit-of-use (unit-dose) or blister packs (sometimes called overpackages). Recent guidance from the FDA places restrictions on this process.[46]

Dispensing Machines

Dispensing automation is the largest category of pharmacy-automated equipment. Pharmacy automation is now categorized by where it is used: in the central pharmacy, in decentralized areas, or in other pharmacy automation. Devices can be divided into two basic kinds: (1) systems that perform storage and medication picking within the central pharmacy and (2) systems that perform medication storage and retrieval on patient care units.

Within the central pharmacy, there are software-driven hardware systems that govern the distribution of medications from the pharmacy. These systems may drive unit-dose cassette-filling robots, carousel systems that minimize footprint and bring the shelves to the technician rather than making the technician walk to the shelves, or box-picking robots that maintain their own shelving, and bring individual items from their internal shelving to the user.[47–49] These devices interface with the pharmacy information system to automatically queue up and then deliver medications the pharmacy needs to dispense either to cart fill, individual patient supplies, or automated dispensing cabinets on the floors.

On patient care units, there are automated dispensing machines (ADM), such as Pyxis® or Omnicell®, that maintain computer-controlled floor stocks of medications that are immediately available to nurses. These may represent "cartless" dispensing (in which 90% or more of medications come from these stations), or "hybrid systems" (in which "as needed" and first-dose medications are stored in the cabinets, and regularly scheduled medications are delivered directly from the pharmacy at regular intervals in patient-specific packaging [cart fill]). Swisslog is one manufacturer that provides automation for the cart fill portion of these hybrid systems.

In either case, these ADMs are usually interfaced to the pharmacy information system so that doses may not be released for use to a nurse unless there is an active medication order for the medication that has been reviewed by a pharmacist. There are software controls that permit some nurses to override the medication order controls, and part of the pharmacy's responsibility with these systems is to monitor override activity and work with nursing to minimize the causes.

More recently, similar devices are now used to provide medications to anesthesiologists during surgical procedures to track and account for use of drugs, especially controlled substances.

Safety of Automated Devices

Have automated devices made medication administration safer? This is a good question, but the jury is still out on this issue. Automated devices in pharmacy have their limitations. The devices need to be loaded properly with the correct medication in the correct location. This procedure is critical and deserves strict policies and procedures to ensure everything will be all right. Who can load the device and whether there should be a double check on loading the device should be spelled out in a policy and procedure statement.

Devices that use a barcode to check the medication going into the device is correct are safer than those that do not have this check. Automated dispensing devices in the VA's *Consolidated Mail Order Program* (CMOP) will not release the top of the automated device's storage area for medication until the medication is run past the barcode reader linked to the pharmacy computer and the computer gives a signal that everything is correct.

Assigning and keeping an up-to-date file in the computer of who may enter the information in automated systems is a must. There is a tendency to rely on automated systems as being safe, and thus education and reminders are needed for those using automated dispensing systems to double-check everything and to think about what is being done. All doses removed from an ADM need to be double-checked against what the screen on the device is showing.

As noted previously, *barcode medication administration* (BCMA) systems are now used in more than 90% of hospitals, resulting in closed-loop checking between the order as entered in the electronic medical record and the medication being presented by the nurse for administration. These systems still require that the nurse use the scanning system *before* administering drugs to the patient, and that the underlying database of codes is maintained to ensure that the scanner correctly recognizes the data in the barcode.

Some ADMs supplement this system by performing a "scan on remove" that verifies the nurse has removed the correct item from the ADM. Similarly, central pharmacy picking systems offer "scan on pick" capabilities to ensure that the correct items were removed in the pharmacy, and "scan on load" features to ensure that the correct items are placed in the correct ADM locations. IV workflow systems scan ingredients before they are injected into IV containers, and use both photographic and gravimetric checks to ensure that the admixture was performed properly.

Community pharmacies and consultant (long-term care) pharmacists should also be using systems that are closed-looped. Computer systems that have barcode readers that read the barcode on the medication container before the medication is dispensed should be used. This system and other systems that allow physicians to transmit their prescriptions to the community or consultant pharmacist's computer system would be true closed-looped systems.

Community, hospital, and consultant pharmacists still need to check all orders for the eight medication-related problems, under the pharmaceutical care model (see Chapter 7), and are required by law to check the final product before releasing it for administration. Fortunately, barcode scanning of selected products is now commonly available in most of these venues.

AUTOMATING THE PHARMACY

Automating the medication distribution system is not an easy task, and it is expensive. However, one tragic error can result in even more of an expense to an organization and cause bad publicity. Before automating, the *Chief Pharmacy Officer* (CPO) or *Director of Pharmacy* (DOP) should read ASCP's white paper on automation in pharmacy.[50]

For pharmacy automation to take place, the pharmacist must take charge and have a good plan supported by rationale and clear goals.[51] "To realize the full benefits inherent in automation systems, it is necessary to understand the basic ideas of automation and to realize that automation is simply a tool to help achieve safety, efficiency, and the goals of pharmacy practice.

The goal of pharmacy practice is pharmaceutical care."[52] To do this, the work must be redesigned to improve workflow, minimize distractions, and place the pharmacist at the front of the medication preparation process. The middle of the *medication use process* (see Table 6.1) is where pharmacy technicians and automation do the medication preparation and dispensing.

In community pharmacies, it is recommended, under the pharmaceutical care model, the pharmacist greet the patient, review the medication for appropriateness—by reviewing the eight medication-related problems, check the final product, and counsel the patient. In the hospital, the pharmacist should review the medication for appropriateness and check the final product before releasing it for administration. In the future, terminal bar coding or closed-looped systems will remove the need for this final check by the pharmacist.

FREEING PHARMACISTS FOR PHARMACEUTICAL CARE

Using pharmacy automation makes the medication process safer for patients and frees pharmacists to perform pharmaceutical care, which in turn improves the quality of drug therapy for the patient. Add to this mix the pharmacy technician, who must understand the *medication use process* and the goals of pharmacy practice. With these in place, pharmacy technology and automation can be used more as a quality assurance tool.[53]

There are several success stories about hospital and community pharmacies using automation and freeing pharmacists to perform pharmaceutical care.[54,55] At the same time, it is disturbing to observe the average community pharmacist spending much of the workday using the computer rather than spending more time with patients. Equally disturbing in how often pharmacists override safety alerts from the pharmacy computer system.

THE FUTURE

It is hoped that soon:

- The "Internet of things" (IOT) will include the variety of automated and semi-automated dispensing systems both within and without the pharmacy that will permit aggregation and analysis of detailed information about the flow of medications and supplies. Such analysis will not only guide optimization of services, but will predict the need for action using historical trends.
- The automation of dispensing activities and the above-mentioned analytics will permit a minimal number of pharmacists to govern dispensing, and will provide

sufficient safety controls so that most manual dispensing activities can be performed by technicians.
- Clinical analytics and inference engines will scour the growing mountains of clinical data, and will identify and rank data associations for review by pharmacists and other clinicians, permitting more rapid and complete advancement of clinical knowledge. Using these engines, clinical decision support can include contextual understanding of each patient, minimizing the amounts of alert fatigue generated by current CDSS systems.

SUMMARY

Information technology and automation are tools that should be used in all pharmacies. These improve the *medication use process* by making it safer and more efficient. It is also a way to free the pharmacist to perform pharmaceutical care and, in turn, improve the quality of drug therapy for patients. Pharmacists need to take responsibility for gaining information about technology and automation. They must also see that these systems meet the needs of the pharmacy staff and other healthcare workers who use them and that it is improving the care of patients. Although expert systems are in the future, pharmacists can help make them arrive sooner than later.

DISCUSSION QUESTIONS AND EXERCISES

1. Find three Internet sites providing drug information.
   a. Rate the quantity and quality of drug information at each of the Internet sites you found.
   b. How do you know the information at the sites you viewed is accurate and complete?
   c. How does the quality of drug information at Internet sites differ from the primary and secondary sources of drug information?
2. Today, there are hand-held electronic organizers that can store and record information. Discuss how they can help a clinically oriented pharmacist.
3. How can pharmacy automation make the drug-use process safer?
4. How can pharmacy automation make the drug-use process more dangerous?
5. Discuss how a closed-looped pharmacy automation system in an organizational healthcare system (such as a hospital) would work—start with prescribing and end with charting and charging for the medication.
6. Discuss how pharmacy automation can advance and enhance pharmaceutical care.
7. The drug-use process may be totally automated in the future.
   a. Discuss how this may affect pharmacy.
   b. What may happen if the drug-use process is totally automated and pharmacists do not practice pharmaceutical care?

CHALLENGES

1. For extra credit, and with the permission of your professor, visit a pharmacy that uses automation and prepare a concise report on the automation in the pharmacy. What effect did automation have on safety? Documentation? Freeing up the pharmacists?

If time was saved, was it used for patient care? Include your observations and opinions in the report.

2. Many pharmacists are using handheld devices to have ready-to-use drug information at their fingertips. For extra credit, and with the permission of your professor, investigate and prepare a concise report on these devices and identify the kinds of information available that would help improve pharmacy practice.

WEBSITES OF INTEREST

Epocrates: http://www.epocrates.com/index.html
Skyscape: http://skyscape.com
RxInformatics: http://RxInformatics.com
American Society for Automation in Pharmacy: http://www.asapnet.org/
Pharmacy Automation: http://www.pharmacyautomation.com/
Pharmacy Automation and Robotics: http://www.rxshowcase.com/trade_show.php/catid-71/catname-Pharmacy_Automation_&_Robotic_Systems

BLOG SITES OF INTEREST

Blogs are increasingly becoming a source of information. The Blogs followed on a regular basis by John Poikonen can be found here: http://www.google.com/reader/bundle/user/13667770605630287621/bundle/Informatics. They include the following:

- VA PMAS Health Projects BCMA—Google Blog Search
- The cHealth Blog
- Chilmark Research
- DirkMD—Free CMIO Perspective
- The Medical Quack
- iPhone Medical App Review
- Journal of Medical Internet Research
- Medgadget
- Neil Versel's Healthcare IT Blog
- Pharmacy Software Technology Resource Blog
- The Efficient MD
- Latest News from Healthcare Informatics
- Health Informatics Blog
- Nursing Informatics Online
- HIMSS.org—Clinical Informatics Feed
- EMR and EHR
- Goomedic.com
- EHR Decisions (CCHIT)
- Health Informatics Blog
- Dispatches from the hi-blogs.info krew
- Medicine and Technology by Dr. Joseph Kim
- Life as a Healthcare CIO
- NIH Funding Opportunities (Notices, PA, RFA)
- Intelligent Healthcare Information Integration.plus
- Healthcare Renewal

- Healthcare & Security Solutions
- Health Interoperability & Intelligence Exposed
- Federal Advisory Committee Blog
- Health IT Buzz
- healthsystemcio.com
- HIStalk
- HIStalkPractice
- Informatics Professor
- On Informatics
- PharmacyIT.net | Pharmacy Informatics: Where Pharmacy and ...
- RxDoc.Org
- RxInformatics.com
- BMC Medical Informatics and Decision Making—Latest articles
- Clinical Architecture Healthcare IT Blog
- Evernote Openbook: Public Pharmacoinformatics
- Fred Trotter
- Newsletter The Daily Scan articles
- The Health 2.0 Blog
- HIStalk Discussion Forum
- Roni Zeiger
- International Journal of Medical Informatics
- International Journal of Medical Informatics—Articles in Press
- The Informatics Review
- Medicare.gov Site Updates
- Informaticopia
- himsseprescribingwiki

Twitter Accounts of Informatic Pharmacists

- brent_fox
- JFahrni
- pillguy
- Carpijam
- ToddEury
- chrishartman
- Poikonen

Medical Informatics Twitter Accounts

- jhalamka
- kevinMD
- ePatientDave
- dirkstanley
- MedicalQuack
- ahier

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7 Pharmaceutical Care

INTRODUCTION

Pharmacy practice has changed in the United States from making drug preparations from plants found in nature to helping physicians decide which drug to prescribe and helping patients make the best use of their medication. This evolution from apothecary to clinical practitioner has not been easy, but it has been based on an ethos of helping patients and love of the profession. Today, many pharmacists strive to practice pharmacy using the principles of pharmaceutical care, which is the profession's version of health care's "*patient-centered care*."

This chapter begins with a short history of pharmacy practice in the United States. It then moves to defining pharmaceutical care and showing how it differs from *clinical pharmacy*. The issues discussed include what it means to deliver pharmaceutical care and why this practice model is important. Last is a section on the enablers and challenges to performing pharmaceutical care and some information on how pharmaceutical care is evolving into the new stage called "*shared care*."

LEARNING OBJECTIVES

After reading this chapter, the reader should be able to:

- Write a brief paragraph on your understanding of the history of pharmacy.
- State the societal purpose of pharmacy.
- Define pharmaceutical care.
- Compare and contrast pharmaceutical care and clinical pharmacy.
- Identify and explain the six elements of pharmaceutical care.
- Identify the eight medication-related problems.
- Explain the term "soaping the patient."
- Explain two challenges and provide two solutions to these challenge for pharmacists to provide pharmaceutical care.
- Finish this sentence—Pharmacists can help achieve positive patient outcomes by _____.
- Explain the term "quality of life."
- Describe briefly how pharmaceutical care is evolving into a "shared care" concept and why this is important for pharmacy.

THEORY OF PRACTICE

Every profession has three bodies: a body of knowledge, a body of practice, and a body of ethics.[1] A body of practice must have a mainstream purpose that provides a badge of identification to other professionals and to the client.

Donald C. Brodie, professor of pharmacy at the University of California at San Francisco, was the first to suggest that the pharmacy profession needed a theoretical model to distinguish itself and to evolve and actualize its preferred destiny.[1] In 1967, Professor Brodie suggested that *drug use control* should be the societal purpose of pharmacy. Brodie defined drug use

control as those events that happen "from the time the specifications of a drug are determined until the time the nurse administers it."

In 1981, Donald C. McLeod wrote a chapter in *The Practice of Pharmacy: Institutional and Ambulatory Pharmaceutical Services* titled "Philosophy of Practice," where he built on Brodie's premise by saying that "dispensing, while being controlled by the profession, must not control the profession. Pharmacy must seek to maximize its contribution to patient welfare, and it must do so by enhancing the contribution of the individual pharmacist."[2]

In 1985, at an invitational conference of national thought leaders in pharmacy practice, Professor Charles Hepler provided the audience with a compelling argument that pharmacy's societal purpose was to ensure the safe and effective drug therapy of the individual patient.[3]

In 2010, the American Society of Health System Pharmacists (ASHP) and its Research and Education Foundation sparked a profession-wide endeavor to promote and advance the practice of pharmacy called "The Pharmacy Practice Model Initiative."[4] In November 2015, the title of the endeavor was changed to the "Practice Advancement Initiative" (PAI) to more fully reflect the entirety of pharmacy services and care settings. The initiative has fourteen recommendations that achieved consensus, and six statements about the ideal pharmacy practice model.[5]

- Pharmacists should be accountable for the development and documentation of medication-related components, and must have oversight and responsibility for drug distribution.
- The role of pharmacists in frontline practice should not be limited to drug distribution and reactive order processing.
- Individual pharmacists must accept responsibility for both clinical and distribution activities of the pharmacy department.
- Individual pharmacists should not be engaged in *drug therapy management* (DTM) without an understanding of and responsibility for the medication use or delivery systems.
- Clinical specialists are necessary to advance practice, education, and research activities
- Contemporary pharmacy education must prepare pharmacists for an expanded role in DTM in hospitals and health systems.

A BRIEF HISTORY OF PHARMACY PRACTICE IN THE UNITED STATES

The Apothecary

The first apothecaries in the United States used methods learned in Europe, primarily England. The basis of most medicine was plant material and included sources in nature such as barks and roots of trees. The pharmacist prepared the medicine by incorporating substances from nature into a tincture, syrup, tea, cream, ointment, suppository, or capsule. Pharmacists prided themselves on the *art of pharmacy* by making accurate, eloquent, custom-designed pharmaceutical products.

As pharmaceutical companies grew, the art of pharmacy dwindled. By the early 1960s, drug companies made most products. The emphasis of pharmacy practice shifted from drug preparation to drug dispensing. By the early 1980s, most pharmacy schools taught only the most basic steps in drug compounding. Today, pharmacy students are learning to achieve positive health outcomes in patients by ensuring the provision of rational drug therapy.

Drug Dispensing and Distribution

During the 1960s and 1970s, hospital pharmacy focused on making drug distribution safer. It found that delivering medication by the *unit dose system* of drug distribution was much safer than traditional methods of drug distribution in hospitals.[6,7] This was followed by the discovery that centralizing the preparation of *intravenous admixtures*—adding injectable drugs to sterile intravenous solutions—in the pharmacy was safer than having each nurse prepare them on the patient care unit.[8] Between 1960 and the present, pharmacy has made many improvements in the dispensing and distribution of drugs to patients.

In the mid-1960s, pharmacy reflected on its role in health care. The pharmacist's role until then was confined to preparing and supplying medication. The pharmacist was expected to supply the medication to the patient as ordered by the physician. Only the dose could be questioned, and pharmacists were not to interfere with the *physician–patient* relationship. Thus, the interaction between the pharmacists and the patients was minimized.

Clinical Pharmacy

Pharmacy schools and pharmacists became more patient oriented during the 1960s. This practice was eventually termed *clinical pharmacy*.[9] *Clinical pharmacists* were defined as participants in drug therapy decisions and regarded as drug experts or specialists. Between 1960 and 1980, a growing number of pharmacists, most of whom had doctor of pharmacy degrees and had completed pharmacy residency training, were calling themselves "clinical pharmacists" and practiced clinical pharmacy in most large hospitals and academic medical centers.

Some functions of these early clinical pharmacists were to be available when the drug was prescribed, make recommendations on drug selection and the dose and duration of therapy, and monitor the drug administration and effects of the drug. These clinical pharmacy pioneers were often questioned by physicians and nurses about their presence on the patient care unit, and were sometimes rebuffed. However, the clinical education gained while earning the doctor of pharmacy degree and the patient care skills gained during residency programs carried them through. Many physicians and nurses were gradually won over to clinical pharmacy. Physicians and nurses started to understand the benefits—to themselves and to the patients—of having a clinical pharmacist available on the patient care unit.

In the early 1980s, concern evolved that clinical pharmacy was not being interpreted the same way by all pharmacists. In addition, some clinical pharmacists were becoming so specialized and their practices so different from other pharmacists that this practice started to become its own discipline. Thus, in 1985, the American Society of Health-System Pharmacists (ASHP) and its Research and Education Foundation conducted an invitational conference at Hilton Head Island titled "Directions for Clinical Practice in Pharmacy."[3] The objectives of this conference were to examine the extent to which the profession had established goals about clinical pharmacy, to assess the current status of clinical pharmacy practice and education, and to identify some practical ways for advancing clinical pharmacy.

Few, if any, of the 146 invited pharmacy practitioners and educators had any idea they were about to take part in something that would start the profession on its way to its true clinical potential. The keynote address by Charles D. Hepler, "Pharmacy as a Clinical Profession," was the stimulus that encouraged the group to think about the societal purpose of pharmacy.[10]

Hepler's premise was that once pharmacy agreed on its societal purpose, building a plan to fulfill that purpose should be obvious. The invitees agreed strongly on several points:[11]

- Pharmacy is the health care profession most concerned with drugs and their clinical application.
- A fundamental purpose of the profession is to serve society by being responsible for the safe and appropriate use of drugs.
- A fundamental goal of the profession is to promote health, and pharmacists can best do that by working to promote the best use of drugs.
- In following the preceding goal, pharmacy should provide leadership to other health care professions. This implies that pharmacists should advocate rational drug therapy rather than just reacting to treatment decisions made by others.

The conferees went on to agree that pharmacists should continue to be responsible for drug distribution and drug control activities, but these functions should be carried out by well-trained pharmacy technicians under pharmacist supervision. This would free the major portion of the pharmacist's time for clinical services. It was also agreed that drug distribution should be automated to as great an extent as possible.

It was obvious after the conference that the greatest force for change in the profession was within it. The Hilton Head conference on clinical pharmacy helped propel pharmacy toward its clinical destiny and planted the seeds for the next evolutionary step in pharmacy's clinical development: *pharmaceutical care*.

FROM CLINICAL PHARMACY TO PHARMACEUTICAL CARE

Between the Hilton Head conference in 1985 and 1989, enthusiasm for a more clinical role was building among the leaders of pharmacy. Its educational curriculum needed to change, and pharmacy practice would need to do things much differently to become a true clinical profession. A conference titled "Pharmacy in the 21st Century" was called for by 17 national pharmacy organizations in 1989. Like the Hilton Head conference, something dramatic took place here as well. This time, Charles Hepler and Linda M. Strand delivered a riveting paper, "Opportunities and Responsibilities in Pharmaceutical Care," at the second conference on "Pharmacy in the 21st Century" (1989).[12,13]

Hepler and Strand argued that clinical pharmacy represented a transition of pharmacists seeking self-actualization and the full achievement of their professional potential. "Many pharmacists are standing at the threshold of professional maturation; indeed many have crossed over that threshold into patient care."[13] The authors felt self-actualizing functions are slow to develop, and the functions (like pharmacokinetic monitoring) were still focusing on the drug rather than the patient. Something was needed to rally pharmacists to serve a higher good.

It was suggested that the higher good for pharmacy to serve was to prevent *drug-related morbidity* (drug-induced disease) and *drug-related mortality* (drug-induced death). Both the incidence and cost of drug-related morbidity and mortality were unacceptable. Much preventable drug-related morbidity and mortality could have been prevented by patient-focused pharmacists.[14]

Hepler and Strand appealed to pharmacists to accept the mandate of preventing drug-related morbidity and mortality, but they cautioned that the application of clinical knowledge and skill (then known as clinical pharmacy) was not enough for effective pharmaceutical services. There needed to be an appropriate philosophy of practice and organizational structure in which to practice. It was proposed that the necessary philosophy of practice be called *pharmaceutical care* and that the organizational system to facilitate the provision of this care

be called a *pharmaceutical care system*. Thus, the *mission of pharmacy practice*, which is consistent with its mandate, is to provide pharmaceutical care.

The paper and presentation by Hepler and Strand galvanized the profession. There was little argument about the mandate. The definition and concept of pharmaceutical care were appealing. In contrast to clinical pharmacy, all pharmacists, regardless of educational degree or practice setting, could provide pharmaceutical care. The profession soon settled on the mission of pharmacy practice—to help patients make the best use of their medication.[15] It was agreed that the best way to fulfill the mission of pharmacy practice was to practice pharmaceutical care.

WHAT IS PHARMACEUTICAL CARE?

The initial definition of *pharmaceutical care* by Hepler and Strand was "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life."[12,13] In 1993, out of concern that the original definition meant that pharmaceutical care could be delivered by anyone and fear that other health care practitioners would misinterpret this to mean that pharmacists would practice independently, the ASHP drafted a new definition for pharmaceutical care:

> *Pharmaceutical care* is defined as the functions performed by a pharmacist in: Ensuring the optimal use of medications to achieve specific outcomes that improve a patient's quality of life; further, the pharmacist accepts responsibility for outcomes that ensue from his or her actions, which occur in collaboration with patients and other healthcare colleagues.[15]

This definition was later revised to the following:

> The mission of the pharmacist is to provide pharmaceutical care. Pharmaceutical care is the direct responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality-of-life."[15]

In 1997, Linda Strand provided a newer definition:

> Pharmaceutical care is a practice in which the practitioner takes responsibility for a patient's drug-related needs and is held accountable for this commitment.[16]

There continues to be controversy about the term *pharmaceutical care*. Some pharmacists—mostly community pharmacists—feel the word *pharmaceutical* should be replaced with the word *pharmacy* or *pharmacist* (e.g., pharmacy care or pharmacist care). The rationale is that the word *pharmaceutical* is too associated with drug products, and by calling it pharmaceutical care, anyone can provide it. The term *pharmacy* or *pharmacist care* avoids these problems. However, most professional pharmacy organizations and schools of pharmacy are still using the original term *pharmaceutical care* or the term *patient care*.

Whether it is called pharmaceutical care, pharmacy care, or patient-centered care, it means the same thing—the patient is the central focus—not the pharmacist or what he or she does, not the drug, and not the prescriber.

Elements of Pharmaceutical Care

Regardless of which definition of pharmaceutical care is used, each definition encompasses six elements: responsible provision of care, direct provision of care, caring, achieving positive

outcomes, improving the patient's quality of life, and resolution of medication-related problems (MRPs).

Responsible Provision of Care

The pharmacist should accept responsibility for the patient. The pharmacist should say "my patient" rather than "the patient."

A professor who taught student pharmacists asked the class on the first day: "How do you accept responsibility for the patient? How will I be able to tell if you are accepting responsibility for the patient?" The classroom became deadly silent. None of the 120 students raised a hand and some hid behind their laptops. The professor repeated the question and waited. Finally, one brave student said, "I think accepting responsibility for patients has something to do with worrying." Intrigued, the professor asked the student to explain her answer.

"Well," the student said, "if a pharmacist works all day, goes home and never worries about a patient, then that pharmacist probably is not accepting responsibility for his or her patients." This is exactly right—without worry, little responsibility has taken place.

Other examples of accepting responsibility for a patient are discovering how well the medication is working and if the patient is experiencing any problems with the medication.

How do you take responsibility for a patient? First, you see every new patient as an opportunity. Second, you do everything in your power to help patients make the best use of their medication.

Direct Provision of Care

Pharmaceutical care is directly provided to patients. This means pharmacists must be in direct contact with patients. They must see and talk with patients.[17] The patient–pharmacist interface is critical to helping patients and to helping make pharmacy a true clinical profession. Pharmacists who work in a hospital pharmacy and never go to the patient care units to see patients and pharmacists in community pharmacies who never get out from behind their dispensing counters, may be contributing to pharmaceutical care, but are not providing it. The patient, rather than the physician or the drug, should be the pharmacist's primary focus. The factors important in becoming a "good pharmacist" are shown in Figure 7.1. The term *good pharmacist* is used in the context of the ideal or most admired, and patient-centered, rather than technically proficient.

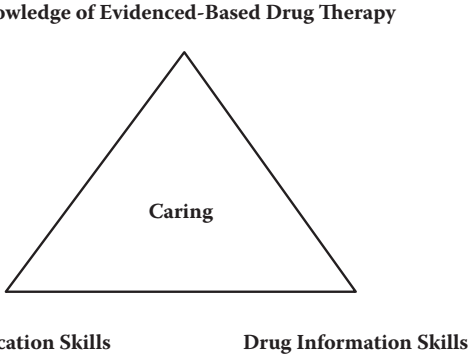

FIGURE 7.1 Important factors in being a good pharmacist.

Caring

The virtue of caring, a key characteristic among nurses and physicians, has been the most understated aspect of pharmacy. It is the heart of pharmaceutical care.

Good pharmacy practice involves a genuine interest in humanity. If true, do you as a pharmacist, student pharmacist, or prepharmacy student love and care about patients? Why? The answer to this question is a barometer for how you will perform your duties as a pharmacist.

Caring about patients is sometimes difficult for student pharmacists to grasp. The same professor who asked his class about accepting responsibility for patients asked the class to close their eyes and think about the person they loved the most—a husband, wife, girlfriend, boyfriend, mother, father, sister, brother, daughter, son, grandmother, grandfather, or grandchild.

After a minute, the professor said, "Open your eyes and listen. Every time you interact with a patient—across the counter, or when they are in a hospital or health-system bed—pretend like that patient is the person you love the most." The professor then asked, "If you do this, what will happen?" Students answered: "I would do my best," "I would make extra effort," and "I would make sure they understood everything."

In caring for patients, you will also need:

Up-to-date knowledge of drugs and drug therapy: Without this, it would be difficult to remain competent and be useful to patients or prescribers. Lack of up-to-date knowledge is dangerous and can lead to recommendations (or lack thereof) that result in therapeutic failure—even death.

Good drug information skills: Even if a pharmacist's knowledge base or memory is not as good as it needs to be, these deficiencies can be overcome by knowing where to find information about drugs, quickly retrieving the information, and then getting back to the person asking the question.

Communication skills: Even if you are knowledgeable about drugs or find the information when needed, it does not mean you will be able to communicate that information effectively. That means putting the patient and physician at ease, using terminology they understand, and not overwhelming them.

Style: Even if you are not the most knowledgeable or do not have exceptional drug information and communication skills, you can be effective by showing you care. Turf battles with physicians often melt away if the physician feels you are working in the best interest of the patient. Caring and conducting yourself in a professional manner is not less important than the other characteristics, but it is arguably more powerful.

Achieving Positive Patient Outcomes

Several positive clinical outcomes can occur as a result of taking medication: (a) curing disease, (b) eliminating or lessening a patient's symptoms, (c) arresting or slowing a disease process, or (d) preventing a disease or a symptom.

There are also negative outcomes from taking medication: (a) the medication fails to work as expected, (b) there are undesirable side effects, or (c) there are *adverse drug reactions* (ADR) that cause moderate patient morbidity, a life-threatening or permanent disability, or death.

Besides clinical outcomes, there are also economic (cost) and humanistic (functional status, quality of life, and patient satisfaction) outcomes. Under pharmaceutical care, it is the pharmacist's responsibility to do everything he or she can do to achieve positive patient outcomes and to avoid the negative effects of taking medication.

Improving the Patient's Quality of Life

Everyone has a certain and measurable *quality of life*. Many factors determine a person's quality of life, including socioeconomic status, educational background, social and business contacts, and health. Of these, health status is a major factor of a person's overall quality of life. A person's *health-related quality of life* represents the functional effects of an illness and its effects as felt by the patient. Most patients measure their health-related quality of life by what they can do versus what they could do before they were ill.

Under the pharmaceutical care model of delivering care, the pharmacist must, with the patient and the physician, set reasonable *treatment goals* for each drug prescribed that will improve the patient's functioning and health-related quality of life. Treatment goals should be set by the pharmacist in a hospital or long-term care setting. Likewise, community pharmacists should mutually set treatment goals with every patient presenting a new prescription, and check on progress during each refill by asking: a) how is the drug working for you?; and, 2) are you having any problems with the drug?

Resolution of Medication-Related Problems

The task of pharmaceutical care is to resolve *medication-related problems* (MRPs).[12] MRPs are undesirable events a patient experiences that involve (or are suspected of involving) drug therapy that actually (or potentially) interferes with a desired patient outcome.

Pharmaceutical care involves identifying potential and actual MRPs, resolving actual MRPs, and preventing potential MRPs. There are eight kinds of MRPs:[18,19]

1. *Needed drug therapy:* The patient has a medical condition that requires the initiation of new or additional drug therapy.
2. *Use of wrong drug:* The patient has a medical condition for which the wrong or suboptimal drug is being taken.
3. *Dosage is too high:* The patient has a medical condition for which too much of the correct drug is being taken.
4. *Not receiving the drug:* The patient has a medical condition for which the patient is not receiving the drug.
5. *Unnecessary drug therapy:* The patient is taking drug therapy that is unnecessary given his or her present condition.
6. *Dosage is too low:* The patient has a medical condition for which too little of the correct drug is being taken.
7. *Adverse drug reaction:* The patient has a medical condition because of an ADR or event.
8. *Drug interaction:* The patient has a medical condition and there is a drug–drug, drug–food, or drug–laboratory test interaction.

Note: Some people add a ninth MRP: Therapy not properly monitored. Table 7.1 lists some of the common causes of MRPs.

TABLE 7.1
Common Reasons for Medication-Related Problems in Patients

Needed Drug Therapy
- New medical condition
- Preventive therapy needed
- Return of an old medical condition

Use of Wrong Drug
- More effective drug available
- Drug not indicated for condition
- Contraindication present
- Dosage form inappropriate
- Condition refractory to drug

Dosage Is Too High
- Wrong dose
- Dosing frequency inappropriate
- Dosing duration inappropriate
- Drug interaction

Not Receiving the Drug
- Forgets to take drug
- Cannot afford the drug
- Side effects
- Prefers not to take the drug
- Administration error

Unnecessary Drug Therapy
- No medical indication
- Nondrug therapy more appropriate
- Duplicative therapy
- Treating avoidable adverse reactions
- Substance abuse

Dosage Is Too Low
- Wrong dose
- Frequency inappropriate
- Duration inappropriate
- Incorrect storage
- Incorrect administration
- Drug interaction

Adverse Reaction
- Allergic reaction
- Unsafe drug for patient
- Incorrect administration

Drug Interaction
- Dose increased or decreased too fast
- Drug causes decrease in second drug
- Drug causes increase in second drug
- Effects of two drugs are cancelled
- Drug–food interaction
- Drug interference with laboratory test

PHARMACEUTICAL CARE VERSUS CLINICAL PHARMACY

As shown in Table 7.2, pharmaceutical care is not the same as clinical pharmacy, although it evolved from clinical pharmacy. Everyone's practice is different; thus, exceptions exist for the comparison of pharmaceutical care and clinical pharmacy provided in the table. However, in general, the comparison is valid.

The major difference between the two practice models is the primary recipient of the pharmacist's service. Under clinical pharmacy, the physician is usually the primary focus of the pharmacist's attention. The pharmacist provides the physician with drug information and performs drug and pharmacokinetic monitoring for the physician. The patients rarely, if ever, know the pharmacist is involved with their care.

Providing services for the physician was a necessary step for the pharmacist to evolve clinically. It was necessary to establish credibility with physicians before pharmacists could begin to interact directly with patients. Until clinical pharmacy, the physician–patient relationship was sacred. Many physicians believed that no one else should have a similar relationship, particularly if that new relationship eroded the existing physician–patient relationship. Thus, it is important that pharmaceutical care be done cooperatively with the other health professionals providing care for the patient.

Other major differences between pharmaceutical care and clinical pharmacy are that pharmaceutical care focuses on various patient outcomes, shows caring, and can be provided by all pharmacists regardless of educational background or training.

LEARNING ABOUT PHARMACEUTICAL CARE

New pharmacy students—those in their first professional year of pharmacy school—may have to complete an introductory pharmacy practice experience in patient care. This experience often involves "shadowing" an advanced practice experience student—a pharmacy student in his or her last professional year of pharmacy school—and see pharmaceutical care in action. Students are scheduled or provided options for various shadowing experiences. However, because of unfamiliarity with the terms used for these rotations, the first-year student may not know what to select or may feel unprepared for this experience. With this in mind, a description of the typical clinical rotations available for introductory practice experiences is provided here.

TABLE 7.2
Comparison of Pharmaceutical Care and Clinical Pharmacy

Pharmaceutical Care	Clinical Pharmacy
More of a primary care model	More of a specialty, consultant model
Patient focused	Mostly physician focused
Provided directly to patients	Usually provided indirectly to patients
Outcome directed	Process directed
Focused on a variety of outcomes	Mostly focused on clinical outcomes
Based primarily on caring	Based primarily on competency
Pharmacist responsible for patient outcome	Physician responsible for patient outcome
Quality-of-life role	Quality-of-care role
Practice in all settings	Practiced mostly in acute care settings
All pharmacists can provide	Some pharmacists provide

Ambulatory (Primary) Care: This might also be called *general medicine*. The patients in this rotation may have acute and chronic health care problems, but they are outpatients (not hospitalized). They are seen in hospital clinics and in physician's offices. Because of the environment, these patients often have different concerns and issues than inpatients (those in hospital beds).

Adult (Internal) Medicine: This may also be called *internal medicine*. This rotation includes hospitalized patients with acute and chronic illnesses treated by medical internists, and sometimes family physicians, who are members of the Department of Medicine. These are important rotations for students as these patients usually have many medications prescribed and are excellent candidates for pharmaceutical care.

Pediatrics: Pediatric patients are usually less than 12 years old, and may be inpatients or outpatients. Pediatric patients have different medication issues than adults. Their medication is usually not complicated, but it is important.

Geriatrics and Long-term Care: Patients in this rotation are usually age 65 years or older. Rotations for students are usually at various long-term care facilities, but they also can be at geriatric inpatient units. These are good rotations for students as geriatric patients usually use much medication and need counseling about their medications.

Psychiatry: This pharmacy practice experience exposes the student to the area of mental health. The student will work with other members of the health care team to monitor drug therapy of patients with psychiatric diseases or substance abuse problems.

Surgery: Surgery rotations involve hospital-based experiences designed to enable the student to gain ability in basic principles of surgery and drugs used before, during, and after surgical procedures. Specialty surgery rotations include general, orthopedic, cardiovascular, plastic, obstetrics, ophthalmic, and more.

Cardiology: This practice experience is designed to help the student gain skills in treating and monitoring therapy for cardiovascular disorders.

Infectious Diseases: During this practice experience, students learn about specific infectious diseases and about their prevention and treatment with drugs.

Home Health Care: Increasing numbers of patients are being treated at home or are being released from the hospital to be treated at home. Pharmacy is responsible for providing and monitoring the use of sophisticated infusion drugs (given intravenously).

Advanced Community Pharmacy Practice: This rotation is designed to introduce the student to pharmaceutical care in the community pharmacy. New, innovative, and billable pharmaceutical care services will be learned.

Drug Information: The student will learn how to research and answer drug information questions from physicians, nurses, pharmacists, and patients, as well as how to evaluate drugs and drug literature.

Neonatology: This is a hospital-based practice experience designed to enable the student to acquire skills and knowledge about the basic principles of drug therapy in the neonate (infant less than 30 days of age).

Critical Care: This experience concerns the intense drug therapy of patients in critical condition and confined to a critical care or intensive care unit of a hospital.

Hematology/Oncology: This is usually a hospital-based experience, but it could be an ambulatory experience or both. It concerns learning the treatment of patients with various blood disorders or cancer. The student learns the principles of pain therapy and cancer chemotherapy.

Substance Abuse: This experience is designed to expose the student to the problems of drug and alcohol abuse and the treatment most often used in the clinical setting.

Pharmacokinetics: This experience is designed to give the student hands-on experience in mathematically modeling the distribution and elimination of critical drugs in the body and determining the correct dosage of the drug based on these models. This practice is sometimes called *therapeutic drug monitoring* (TDM).

Toxicology/Poison Control: This experience will allow the student to gain experience in toxicology and the treatment of poisoning and overdose by working at a regional poison control center.

Emergency Medicine: This experience involves learning how to treat patients admitted to the emergency room for critical and acute conditions, including drug overdose.

Nutritional Support Pharmacy: This experience is a hospital experience designed to teach the student how to treat, prepare, and monitor intravenous nutrition therapy in patients unable to eat or to absorb nutrients from their gastrointestinal tract.

Nuclear Pharmacy: In this experience, the student will learn about the basic principles of nuclear medicine and how to prepare and monitor nuclear pharmaceuticals—drugs that are radioactive—and care for patients who receive these agents.

Health Outcomes Management: In this experience, the student will become well versed in the various health outcomes (clinical, humanistic, and economic) and be able to measure these to see if there is an association with specific drug therapy.

Transplantation: This experience is designed to give the student the opportunity to provide patient care services related to the use of various immunosuppressive therapies in the inpatient setting. During this experience, the student will develop a pharmacotherapeutic care plan for patients receiving immunosuppressive therapies, develop the skills necessary to provide monitoring and counseling for patients receiving immunosuppressive therapies, and learn to participate in a multidisciplinary healthcare team.

Pain Management: This practice experience enable the student to develop proficiency in the knowledge of pain management and other targeted symptoms commonly seen during end-of-life situations.

Compounding: This practice experience is designed to give the student a general understanding of the rationale for and the various techniques used in the extemporaneous compounding of pharmaceutical products.

Medication Reconciliation: Medication reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. This practice experience is designed to give the student an understanding of the importance of medication reconciliation across all healthcare settings. Through this experience, the student will develop skills necessary to participate in and provide leadership for the medication reconciliation process, enhance written and verbal communication skills, and learn to participate within a multidisciplinary healthcare team.

Pharmacy Informatics and Technology: This practice experience is designed to introduce the student to the use of healthcare information technology as a means to improve medication use, enhance patient safety, and advance patient care. Through this experience, students will gain insight into the important role pharmacists play in integrating medication use with various levels of technology.

Regulatory Pharmacy: This practice experience will give the student a general understanding of the duties and responsibilities of a regulatory agency within the profession of pharmacy.

Transitions of Care: This experience is designed to expose the student to the importance of the pharmacists' role in the transition of care of a patient in both the inpatient

and outpatient setting. This practice experience is designed to give the student an understanding of the importance of medication reconciliation, direct patient care, andambulatory follow-up across all settings. Through this experience, the student will develop skills necessary to participate in and provide leadership for the medication reconciliation process, enhance written and verbal communication skills, and learn to participate within a multidisciplinary healthcare team.

Global Medical Missions: This practice experience will introduce the student to the practice of pharmacy within a medical missions-related setting. Through this experience, the student will participate in pharmacy-related activities as a means for global outreach, service, and personal growth.

Leadership in Pharmacy Management: This experience exposes the students to the duties and responsibilities associated with upper-management executives within a pharmacy corporation or business entity. This experience is designed for students interested in pursuing a pharmacy career in upper-management and enhancing their leadership skills. The student will interact with executives in both clinical and business aspects of a company or healthcare system. This experience is specifically designed to give the student experience in practice issues, employee management, human resource services, recruiting, staffing and employee development needs, policy and advocacy, public relations, and in understanding the importance of professionalism and operational standards.

Managed Care Pharmacy: This experience is designed to provide the student with the general knowledge and a high level of exposure to a variety of activities conducted by managed care organizations (MCOs). MCOs manage healthcare services in a manner that is designed to effectively meet the needs of its members while incorporating clinical and economic factors.

Medication Safety: This practice experience is designed to expose the student to the duties and responsibilities associated with the recognition, prevention and reporting of medication errors. This APPE is designed to provide students with both direct and indirect patient care. Students will work to provide improved medication safety throughout the health care facility.

Obstetrics/Gynecology: This practice experience is designed to expose students to the duties and responsibilities of a pharmacist practicing on a high risk perinatal and labor/delivery service.

Medication Therapy Management: This course will be an experience-based rotation to help the student become an active participant in the management and provision of a managed care Medication Therapy Management (MTM) program. Emphasis will be placed on learning basic MTM principles while the student learns how to provide these services to patients.

Pharmacy Association Management: This experience is designed to broaden the student's knowledge and understanding of Pharmacy Association Management. It is structured to provide experiences in national and state practice issues, education, member services, student development, policy and advocacy, and public relations. This experience can be completed at one of several sites.

Academic Administration: This practice experience is designed to stimulate the interest of pharmacy students in academia and provide the student with an understanding of the function and process of the academy. Through interviews with faculty, readings in the literature, participation in academic and administrative meetings, development of teaching materials with pharmacy faculty chosen as preceptors in the students' area of

interest, the exploration of teaching methodologies and several "hands on" projects, the student is better able to evaluate the possibility of a career in academia as well as assume a position in academia.

Health Outcomes Management: This practice experience is designed to provide the student with a basic understanding of health outcomes (clinical, economic, humanistic) focusing on pharmacoeconomics and health care quality assessment. Didactic and practical experience in these core areas will expose the student to a variety of competencies utilized in a health outcomes research and consulting firm. The practice environment involves working directly with a number of managed care organizations, pharmaceutical manufacturers, pharmaceutical providers, pharmacy benefit managers and various other health care providers. The student will be exposed to and/or directly involved with the many steps in conducting quality focused, outcomes-based research—from proposal development to analysis and manuscript preparation.

Prescription Benefit Management: This practice experience is designed to give the student general knowledge and a high level of exposure to a variety of activities conducted by a Prescription Benefit Manager. A Prescription Benefit Manager is responsible for managing the drug benefits for a health care plan. Specific activities include Formulary Management and Drug Utilization Review activities.

Research: The research experience will provide the student with the opportunity to participate in an ongoing research project and develop skills necessary for pursuit of graduate education, fellowship, or a research-oriented career.

Pharmacogenonics: The goal of this experience is to provide opportunities to build on knowledge and skills acquired through didactic education and introductory pharmacy practice experiences and apply them in patient care and other activities within a clinical pharmacogenomics service. This course takes place where medication therapy management for select patient populations includes pharmacogenomic information. Activities may include: assisting with the development of a clinical pharmacogenomics service at Pharmacy Plus; analyzing tumor DNA to identify molecularly targeted treatment options for cancer patients managed using a team-based approach; evaluating literature relevant to pharmacogenetic implementation and clinical care; performing pharmacogenomic consults; identifying problems requiring therapeutic interventions; consulting with physicians; or providing educational sessions for the professional staff.

Hospice/Palliative Care: The goal of this experience is to see how pharmacists care for patients in the last chapter of their lives, and how to provide pain-free therapy.

Advanced Institutional Pharmacy Practice: This experience is designed to expose the student to broad-based daily duties often required of an institutional-based pharmacist including but not limited to dispensatory functions of a pharmacist in the hospital setting, medication reconciliation, and participation within a multidisciplinary healthcare team.

Anticoagulation: This experience is designed to give the student the opportunity to provide patient care services related to the use of various anticoagulation therapies in the inpatient setting. During this experience, the student will develop a pharmacotherapeutic care plan for patients receiving anticoagulant therapies, develop the skills necessary to provide monitoring and counseling for patients receiving anticoagulation therapies, and learn to participate in a multidisciplinary healthcare team.

All pharmacists are teachers. They teach patients, pharmacy technicians, nurses, and others. Students in advanced practice experiences learn by observing and listening to pharmacy practitioners who model professional behavior. Students also learn by doing rather than by hearing about pharmaceutical care, but always under the watchful eye and guiding hand of the pharmacist preceptor.

PROVIDING PHARMACEUTICAL CARE

Standardized Approach to Patients

No matter where a physician is educated or trained, the approach to the patient is the same, and as a patient, we recognize it when we see it. First, the physician asks for the patient's *chief complaint* (CC). Next are questions on *history of the present illness* (HPI), and then the *past medical history* (PMH). A physical examination is next, followed by a preliminary diagnosis. Last, laboratory tests are performed to confirm the diagnosis.

Like medicine, pharmacy needs a standardized approach to the patient, one that patients recognize.[20] Thus, the following approach to pharmaceutical care is recommended:

1. Collect and organize information about the patient.
2. Establish the patient–pharmacist relationship by being cordial.
3. List and rank the patient's MRPs.
4. Determine feasible solutions for each MRP.
5. Choose the best solution for each MRP.
6. Set a treatment (outcome) goal for each drug.
7. Discuss and negotiate the plan with the physician as needed.
8. Educate and counsel the patient about the medication.
9. Design and implement an effective monitoring plan.
10. Follow up, measure, and document progress.
11. Bill for services as appropriate.

Selecting Patients to Monitor

Theoretically, all patients should receive pharmaceutical care. However, based on the numbers of patients, prescriptions, and drug orders, providing all the steps in the pharmaceutical care process is not possible for all patients. One service that cannot be ignored is the pharmacist's (not the clerk, not the technician) offer to counsel patients about their medication. It is required by law.

Beyond this, certain patients benefit more than others from pharmaceutical care. Thus, criteria can be established to select patients who will benefit the most from a pharmacist using all the recommended steps in the pharmaceutical care process. Some pharmacists select patients age 65 or over to monitor, as these patients usually take more than the average number of drugs. These patients should be monitored because liver function (metabolizes or converts drugs so they can be eliminated) and renal (kidney) function (eliminates drugs from the body) diminish as patients get older.

Other criteria for selecting patients for pharmaceutical care can be as follows: patients taking more than six drugs, patients with reduced liver or kidney function, and patients taking certain potent drugs. In community pharmacy practice, an area may be to select patients

that appear not to be taking their medication as prescribed. The possibilities are endless and based on personal interest.

Recently, some pharmacists are selecting patients to monitor (follow) based on their risk for returning to the hospital, going to the emergency room, or having to go back to see their physician because of therapeutic failure. These negative experiences are often based on poor drug selection or patient adherence.

Identifying, Resolving, and Preventing Medication-Related Problems

Once a process for identifying the patients who will benefit the most from pharmaceutical care is established, the next step is to follow the recommended process for providing pharmaceutical care.[21] The heart of this process is to identify, resolve, and prevent MRPs. How is this best done?

Identifying Medication-Related Problems

As shown in Table 7.3, there are various ways to identify a patient's MRPs. One of the most efficient and comprehensive ways, and thus the best way, is by talking to the patient.

Every patient has a story. In *the patient's story* will be the patient's MRPs. However, to gain clues about the MRPs, the pharmacist must win the trust of the patient and listen carefully. Trust begins in establishing the patient–pharmacist relationship. Trust is based on kindness, caring, empathy, honesty, justice, and confidentiality and is strengthened by actions of past caring—all virtues of a "good pharmacist." Listening has to be done with the whole mind and heart and by trying to feel the patient's vulnerability. Listening carefully and asking probing questions will identify the patient's MRPs.

Resolving Medication-Related Problems

Once MRPs are identified, they need to be resolved. Some ways of resolving MRPs include adding a drug, canceling a drug, changing the dose of a drug, changing the way the drug is given, or counseling the patient.

TABLE 7.3
Ways to Identify MRPs in Patients

	Ways to Identify			
MRP	**Rx or Drug**	**Patient's Computer Profile**	**Patient's Medical Record**	**Talk with the Patient**
An untreated problem		X	X	X
Wrong drug prescribed			X	X
Taking too little drug	X	X	X	X
Taking too much drug	X	X	X	X
Not taking the drug	X	X	X	X
Taking an unneeded drug				X
Experiencing a drug interaction	X	X		X
Experiencing an adverse drug reaction			X	X

Note: Rx = an effective prescription; X = way to identify.

Preventing Medication-Related Problems

It is important to prevent MRPs before they begin. Some ways to do this are to: (a) educate, counsel, and listen to patients; (b) educate physicians and nurses about drugs; (c) program the computer to screen drug orders for problems; (d) require the diagnosis or use of the medication on the prescription; (e) require physician order entry of all drug orders; (f) require the electronic transmission of prescriptions and drug orders to the pharmacist; (g) have the pharmacist be present when the medication is ordered in the hospital or clinic; (h) implement unit dose and centralized intravenous additive systems in all hospitals; (i) reduce floor stock medication; and, (j) eliminate sound-alike and look-alike drug names.

The Patient Problem List

A practical tool for assessing patients, used for years by the medical profession, is *SOAPing*, where S = subjective findings, O = objective findings, A = assessment, and P = plan. The subjective findings are the patient's signs (what can be seen) and symptoms (what the patient reports). The objective findings are what can be measured on physical examination or laboratory measurement. The assessment is the working diagnoses based on the subjective and Objective (laboratory) findings. The plan is a *problem list* in order of priority and what is to be done.

SOAPing can be used by pharmacists when identifying and resolving MRPs. For example:

S: Patient complains of being tired, thirsty, and sluggish. Patient states he has "sugar."
O: Blood glucose level is 220 mg/dL (high).
A: Diabetes is uncontrolled owing to poor adherence with taking insulin.
P: Determine why patient is not taking enough insulin. Remind the patient of why it is important to take the insulin and what may happen if it is not taken as prescribed.

Some pharmacists go through the subjective, objective, and assessment parts of SOAPing and then use a *problem list*. The problem list is a record of each MRP. After thinking of various solutions to each MRP, the pharmacist records the plan and therapeutic goal (developed between the patient and the pharmacist or one already selected by the prescriber) or best outcome for that MRP. An example is shown in Table 7.4.

TABLE 7.4
Medication-Related Problem List for a Patient

Number	Medication-Related Problem	Plan	Therapeutic Goal
1	Respiratory depression from opioid	Reduce dose to 100 mg every 8 hours as needed	Reduction or elimination of the side-effect.
2	Potential drug interaction	Smoking and oral contraceptive	Patient stops smoking or uses other methods of birth control
3	Rash on face and neck	Investigate penicillin allergy	Prove or disprove allergy
4	Antihistamine no longer needed	Recommend discontinuation	Stop order written

The Pharmaceutical Care Plan

The problem list is part of something bigger: the *pharmaceutical care plan*. The plan documents the pharmaceutical care process and lists:

- Information about the patient
  - Age and gender
  - Height and weight
  - Renal and liver function
  - Diagnoses
  - Quality of life
- Medication
  - Current medications
  - Medication allergies
- Problem list
  - MRP by priority
  - Recommended solutions
  - Goals for each drug and MRP
  - Status of recommendation (pending, followed, not followed)
- Patient outcomes (clinical, humanistic, economic)

The pharmaceutical care plan need not be extensive and can be individualized for your type of practice. The most important aspect of the pharmaceutical care plan is that you have one for each patient you follow. Why? First, you can remember what you did during your last contact with the patient. Second, it provides a record for another pharmacist who may see the patient if you are not available. Third, it documents for potential reimbursement of the service provided to the patient.

Making Cents of Pharmaceutical Care

Pharmacists have traditionally been paid for their knowledge and skill in dispensing medications correctly. Billing and payment for pharmaceutical care has been slow to develop, but this has been expected. Pharmacists have always given their advice and counsel away for free. Thus, some pharmacists are uneasy with charging for these services. In addition, pharmaceutical care and its value are unfamiliar to patients and to payers such as insurance companies. In addition, most pharmacists are still learning what to charge for, how much to charge, and how to bill these services.

However, many pharmacists feel they are providing value-added pharmaceutical care for patients and should be paid. Even pharmacists working for chain pharmacies feel they should receive a portion of the reimbursement earned by the chain because of their direct patient care services.[22]

Some pharmacists are requesting and are being paid from Medicare and some commercial insurance programs for *medication therapy management* (MTM). MTM means working closely with the patient and physician in the pharmaceutical management of the patient's chronic disease (diabetes, asthma, hypertension, cholesterol levels), administering immunizations, and identifying and resolving MRPs.[23]

Charging patients up front: The best way to ensure payment is to require payment directly from the patient at the time the service is delivered. This is easier than one would think if the services are promoted, proposed, and delivered in the proper manner.[24,25]

Billing major medical payers for the patient: Some insurance plans cover pharmaceutical care services.[25] Requiring payment at the time of service is always best, as is assisting patients in submitting their own claims. If the pharmacist or pharmacy decides to bill an insurance company for pharmaceutical care services, it must be done properly by using one of two claim forms—the Health Care Financing Administration (HCFA) 1500 or Pharmacist Care Claim Form. The latter is the most user-friendly claim form for pharmacists to use. However, the HCFA 1500 claim form is the claim form most recognized by claims payment agencies across the nation. This claim form is not as easy to use, but once mastered will probably result in the most claims being paid.

Becoming a provider in a state or federal disease state management program: These programs are usually administered through Medicaid (state) or Medicare (federal) agencies. States such as New Jersey, Oklahoma, Texas, and Mississippi have state disease management programs that pay pharmacists to help manage the therapy of patients with certain chronic diseases. One example is the Mississippi Medicaid program that has a federal waiver allowing reimbursement to pharmacists for providing drug therapy management and patient education. Working under protocols drafted collectively with physicians, *credentialed* pharmacists in Mississippi are now eligible for reimbursement in the following clinical areas: diabetes, asthma, hypercholesterolemia, and anticoagulation therapy.

Contracting with major medical groups to manage specific patient populations: Major group health providers are starting to pay pharmacists to help manage certain patient populations taking certain categories of drugs to help improve patient adherence with taking the medication appropriately and to contain costs.

A breakthrough on billing for cognitive services provided by the pharmacist occurred on January 1, 2006. On this date, pharmacists received three nationally recognized codes to bill third-party payers for providing MTM services. A comprehensive medication review (CMR) must be completed and a third party (Pharmacist Billing Company) is needed to do the billing. They base their billing off a percentage, send the bill to CMS, and CMS sends the payment to the pharmacy. The billing codes approved for MTM are located in Table 7.5.

TABLE 7.5
Billing Codes for Established Office Patients

Level of Severity	E/M Code	History	Physical Exam	Medical Decision Making	Time
1	99211	None	None	None	5
2	99112	Problem Focused	Problem Focused	Straightforward	10
3	99113	Expanded Problem Focused Exam (ROS)	Expanded Problem Focused Exam (ROS)	Low	15
4	99114	Detailed	Detailed	Moderate	25
5	99115	Comprehensive	Comprehensive	High	40

Note: Pharmacist can only use incident-to billing (non-physician practitioner) 99211; Pharmacist can't use codes 99213–99215 unless they have been granted "provider status"

A good guide on compensation models of MTM is available.[26] An excellent guide is also available on pharmacist billing for ambulatory pharmacy patient care services in a physician-based clinic and other non-hospital-based environments.[27]

IS ACHIEVING PROVIDER STATUS THE ANSWER TO PAYMENT?

The pharmacy profession is methodically pursuing provider status to improve status and gain payment for providing cognitive services. However, as discussed in Chapter 1 of this book, it may not be necessary under accountable care.

WHY PERFORM PHARMACEUTICAL CARE?

There are many reasons for pharmacists to expand their practices to perform pharmaceutical care. Reasons can be because of the patient, because the drug use process is not perfect, because there is drug morbidity and mortality, because it works, and because it may mean survival and recognition of pharmacy as a true clinical profession.

The Patient

The patient deserves the best of pharmacy. Because drugs are so complex, and some so powerful, patients are often confused about their medication. Patients need to know their drug, what it is, how it works, how they should take it, why they should take it, what may happen if they do not take it, and what kinds of problems to look for when taking it.

Most patients feel vulnerable because of a lack of knowledge about drugs and drug therapy. What they need is a medication advocate. Physicians are usually too busy, and most of them are not interested in spending time with patients discussing this subject. Medication advice and counseling is not the central role of nurses. Pharmacists are in the best position to do this and are the best trained to fulfill this important role.

Problems in the Drug Use Process

Although the *drug use process* is well organized and has many checks and balances, it is far from perfect. Drugs are not always prescribed, dispensed, administered, and monitored correctly. There are even times when all of these steps are done correctly and the treatment fails because of misdiagnoses or physiological variations within patients.

Drug-Related Morbidity and Mortality

Patients often experience unwanted effects of their medication. If these unwanted effects are more than mild side effects, and unexpected, they are called *adverse drug reactions* (ADRs). ADRs, drug interactions, medication allergies, and medication errors are sometime referred to as *adverse drug events* (ADEs) or *drug misadventures*.

Early Reports: A well-publicized report by the Institute of Medicine (IOM) of the National Academy of Science estimated that between 44,000 and 98,000 hospital patients die each year in the United States because of medical errors![28] This report estimates that at least 7,000 patients die each year from medication errors, but this is a modest number as it does not include deaths from medication allergies, drug interactions, and ADRs, and patients outside the hospital.

TABLE 7.6
Range of Likely Drug Misadventure Outcomes

Morbidity and Mortality	Likely Outcome
Mild discomfort	None
Moderate discomfort	Physician visit
Severe discomfort	Emergency room visit
Life-threatening event	Hospital days
Permanent disability	Lifelong care
Death	Invaluable

About 0.2% of emergency room visits are because of the adverse effects of medication.[29] This translates into roughly 125,000 visits, or 4.77 visits per 10,000 people per year. The prevalence of hospital admissions because of the adverse effects of drugs, based on a meta-analysis of 36 studies, ranged from 0.2% to 21.7%; the median was 4.9% (range 2.9% to 6.7%), and the mean was 5.5% (±4.1%).[30]

The severity of drug morbidity varies. Bates et al. reviewed 4,031 adults admitted to a hospital over a 6-month period.[31] Over time, 441 ADRs were identified. Of these, 1% were fatal, 12% life threatening, 30% serious, and 57% significant. Table 7.5 lists some likely outcomes of drug misadventures based on the severity of morbidity and mortality.

Latest Data: The sad news is that these numbers have not changed much, and the problem of medication-related morbidity and mortality is not yet under control. The good news is this is a wonderful opportunity for pharmacists to show how they can help improve patient outcomes (Table 7.6).

Many drug misadventures are preventable and can be prevented by pharmacists practicing pharmaceutical care.

PHARMACEUTICAL CARE WORKS

Patients are Spared Medication-Related Morbidity and Mortality

Another good reason to practice pharmaceutical care is that it works—it identifies, resolves, and prevents MRPs. Studies are being done to measure its impact on patient outcomes and quality of life.

Even student pharmacists can have a positive impact on patients. For example, a study measured the clinical interventions completed by doctor of pharmacy students on an 8-week internal medicine rotation.[32] Student pharmacists documented 1,315 interventions. The average interventions per student was 41, and each intervention took an average of 11.5 minutes. Clinical interventions, in rank order, were appropriate therapy, dosing issues, switching from the intravenous route to the oral route of administration, duplicative therapy, contraindications, drug interactions, allergy prevention, and pharmacokinetics. A majority of pharmacist recommendations were accepted by the prescribers.

In another study, 93 senior student pharmacists documented 5,031 interventions on 3,320 intervention forms using an Internet-based documentation system.[33] The most common interventions were as follows: dosage (13.5%); ADR, toxicity, side effects (19.2%); and drug product selection (13.5%). Of the 5,031 recommendations, 41.9% of the MRPs were classified as "moderate risk." Prescribers accepted 87.1% of the recommendations, and the interventions took 15 minutes or less to complete.

In another study, there was a significant difference in 30-day readmission rates when student pharmacists and residents counseled heart failure patients about their medication versus a group of heart failure patients that did not receive pharmacist counseling.[34]

Four points can be made about these data:

- MRPs happen, and patients are not receiving the full benefit of their medication or are being harmed.
- If the doctor of pharmacy students can find this many MRPs, think how many MRPs can be found and solved by experienced pharmacists.
- MRPs vary by patient—ambulatory versus inpatient.
- Pharmacists can identify, resolve, and prevent MRPs, and they should be recognized for these contributions to improving the health of patients.

A good model for pharmacy students to learn about pharmaceutical care is in the ambulatory care setting. Veterans Affairs medical centers have the premier model.[35] Pharmacists, especially those with a doctor of pharmacy degree and residency training, are delivering high-quality pharmaceutical care to veterans, especially in ambulatory care clinics. Another good model for pharmacy students to learn pharmaceutical care is in the U.S. Indian Health Service, which is part of the U.S. Public Health Service. Commissioned pharmacy officers deliver the most independent, high-level pharmaceutical care to populations of Native Americans. Their patient care services have been an inspiration to many pharmacists.[36]

Pharmaceutical Care is Cost-Effective

Pharmaceutical care no longer has to be cost justified. There is a long list of well-designed studies that show that pharmaceutical care can improve quality drug therapy and reduce drug-related morbidity and mortality.

The first cost-benefit analysis of a clinical pharmacy service was published in 1979.[37] In a systematic literature search of economic studies published on the value of clinical pharmacy services between 1996 and 2000, the investigators found 59 controlled studies.[38] Sixteen studies included a benefit-to-cost ratio that ranged from 1.6 to 1 for a target drug program in a hospital-associated clinic to 17 to 1 for a disease state management program in a university hospital.

In 2010, a systematic review reported—of 126 studies that met the criteria, 20 studies found favorable pharmacist provided care; mixed results in 53 studies; no effect in 6 studies; and unclear results in 47 studies.[39]

It is clear that more research needs to be focused on documenting whether pharmaceutical care keeps patients out of physicians' offices, emergency rooms, and hospitals and whether adults return to work and children return to school earlier than without pharmaceutical care. These are the primary outcomes of interest to the majority payers of health care—business owners and the federal and state governments.

Patients Love Pharmaceutical Care

There are also studies showing that patients love pharmaceutical care. There is even a measurement instrument for determining the degree to which patients love pharmaceutical care.[37]

Other Health Care Practitioners Love Pharmaceutical Care

Evidence also exists that other health care practitioners love pharmaceutical care. For example, the medical and nursing staff of an emergency room where pharmacists practiced pharmaceutical care highly valued the services provided by the patient-centered pharmacists.[40]

Is Pharmacy a True and Recognized Clinical Profession?

Pharmacy has always been patient oriented, even when pharmacies were mostly corner drugstores and pharmacists were compounding most of the medication for patients. Pharmacists became less patient oriented when pharmaceutical companies supplied most of the drugs for the pharmacist to dispense. Pharmacists became even less patient oriented when insurance companies started paying for drugs and the amount of paperwork required to dispense and bill a prescription increased. Being tied to a product hinders the profession from being all it can be. It puts pharmacy more in the category of "retailer" than "professional" or "clinician."

Under pharmaceutical care, the patient is the central focus of the pharmacist, and there must be a patient–pharmacist relationship and interaction between the two parties. This and identifying, solving, and preventing MRPs and focusing on positive patient outcomes should substantially raise the practice of pharmacy to the level of a true clinical profession and help it achieve this status.

When most pharmacists provide patient-centered care, the profession will arrive at a tipping point to be recognized as a true clinical profession.

WHEN WILL ALL PHARMACISTS PRACTICE PHARMACEUTICAL CARE?

There are some barriers and challenges, but also some enablers and proven implementation steps to providing pharmaceutical care. Once most pharmacists practice pharmaceutical care, it will become the standard of practice. Those pharmacists not practicing pharmaceutical care will have to justify—in a court of law, if sued—why they are not using this model of delivering care.

Barriers and Challenges

The following are some of the barriers and challenges to pharmaceutical care:[25,41] the enemy within, resource-related constraints, lack of support, legal barriers, studies documenting the value of pharmaceutical care, and lack of payment.

The Enemy Within

The number one barrier to the practice of pharmaceutical care lies within the profession itself. Some pharmacists are reluctant to change, some lack confidence in their abilities to implement pharmaceutical care, and some fear increased liability. The key to overcoming this is formal education (external doctor of pharmacy programs) and continuing education programs that provide practicing pharmacists with advanced practice skills and increased confidence to practice pharmaceutical care. Pharmacists need to learn the full concept of pharmaceutical care and why it is important to practice in this manner.

The most important key is for pharmacists not to slip into doing technical functions that should be done by pharmacy technicians. Avoiding one-on-one contact with patients short-circuits our duty to help patients and prevents the profession from moving forward.

Resource-Related Constraints

Freeing up enough time to perform pharmaceutical care is a major challenge to its implementation, especially in the community pharmacy environment, where the volume of prescriptions and paperwork is ever increasing. Unfortunately, the priority in most pharmacies is providing the medication to the patient, even if it is not the best medication (is poorly prescribed) for the patient. Freeing pharmacists' time for pharmaceutical care involves commitment, the increased use and expanded practice of pharmacy technicians, work redesign and automation, and an electronic medical record available to all licensed health practitioners.

Some pharmacists are under the misunderstanding that large sums of money are needed to provide pharmaceutical care. Changes are needed in space, equipment such as computer programs, and personnel, but these need not be expensive and can be phased in over time.

Lack of Support

Sometimes, there is lack of support from owners, managers, and supervisors of pharmacists motivated to practice pharmaceutical care. It is frustrating when these doubters have business rather than pharmacy backgrounds. This is a difficult, but not impossible, barrier to overcome. Pharmacists in this circumstance often find it helpful to dedicate themselves to patients and to prove that pharmaceutical care works by providing it whenever possible. Even if they can only work with two patients a day (i.e., 10 a week and over 500 a year), it will still have an impact.

Patients, nurses, and physicians are more easily impressed with pharmaceutical care, especially if it is obvious that the pharmacist is interested in helping patients and displays a caring attitude. It is also helpful if the pharmacist thinks of ways to help physicians and nurses in their prescribing and drug administration roles. Even from a business perspective, a pleased customer is likely to become a repeat customer.

Legal Barriers

Some laws and regulations made by state boards of pharmacy need changing to improve the pharmacist's clinical role. Here are a few changes that will help propel pharmacy's clinical role: (a) replacing technician–pharmacist ratios with regulations that make the pharmacist accountable for the work of a safe number of technicians, (b) allowing terminal dispensing by use of a bar code check, (c) electronically transmitting all prescription and drug orders, (d) allowing pharmacists to perform immunizations and some routine laboratory testing (such as finger sticks for drug-level testing), and (e) enhanced collaborative practice agreements between pharmacists and physicians.

Studies Documenting the Value of Pharmaceutical Care

There is no question that well-designed studies documenting the value of pharmaceutical care will help advance its practice. Some pharmacists incorrectly believe there is a lack of such studies, when the truth is that there are plenty of such studies.[39,42,43] Thus, questions become—Why isn't this evidence being read, believed, or used? Why isn't it enhancing the pharmacist's image and advancing the payment of cognitive services at a faster rate?

Lack of Payment

Some pharmacists—a minority—believe they should not perform any pharmaceutical care or any new service without being paid first, whereas others believe the profession needs to demonstrate the value of the new service before requesting payment.

Enablers to Pharmaceutical Care

Several trends enable pharmaceutical care to be the practice model of choice for all pharmacists: changes in pharmacy education, certified pharmacy technicians, function analysis and workflow redesign, collaborative practice agreements, pharmacy automation and information technology, medication errors, and health care reform. The real key is demonstrating pharmacists can help reduce healthcare utilization and cost.

Changes in Pharmacy Education

All colleges of pharmacy now have the doctor of pharmacy degree as the entry-level degree to practice pharmacy. This was a long time coming, but it has arrived. Continuing education programs are available for all pharmacists to learn or to enhance their clinical skills.

Certified Pharmacy Technicians

Pharmacy technicians now have a means of being certified to verify they have certain knowledge about pharmacy. Using more and more qualified pharmacy technicians will allow pharmacists to spend more time with patients.

Function Analysis and Workflow Redesign

Pharmacists are starting to understand that major changes will need to take place in the workflow to free time for them to perform pharmaceutical care. What is less understood, and perhaps more important, is that an analysis of work function and responsibility needs to take place.

Many pharmacists are performing functions that can and should be performed by technicians. The problem is that many like it this way. However, these pharmacists are being overpaid for what they are doing, and they are wasting their knowledge and skills by not performing higher patient care functions. Information is available on how to redesign workflow and perform a function analysis.

Collaborative Practice Agreements

Many professional pharmacy organizations and state boards of pharmacy have been successful in achieving *collaborative practice agreement* (CPA) legislation through state legislatures. These agreements establish a working relationship of a pharmacist or group of pharmacists working in a pharmacy with a physician or group of physicians. The pharmacist is able to manage some therapy of patients under a protocol or the umbrella of a physician.[44] CPAs expand the pharmacist's scope of practice and will advance pharmaceutical care.

The next stage is to have an "enhanced CPA," whereby the pharmacist, can make changes in the drugs, dose, and duration of therapy according to national guidelines or by prior approval, as long as he or she documents, justifies, and communicates the change to the physician in a timely manner.

Pharmacy Automation and Information Technology

Automated equipment for drug dispensing, preparation, and distribution is a boon to pharmacists as it is usually safer and frees pharmacists to spend more time with patients. Automated systems are available for dispensing prescriptions, preparing intravenous admixture and total parenteral nutrition (TPN) solutions, dispensing patients' unit dose drawers, and dispensing floor stock, narcotics, and other controlled substances in hospitals.

Medication Errors

Publicity from the media on "slow news days" about medical and medication errors provides pharmacists and pharmaceutical care an opportunity to flourish.[28] Pharmacy needs to step forward proudly and boldly and prove it is ready to take a leadership role in decreasing this important health care problem.

HEALTH CARE REFORM

Health care reform offers an unprecedented opportunity to show how pharmacists can help improve the health outcomes of patients. The professional organizations of pharmacy will take the lead in addressing this important opportunity; however, we win patients over, one pharmacist, one patient at a time.

IMPLEMENTING PHARMACEUTICAL CARE

Changing to a new practice style is not easy. It takes courage and commitment. However, some things have been learned that can be helpful to those starting to make the transition to pharmaceutical care.

Changes the Profession Needs to Make Happen

Many things need to happen to make it easier for pharmacists to implement pharmaceutical care. Pharmacy practice acts and the regulations that support them need to be reviewed and changed to use pharmacy automation and allow pharmacists to make decisions about the safe and effective use of pharmacy technicians. Pharmacy laws that say "the pharmacist must terminally check the prescription before it is dispersed to a patient" are outdated; this check can now be done faster and more accurately by automation. The profession also needs to expand the use of collaborative practice agreements and expand laws allowing pharmacists to perform more laboratory testing. More work needs to be done about allowing pharmacists with proper training to gain provider numbers and bill for the clinical services they provide.

Freeing Pharmacists' Time to Provide Pharmaceutical Care

In general, four things are required to free pharmacists to provide pharmaceutical care:

1. *Radically reengineer the drug dispensing and drug distribution systems.* Pharmacists need to do pharmacist-only and only pharmacist-only functions, and technicians need to do all the rest. Within each pharmacy, the pharmacists, as a group, should decide which functions they and only they will do. In a community pharmacy, this should include greeting patients, accepting prescriptions, and counseling the patients about their medication. Depending on state law, it should also include taking verbal orders, overseeing controlled substances, and checking the final product dispensed. In the hospital, it will only include checking pharmacy technicians and probably taking verbal orders.
2. *Use as many certified pharmacy technicians as possible.* To have enough time to do pharmaceutical care, pharmacists should use all the certified pharmacy technicians the law allows and they feel comfortable supervising.

3. *Automation.* As much of the drug dispensing, preparation, and distribution process as possible should be automated, even if it means employing fewer people to free money to purchase the equipment. There are multiple rewards for using automation: increased patient safety and more time for pharmacists to care for patients, which in turn makes for safer, more appropriate drug therapy for patients.
4. *Increased use of information technology.* Information technology, such as software programs to identify patients to monitor, providing up-to-date drug information, and treatment algorithms, can help the pharmacist provide the best pharmaceutical care for patients.

Leadership and Teamwork in Implementing Pharmaceutical Care

Strong leadership is needed to implement pharmaceutical care. The leader, whether it is the owner, the director of pharmacy, or a motivated pharmacist, needs to know how to lead. The leader must also remember that pharmaceutical care is a team effort that includes prescribers. Thus, it is important to work as a team when planning pharmaceutical care services. Everyone working in the pharmacy should know what pharmaceutical care is and why it is needed and have input on how it will be implemented and provided. It is important to establish goals, develop an implementation plan, and provide necessary training and the resources to fulfill the plan.

Pharmaceutical Care in the Community and Hospital Environments

How pharmaceutical care is being implemented and provided in the community pharmacy and hospital environments is covered in Chapter 8, "Ambulatory (Community) Pharmacy" and Chapter 9, "Health-System Pharmacy."

DOCUMENTING PHARMACEUTICAL CARE

The pharmaceutical care plan documents the pharmacist's care. This documentation is needed for several reasons; it: (a) is a way to put all the important information the pharmacist needs in one place; (b) keeps the pharmacist from having to remember everything about the patient; (c) helps the pharmacist to organize his or her thoughts; (d) serves as a record of the pharmacist's recommendations and care; (e) documents patient's outcomes that can be correlated with what the pharmacist has done for the patient; and, (f) can be the basis for the pharmacist billing for the care rendered.

The ASHP has established guidelines on documenting pharmaceutical care in patient medical records:[45] guidelines for gaining approval to document pharmaceutical care and what documentation should include as a minimum. However, the guidelines seem limited in scope and might include documenting, and when possible, the benefit of the pharmaceutical care consultation.

PROGRESS IN ESTABLISHING PHARMACEUTICAL CARE

It has been 25 years since the profession first learned of pharmaceutical care. Is progress being made? Yes. Is pharmaceutical care becoming the practice model of choice? No.

The profession has fully embraced pharmaceutical care, as noted by every national and most state pharmacy organizations making individual and joint statements and resolutions. The profession has also taken some bold steps to see that pharmaceutical care becomes

the practice model of choice. Examples of this boldness include adopting the Doctor of Pharmacy degree as the sole entry-level degree to practice pharmacy; the implementation of external Doctor of Pharmacy Degree programs; the expansion of pharmacy residencies, including community pharmacy; the certification of pharmacy technicians and various pharmacist specialties; and the arrival of collaborative practice agreements.

Despite all of these bold moves by the profession, pharmaceutical care is not happening at the pace pharmacy leaders had hoped. Although 84% of pharmacists support pharmaceutical care, many pharmacists are reluctant to make the leap of faith to pharmaceutical care without the safety net of their traditional dispensing role.[46] The increasing number of prescriptions and drug orders do not help, and although pharmacy automation can help, its use is perceived as expensive.

Patients who receive the services of a pharmacist practicing pharmaceutical care benefit from it as they receive superior drug therapy. However, most patients do not receive this benefit. Therefore, pharmacy needs to find the key to making pharmaceutical care happen at a much faster rate.

In 2010, Charles D. Hepler, the chief architect of pharmaceutical care, received the Harvey A. K. Whitney Award. In his address, "A Dream Deferred," Hepler acknowledged that the dream of pharmaceutical care has not been fully realized, but that the dream is still alive.[47] He then stated what he feels needs to be done to achieve the dream of universal pharmaceutical care:

- Put the patient at the center
- Address the demand side (desire accompanied by payment)
- Encourage the use of performance indicators
- Develop new management methods
- Cultivate virtue

Summarizing his Whitney Award address, Hepler left an important and clear message for student and young pharmacists who want to do more than just dispense prescriptions and drug orders. To read what he said, check and investigate "A dream deferred."[47]

MOVING TO SHARED CARE

The latest concept in care in the United States is *shared care*. This is what the Agency on Healthcare Quality and Research says about shared care:[48]

A shared care plan is a patient-centered health record designed to facilitate communication among members of the care team, including the patient and providers. Rather than relying on separate medical and behavioral health care (treatment) plans, a shared plan of care combines both aspects to encourage a team approach to care.

Giving patients the opportunity to help develop and negotiate their care planstransforms the relationship between patients and providers. By emphasizing transparency and cooperation in developing shared care plans, your practice can reshape and improve its relationship with patients. When patients are engaged in the process, providers can better understand patients' preferences and values in relation to their health and health care. In addition, patient engagement through shared care plans promotes shared decision making between patients and providers.

In integrated care settings, it is vital that all members of the care team have access to the same information and can build upon the shared care plan. Team members must act in coordination toward a common goal to provide quality integrated care and avoid errors.

Progress on the profession's practice advancement initiative

The Practice Advancement Initiative (PAI), started under the name of the Pharmacy Practice Model Initiative (PPMI) in 2010, and was discussed earlier in this chapter. Figure 7.2 shows progress through 2016.

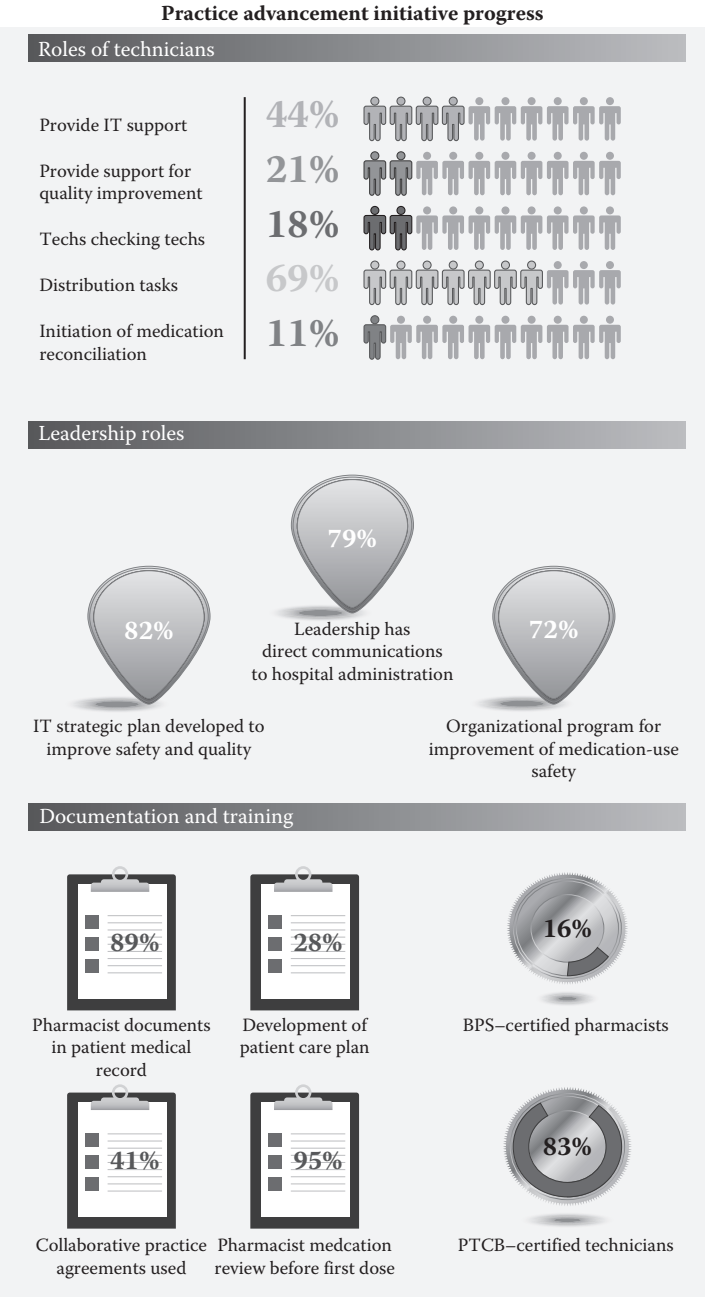

FIGURE 7.2 Practice Advancement Initiative progress through 2016.

SUMMARY

The profession of pharmacy has moved from focusing on the drug to focusing on the patient. The pharmaceutical care model makes pharmacy a true clinical profession. However, pharmacists will need to relinquish the tasks of drug dispensing and distribution and just be accountable for these functions. If pharmacists focus on and are recognized for improving patient outcome, their likelihood of being paid for this will increase significantly.

DISCUSSION QUESTIONS AND EXERCISES

Approach 1: One pharmacist stays behind the counter all day. The pharmacy clerk greets the patient, accepts the prescription, and hands it to the pharmacist. The pharmacist types the label, retrieves the medication, counts out the medication, puts it in the bottle, and hands it back to the clerk. The clerk puts the medication into a bag, hands it to the patient, rings up the sale, and asks for the money. This happens 120 times in 8 hours.

Approach 2: Another pharmacist uses a certified technician rather than a pharmacy clerk. The pharmacist greets and introduces himself to the patient and accepts the prescription. The pharmacist asks the patient about the need for the medication and hands the prescription to the certified pharmacy technician to dispense. While the prescription is being dispensed, the pharmacist interviews the patient to determine if any of the eight MRPs are present. After checking the prescription, the pharmacist shows the medication to the patient, lets the patient know what the medication is for and how it is to be taken, and provides any precautions. The pharmacist thanks the patient for stopping in and lets the patient know that the pharmacist is always available to help. The pharmacy technician bags the medication and rings the sale.

Which of these approaches would:

1. Provide the highest quality of care? Why?
2. Be the most appreciated by the patient? Why?
3. Bring back the most patients to the pharmacy? Why?
4. Produce the most pharmacist satisfaction? Why?
5. Generate the most pharmacy revenue? Why?
6. Generate the most pharmacy profit? Why?
7. What would you call approach 1?
8. What would you call approach 2?
9. What do you feel are the two major challenges in providing pharmaceutical care?
10. List two solutions for each of the challenges you listed in question 9.

CHALLENGES

1. A common expression is that many pharmacists are superb pharmacy technicians. That is, they like spending most of their time performing the technical and clerical functions of pharmacy, such as typing labels, counting drugs, making intravenous additives, and completing paperwork, all of which can be done by pharmacy technicians. These pharmacists minimize their face-to-face contact with patients. For extra credit, and with the permission of your professor, investigate this problem

first hand and prepare a concise report documenting the problem, state why it is a problem, investigate its etiology, and suggest how best to resolve this problem.
2. For extra credit, and with the permission of your professor, outline, design, and describe how workflow in a community pharmacy would maximize pharmaceutical care. What are the functions? Which functions would be accomplished by pharmacy clerks? Pharmacy technicians? Pharmacists? What are the benefits of your recommended work flow to the patients? The pharmacy owner? The pharmacy clerks and technicians? The pharmacists?
3. For extra credit, and with the permission of your professor, read Charles D. Hepler's Whitney Award address, and write a one- or two-page (Microsoft Word, double-spaced) synopsis of his manuscript, ending with what it means to you.[47]

WEBSITES OF INTEREST

American College of Clinical Pharmacy: http://www.accp.com/

Pharmacy Practice Model Initiative: www.ashpmedia.org/pai/docs/MCM10-PPMI Students.pdf

Statement on pharmaceutical care: www.ashp.org/doclibrary/bestpractices/orgstpharm-care.aspx

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8 Ambulatory (Community) Pharmacy

INTRODUCTION

The practice of *ambulatory* (serving those who can walk or move about freely) pharmacy in the community is the oldest pharmacy practice, and remains the first choice of roughly 60% of new pharmacy graduates. There are different types of ambulatory practice settings, but the most common is still independent community pharmacy. Community pharmacists serve patients by providing information and advice about health and drugs, providing medication, and referring patients to other sources of help and care, such as physicians, dentists, clinics, hospitals, and emergency rooms when needed.

This chapter is about the different types of community pharmacies, what it means to provide service, and how pharmaceutical care is practiced in this setting. It provides an overview of the procedures most community pharmacies use in dispensing prescriptions safely, and counseling patients. Also included is information about traditional and newer services offered by ambulatory pharmacies. The chapter also covers the different positions for pharmacists in community pharmacy, how pharmacists spend their time, and how satisfied they are with what they do. At the end are some comments about community pharmacy's future.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Identify, briefly, the four types of community pharmacies.
- Explain how the four types differ.
- Compare and explain patient satisfaction rates for the different types of pharmacies.
- Explain the extent of pharmaceutical care provided in community pharmacies
- Discuss some of the challenges to providing pharmaceutical care in this environment.
- Discuss the types of dispensing errors.
- Contrast traditional and newer patient services offered in community pharmacies.
- Explain the law and the pros and cons of pharmacist counseling.
- Discuss how satisfied pharmacists are working in ambulatory pharmacies
- Identify two current trends in community pharmacy.

TYPES OF COMMUNITY PHARMACIES

There are four basic types of community pharmacies: (1) independent, (2) chain store, (3) mass merchandiser, and (4) supermarket. For each type of community practice site, some things are the same, whereas there are things that are unique. Mail-order pharmacies also serve ambulatory patients, and some data are provided on these types of pharmacies in this chapter and in Chapter 19, "Other Opportunities for Pharmacists."

As shown in Table 8.1, some things that differ among community pharmacies are prescription volume and the changing market share for prescriptions.[1] What is important is not the

specific numbers in the table, but the relationships and trends shown. For example, chain store pharmacies dispensed the most prescriptions in 2015, followed by independent pharmacies. However, since 2009, market share based on sales has dropped for chain pharmacies (–3.4%), independent pharmacies (–1.5%), and supermarket pharmacies (–0.2%), but increased for mass merchandiser pharmacies (+2.4%) and mail-order pharmacies (+8.5%).

Independent Pharmacies

The *independent community pharmacy* is where the profession began, and remains the heart and soul of pharmacy. Many independent community pharmacies started as family-owned corner drugstores in towns both big and small. The pharmacist in the town was a trusted professional and friend, and an active member of the community. Although this nostalgic part of Americana is fading, and the soda fountains are gone, independent community pharmacy is still alive and adapting to new competition.

The uniqueness of independent community pharmacy practice lies in the word "independent." *Independent community pharmacies* are owned by pharmacists who practice the way they choose as long as it is in the law. Each pharmacy owner has the privilege of setting the rules and policies of his or her pharmacy. The success of the business is largely within the owner's hands, but it is getting more difficult to stay in business because of increasing competition and decreasing payment from insurance plans.

Independent pharmacies still outnumber the chains—even though the number of U.S. independent pharmacies has been halved in the past 30 years. The United States had 22,160 independent pharmacies in 2015 (down from 22,478 in 2014) compared to 21,394 chain drug stores; 8,301 supermarket drug stores; and 8,330 mass merchandisers, according to the *National Community Pharmacists Association* (NCPA).[2]

The typical independent pharmacy in 2015 dispensed 194 prescriptions per day (down slightly from 2014).[2] The average independent pharmacy employed 2.9 pharmacists (including the owner) and 3.2 pharmacy technicians. Generic drug utilization was 82% (up from 80% in 2014; 65% in 2010; and 53% in 2004).

Independent community pharmacies provide services other than providing prescription medication. Some provide nutrition products and information (89%), delivery (81%), charge accounts (81%), compounding (67%), and hospice services (62%).[2]

TABLE 8.1
Prescription Activity and Sales, 2015

Activity	Independent Pharmacies	Traditional Chain Store Pharmacies	Supermarket Pharmacies	Mass Merchandiser Pharmacies	Mail-Order Pharmacies
Total prescriptions[a]	739	2,101	522	421	207
Number of outlets	20,879	22,931	9,222	9,066	361
Prescription sales[a]	57.0	133.8	36.2	27.9	61.3
Market share[b]	15.4%	36.1%	9.8%	7.5%	31.3%

Source: National Association of Chain Drugstores. Personal communication, March 23, 2017. With permission.
[a]In billions of dollars.
[b]Based on sales.

Pharmacists who want to know their patients are attracted by the possibility of owning their own business, or who want to find a job in their hometown, will like independent community pharmacy practice. About 20% of new pharmacy graduates select independent community pharmacy as their first job as a pharmacist.

Chain Store Pharmacies

The top chain pharmacies in the United States in 2015 (based on prescription sales in millions) were Walgreens ($53,500), CVS ($52,500), Rite Aid ($18,400), Walmart ($17,900), and Cardinal Health ($17,600).[3]

The practice of pharmacy in chain stores is similar to, yet different from, the practice of pharmacy in independent community pharmacies. What is similar is dispensing. After that, everything is different. First, working in a chain drugstore means you are working for a large corporation rather than a small family business. Therefore, the pharmacist needs to know and be sensitive to corporate culture and policies which at times may be more about business than about being patient-centered.

Positions for pharmacists in chain pharmacies are plentiful as the chain store pharmacy industry is expanding rapidly and there is pharmacist turn over. Signing bonuses are typically available, and salaries are somewhat higher than in independent and hospital pharmacies. Some large chain pharmacy companies offer salary and stock bonuses. There is also job security and opportunity for moving up to management. About 40% of new pharmacy graduates select chain pharmacy practice for their first job.

Chain store pharmacy practice is fast paced, usually much more than independent pharmacies, and it takes intense focus, organization, and efficiency to work in this type of pharmacy. There is usually less opportunity to interact with patients because of the volume of prescriptions to be dispensed. It is important that there be enough pharmacy technician help so the pharmacist can properly practice pharmacy and counsel patients. In fact, this is a key question to ask when applying for a chain store position as a pharmacist—"how much automation and technician support will I have?"

Working in a chain store pharmacy is usually more stressful because of the volume of work. In addition, the frustrations of patients complaining about prescription prices and wait times is worse in chain pharmacies since the patients are more often bargain shoppers.[4] Another frustration can be managers within the corporation who have responsibility for the pharmacy. Most often they have business backgrounds, do not understand patient care, and tend to look at things solely from a business, rather than a patient-centered viewpoint.

Supermarket Pharmacies

The emergence of pharmacies within supermarkets, such as Kroger, Winn-Dixie, Giant Eagle, and Publix, has occurred within the last 20 years. Patients use pharmacies because of convenience for one-stop shopping. Patients can drop off their prescriptions at the pharmacy and do their shopping rather than idly waiting for their prescriptions.

The concept is working. Supermarkets are trying to create an atmosphere that provides a sense of community and a shopping experience the new wellness consumer is seeking. "Consumers are looking for stores, people, brands, and products they can trust."[5] Obviously, supermarket pharmacies seem to be serious about connecting with consumers and are here to stay.

Several years ago, Publix rolled out a dramatic service for patients: free antibiotics (not all, but many). Then, in August 2010, they offered free diabetic drugs as part

of their Diabetes Management System.[6] Patients with a prescription may obtain a free 30-day supply of immediate-release metformin in doses ranging from 500 to 1000 mg. Not to be outdone, Giant Eagle offered five generic diabetes drugs to its customers with the Giant Eagle Advantage card program.[6] Other supermarket pharmacies are taking the same approach.

Some pharmacists feel working in a supermarket is less professional than working in a more traditional setting. Others feel that supermarket pharmacy is a perfect blend between working in a chain store pharmacy and in an independent community pharmacy. You still need to deal with a corporate structure and corporate policies, but there are opportunities to develop relationships with patients, and there is less stress.[7]

However, not all supermarkets are progressive in offering pharmacists opportunities for professional growth and advancement. There is also the requirement to be flexible enough to work any hour of the day or night as many supermarkets now offer 24-hour pharmacy service.[8]

On the plus side, supermarket pharmacies may be embracing pharmaceutical care and patient counseling more than chain store pharmacies, based on efforts at improving customer service, patient satisfaction, and loyalty.

Mass Merchandiser Pharmacies

An even more recent development than supermarket pharmacies is the placing of pharmacies inside stores of mass merchandisers such as Walmart, Kmart, Target, Sam's Club, and Costco. These stores are capitalizing on a major shift in the buying practices of the public. Today, consumers are consolidating their shopping trips and are spending more money for life's basics—such as prescriptions—at discount stores.[8]

Not much has been published about the pros and cons of practicing pharmacy inside these commercial enterprises. How much pharmaceutical care and patient counseling is occurring in *mass merchandise pharmacies* needs to be investigated.

Mail-Order Pharmacies

Market share for mail-order pharmacies fell from 12.6% in 2013 to 11.2% in 2014.[9] Insurance companies sometimes try to pressure employees of companies they insure into mail order by allowing the employee to obtain a 90-day supply (and pay one copay) of chronic medication, but allowing only a 30-day supply of that medication (and charging for three copays over 3 months) if the covered employee goes to a local pharmacist.

A survey showed that 72% of respondents opposed or strongly opposed a plan from their employer that would require them to obtain their medication through the mail:[10] "Additionally, 83% of respondents would choose community pharmacy over mail-order if a 90-day supply of their prescription was available to them for one co-pay."

Working in mail-order pharmacies is fast paced and can be stressful. There are several work stations for pharmacists (order review, order clarification, terminal checking of the dispensed medication, controlled substance inventory control and dispensing, etc.). Pharmacists usually rotate between these various stations throughout the workday. There usually is no face-to-face contact with patients, but there may be telephone calls to patients about their medication. Work schedules are usually stable. One benefit is not needing to dress up.

THE RISE OF SPECIALTY PHARMACIES

Specialty pharmaceuticals is a recent designation for drugs and agents of high complexity and high cost. Some of these drugs are made from living cells that are injected or infused and sometimes available orally. They are used to treat complex or rare chronic conditions. In 1990 there were 10 specialty drugs on the market; in the mid-1990s there were fewer than 30; by 2008 there were 200; and by 2015 there were 300.[11]

The cost of a specialty pharmaceutical may be $10,000 annually, with some costing more than $100,000 annually. They are only available through exclusive, restricted, and limited distribution, and often need special storage, handling, and administrative requirements, through a licensed "specialty pharmacy."

In 2015, specialty pharmaceuticals accounted for $21 billion (37.7% of total drug spending) which is a 15% increase over 2014.[12] This figure is expected to exceed 400% by 2020. The top specialty drugs for 2016 are listed in Table 8.2.[13]

The top specialty pharmaceutical distributors (wholesalers) in 2015 were: McKesson Corporation (30%), AmerisourceBergen Distribution Company (19%), and Cardinal Health (15%).[14] Top *specialty pharmacies* in 2015 were: CVS/Caremark Specialty Pharmacy/Stores ($29.6B), Accredo/Express Scripts ($17.2B), Walgreens Specialty Pharmacy/Stores ($9.8B), Briova Rx/United Health Group ($6.5B), and Diplomat Pharmacy ($3.4B).[15]

Specialty pharmacists work in a variety of practice settings.[16] Some pharmacists practice in pharmacies dedicated to only products that are considered specialty medications. In this setting, pharmacists may dispense, provide MTM, counsel patients, and work with patients on improving medication adherence. Some pharmacists work in health systems like hospitals and *health maintenance organizations* (HMOs), and may be involved in transitioning therapy for patients when they go from in-patient to ambulatory care sites. Other pharmacists work in retail settings and either focus on certain specialty disease states at their practice sites or work with an affiliated specialty pharmacy provider to dispense these complex medications.

TABLE 8.2
Top 10 Specialty Drugs in 2016

Rank	Drug	Therapeutic Class
1	Humira Pen (adalimumab)	Inflammatory Conditions
2	Enbrel (etanercept)	Inflammatory Conditions
3	Tecfidera (dimethyl fumarate)	Multiple Sclerosis
4	Copaxone (glatiramer)	Multiple Sclerosis
5	Harvoni (ledipasvir/sofobuvir)	Hepatitis C
6	Revlimid (lenelidomide)	Oncology
7	Gilenya (fingolimod)	Multiple Sclerosis
8	Truvada (emtricitabine/tenofovir/disproxil fumarate)	HIV
9	Humira (adalimumab)	Inflammatory Conditions
10	Stelara (ustekinumab)	Inflammatory Conditions

Source: Adapted from Express Scripts. Drug Trend Report 2016. https://lab.express-scripts.com/lab/drug-trend-report. Accessed March 1, 2017.

Specialty pharmacy practice offers services over and above what is usually found in a typical retail pharmacy, such as[17]

- 24-hour access to pharmacists
- Medication adherence management
- Pharmacy benefits investigation
- Communication and follow-up with the physician
- Dispensing of specialty pharmaceuticals and shipping coordination
- Enrollment in patient assistance programs
- Financial assistance
- Patient education and medication adverse effect counseling
- Patient monitoring for safety and efficacy
- Payer and/or manufacturer reporting
- Proactive patient outreach for prescription refill and renewal
- Prior authorization assistance

PATIENT SERVICE AND SATISFACTION

No matter where a pharmacist chooses to practice, the success of the pharmacy service is dependent largely on good service, the extent of patient-centered care, and patient satisfaction. These factors are dependent on two other factors: the pharmacist's attitude toward patients and the attitude of management (the corporation or owner) about how the pharmacy and pharmacist should function. When both the pharmacist and management agree that service, patient-centered care, and patient satisfaction are supreme, then pharmacists and patients will be satisfied. More patient satisfaction means patients will return and more will recommend the pharmacy to friends.[18,19]

Pharmacy technicians, pharmacy interns, and pharmacists owe their employer a good day's work, the provision of good service, and doing everything possible to make their employer successful. The more successful the employer is, the more likely employees will succeed as well.

The reasons most often cited for using a specific pharmacy are location, wait time, ability to get a prescription dispensed at multiple locations, refill reminders, after-hour prescription pickup, and a drive-through window. Notice how nothing is said about how well the pharmacist performs. *Note:* It may have not been part of the survey questions.

How satisfied are pharmacy customers? Using data adapted from a May 2016 article by Consumer Reports titled "Pharmacies Buying Guide," the most satisfied customers were those who used an independent pharmacy (93%), a clinic pharmacy (89.5%), or a supermarket pharmacy (88%).[20] Mass merchandiser, chain, and mail order pharmacies lagged behind (<86%). Satisfaction was based on: pharmacist knowledge, courtesy, helpfulness, speed, price paid, cleanliness, OTC (over-the-counter) drug selection, OTC quality, OTC price, personal store brand products (PCPs) selection, PCP quality, and PCP price.

Independent pharmacy customers were the most satisfied, followed by those using pharmacies in supermarkets. Chain store and mail-order pharmacies came in last. Similar results were obtained in 2008 by a different survey company.[21]

PHARMACEUTICAL CARE

One of the principles of pharmaceutical care is that it can be practiced in any setting. A big question is—is pharmaceutical care flourishing in community pharmacies? Or, is the environment too business oriented—too product related—for pharmaceutical care to survive? Many

community pharmacists believe pharmaceutical care is the right direction for pharmacy, but some feel they are just too busy to practice it, especially in chain store practice.[22] Are community pharmacists stepping up to patient-centered care, or are they relinquishing their responsibility to patients and giving in to business demands of employers? And, if so, what can be done about it? Further study is needed.

Extent and Growth

In conducting research for this edition of the book, an internet search was conducted to see how well pharmaceutical care is being accepted and adopted in community pharmacy in the United States. A search for articles published in 2015 or 2016 found numerous manuscripts from other countries such as Canada, China, England, and Holland, but none from the United States where pharmaceutical care started. Are we back to practice as usual?

Some Bright Spots

From a research standpoint, there is some compelling data for pharmaceutical care in community pharmacy. One is the Asheville Project in North Carolina; a group of pharmacists, an employer, a health care system, and two universities decided to test it out.[23–26] A group of pharmacists helped manage patients with diabetes. "They would meet with the patients each month, talk to them about their blood-sugar and other lab values. This experiment was supposed to last just 6 months. The Asheville Project grew from 46 participants with diabetes to 700 people with four different chronic diseases. It is history now, and famous among pharmacists."[23]

In this project, each patient met with a pharmacist for an initial 60-minute consultation. Pharmacists trained patients to make sure they knew how to monitor their blood sugar correctly. Then, patients met with their pharmacists monthly to review blood sugar results, discuss their condition, and set goals. After 6 months, 75% of patients showed at least some improvement in blood sugar. Of these, 63% showed blood sugar in the optimal range, compared to 38% of patients before the intervention. Total medical costs decreased by $1,622–$3,356 per patient per year. This freed money for preventive medications and reduced the need for emergency room and hospital care.

Another bright spot has been demonstration projects in the Iowa Medicaid program and one between Wellmark Blue Cross and Blue Shield of Iowa, the Iowa Pharmacy Association, and the Outcomes Pharmaceutical Health Care network of pharmacies.[27,28] In the latter project, patients with asthma, hypertension, diabetes, or ischemic heart disease were identified and enrolled by pharmacists to participate in the project. Community pharmacists identified and resolved medication problems in these patients and were encouraged to utilize a health outcomes management documentation system.

Pharmacists were reimbursed for patient care services based on a resource-based relative value scale calculation. "Depending on the complexity of the patient's medical needs, the number of current medications, and the number of drug therapy problems identified and resolved, quarterly payments ranged from $14 to $105."[28]

During the project, 9,517 patient care encounters were documented, with 14% of the encounters resulting in resolution of drug therapy problems. What pharmacists encountered most were inappropriate adherence to therapy, adverse drug reactions, and missing medication therapy. Most of their *drug therapy problems* were resolved through pharmacist intervention with the patient.

After deducting the administrative costs of the program, the unadjusted cost per patient of the intervention group was $3,675, compared to $3,907 per patient in the control group, or $232 lower per patient in the intervention group. After adjusting these figures for severity

of illness, the per-patient cost of the intervention group and the control group were similar ($3,762 vs. $3,705). The authors concluded that the implementation of a model to reimburse pharmacists for their patient care services is feasible.

It must be noted, however, the research and demonstration projects quoted occurred right after there was excitement about pharmaceutical care. As dramatic as these findings are, the impact on community pharmacy practice is still cloudy.

Challenges

The results of one of the first randomized controlled studies to examine the effectiveness of outpatient pharmaceutical care programs found that patients enrolled in a pharmaceutical care program had only slight improvements in their medical conditions and were more likely to visit emergency rooms or be hospitalized than patients not in the program.[29,30] Investigators commented that one of the limitations of the study was that, despite their efforts to design a pragmatic program and reinforce its use, the program was not consistently used by the pharmacists. It is clear that "the right incentives and systems need to be in place in busy practices before the value of pharmacy interventions can be demonstrated."[29] On a positive note, patients in the pharmaceutical care program reported more satisfaction than other patients with the pharmacists and health care received.

One reason for less success in the United States versus other countries is that most developed countries have just one electronic medical record for each patient. Community pharmacists have access to the patient's record, and add the pharmacy history to it. They can see the patient's diagnosis, problem lists and all the medication dispensed, not just the ones they dispensed. It may also be that the profession in the United States is now more preoccupied on obtaining provider status. But, what has happened to the patient-centered care which is the hallmark of the pharmaceutical care practice model? Are community pharmacists more or less patient-centered then they were 15 years ago?

Catalysts

It is clear that pharmaceutical care will not reach a tipping point in community pharmacies without catalysts such as (a) improving the pharmacist's clinical skills and knowledge about evidenced-based pharmaceutical care techniques that work, (b) freeing the pharmacist for pharmaceutical care by using more pharmacy technicians and automation, (c) getting reimbursement for pharmaceutical care, (d) providing more privacy for pharmacist–patient interaction, (e) having access to the patients' medical records, and (f) having a closer relationship with patients' doctors.[31–33]

DISPENSING PROCEDURES TO SAFELY DISPENSE AND ADVANCE PHARMACEUTICAL CARE

The following are the *best practices* that form the basis for the *standard of practice* in dispensing a prescription that provides safety and pharmaceutical care.

Accepting the Prescription and Establishing the Pharmacist–Patient Relationship

Ideally, a professionally dressed pharmacist should be the person greeting the patient and accepting the patient's prescription, not a clerk or technician. Patients appreciate this personal

practice. After establishing the pharmacist–patient relationship, the pharmacist should note the date of the prescription, verify the full and correct name of the patient and age, and get the patient's address and telephone numbers. If it is a first visit, the patient should complete a form that gathers demographic and insurance and clinical information, such as drug allergies, about the patient.

Reviewing the Prescription and Patient Information

It is the duty of the pharmacist to review the prescription and patient information from legal and safety standpoints. Important questions pharmacists should ask themselves include

1. Is this a legal or counterfeit prescription?
2. Have I read the prescription correctly? Could I be misreading the name of the drug because of poor handwriting?
3. Does this prescription make sense for the patient, their age, and their condition?
4. Are there any absolute contraindications?
5. Is the dose correct?

The beauty of the pharmacist's initial review of the prescription when presented is that it represents half of a system of checks and balances for drug safety. *Note:* the other half occurs when reviewing the patient's medication profile. If the pharmacist detects something amiss in the prescription, he or she has a duty to call and discuss it with the prescriber.

Entering Data and Reviewing the Patient's Medication Profile

Each patient should have a patient record or profile in the computer system at the pharmacy. The basic information for this profile is gathered on each new patient using a form, and this information should be updated at least once a year on active patients.

Each time a prescription is dispensed, it is added to the patient's profile by entering the information into the pharmacy computer system, which is a pharmacy technician function.

Inactivating or making a note next to medication in the patient's profile that is no longer being used is critical so that software searching for medication duplication, contraindications, and drug interactions will be accurate. This will also provide the next pharmacist reviewing the patient's profile with up-to-date information.

Under the *Omnibus Budget Reconciliation Act of 1990* (OBRA 90), the pharmacist must check the medication for problems some time before it is dispensed. The areas to be screened include

- Therapeutic duplication
- Drug-disease, drug-gender, drug-age contraindications
- Drug–drug interactions
- Incorrect drug dosage
- Incorrect duration of treatment
- Drug-allergy interactions
- Clinical abuse/misuse of medication

Additionally, under the pharmaceutical care model, the pharmacist should review the therapy for eight potential medication-related problems (see Chapter 7, "Pharmaceutical Care").

In addition, there are other questions: Is there anything that will interfere with achieving a positive patient outcome? What does the patient need to know to be compliant with taking the medication as prescribed?

Reviewing Insurance Coverage

Most patients do not pay for their own prescriptions or only pay a portion (*copay*) of their medication. The balance is paid by a *pharmacy benefits manager* (PBM) or an insurance company contracted by the patient's employer or the patient's health plan. The problem that sometimes occurs when trying to dispense a prescription is that the medication or total quantity ordered is not covered under the employee's insurance plan. This slows the prescription process. The bureaucracy and paperwork associated with filing claims is getting worse, which is one of the chief concerns of many pharmacists. A way to deal with this is to pull these ambiguous prescriptions out of the routine processing procedure and into an "*exception area*" where someone works on them separately. In this way, the remaining prescriptions to be dispensed can move along without delay.

Retrieving the Drug or Ingredients from Storage

Once the pharmacist is confident a prescription is in the best interest of the patient and the insurance information is verified, the prescription needs to be dispensed. The first step in this process is for the pharmacy technician to retrieve the correct medication or the ingredients to count, prepare (mix), or compound (make) the medication. The locations of the drugs and ingredients for prescriptions should be carefully planned for safety, efficiency, and inventory control.

To be safe, drugs that can be easily confused should be stored at a distance from each other. Another safe practice is to store potent, potentially dangerous drugs and drugs known to be associated with errors in a separate, special location. That area should have special markings to remind the pharmacist or technician that they are about to dispense a *"high risk drug"* and to be diligent.

Some pharmacies store their medications by product, such as oral medication, ointments and creams, *ophthalmics* (for the eye), and *otics* (for the ear). The drugs in each category are placed alphabetically. Class II controlled substances must be stored separately and be under lock and key. Some pharmacies store their medications by company, especially if they are ordering those drugs directly from the pharmaceutical manufacturer. This makes it easier when taking stock of what needs to be ordered.

No matter how the drugs are stored in a pharmacy, all must be kept under ideal storage conditions where they are protected from extreme temperatures and excessive sunlight. Others must be refrigerated. In addition, all the medication in stock must be up to date. Although some drug wholesalers and pharmaceutical manufacturers will take back and credit outdated stock, they do not like to see this happen often. Thus, the stock needs to be checked on a routine basis for outdated drugs, which is the traditional job of a pharmacy intern so they get to know the drugs. *The Rule of Four*: When retrieving medication or ingredients to prepare or compound a medication, the rule is to check the name of the drug or ingredients four times:

1. When it is taken off the shelf
2. During preparation
3. When putting the stock container or ingredients back on the shelf
4. When presenting the medication to the patient (should be done by a pharmacist, not a technician, especially for all new medication)

Preparing and Compounding

Some medications need to be counted (tablets and capsules) or poured (liquids such as tinctures, syrups, and suspensions). Other medications need to be prepared. An example is reconstituting antibiotic suspensions for pediatric patients. The drug comes in a powder or is freeze-dried and needs to be made into a liquid for the patient to use. This is the job of the technician, not the pharmacist.

Compounding a prescription is more complex to prepare and involves physical chemistry and *secudum artem*—the art of pharmacy. *Secudem artem* involves the careful measurement of ingredients and knowing in what order to make the preparation and what technique to use to make an elegant final product.

In the past, most medications were prepared by compounding them. In other parts of the world, they are still made this way. Up until 1960, many prescriptions were compounded in the United States. From 1960 to about 2000, only 1% of the prescriptions, mostly ointments and creams, were compounded. However, starting about 2000, there has been a resurgence of pharmacy compounding.[34] According to the NCPA, 85.5% of community pharmacies are compounding prescriptions today.[35] Of those community pharmacies that compound, 62% compound 5% or fewer of their total prescriptions dispensed annually, and 72% provide non-sterile compounding services only.

Note: Sterile compounding, no matter the location, requires following *United States Pharmacopeia* (USP) 797 standards.[36]

"*Compounding Pharmacies*" have also been emerging that exclusively compound, or compound a majority of their prescriptions. A supporting framework for these pharmacies is *Pharmacy Compounding Centers of America* (PCCA) that provides independent pharmacists with a complete support system for compounding unique dosage forms.

Compounding prescriptions one patient at a time is considered *the practice of pharmacy*. The pharmacist may compound products in anticipation of immediate needs, for example, enough for the next 24 hours. However, making more than is needed for immediate needs is considered by the *U.S. Food and Drug Administration* (FDA) to be *manufacturing* rather than the practice of pharmacy. If this is the case, the pharmacy would need a *manufacturing license* and would be required to follow *current good manufacturing practice* (CGMP) as set forth by the FDA, a rigorous hurdle to overcome, but doable.

When compounding a prescription, the pharmacist uses tools such as an analytical balance to weigh ingredients, graduates for measuring liquids, spatulas for making ointments and creams, and mortars and pestles for particle reduction. All ingredients must be ±5% of the amount intended to be in the product or they are considered "*misbranded*," which is a violation of federal drug law.

Labeling the Prescription

Once the product is counted, prepared, or compounded and checked by a pharmacist, it needs to be labeled. State law dictates the basic requirements of the label; however, these requirements vary little from state to state. Most labels are computer generated and contain a prescription number unique to that patient, product, and pharmacy. It will also have the date of dispensing, the patient's name, the physician's name, directions, and usually the name and amount of the drug, dispensing information, and the initials of the pharmacist who did the *terminal check* of the medication. It may also have lot number information and an expiration date. Preprinted information on the label will contain information about the pharmacy: its name, address, and telephone number.

Being Sensitive to Health Literacy

Nearly one-half of adult Americans have limited functional literacy skills. In a study to determine the frequency with which pharmacists identify and provide appropriate assistance to patients with limited literacy skills, it was discovered that pharmacists generally do a poor job.[37] Only 2 of 30 (7%) pharmacies reported attempting to identify literacy-related needs among their patients. In another study, approximately half of the pharmacies studied never or only sometimes provided non-English-language prescription labels or information packets, and approximately two-thirds never or only sometimes verbally communicate in non-English languages.[38] USP has developed health literacy recommendations for prescription labeling. All pharmacy personnel need to be sensitive to the differing needs of patients to understand labeling and directions for using their medication effectively and safely.

Checking for Proper Dispensing

Once the medication has been prepared and labeled, it needs to be a terminally checked before it can be dispensed to the patient. State law requires the pharmacist to do this. After checking, the pharmacist's initials or identifier are added to the label and the patient's record. *Note:* This law needs to be changed to allow the terminal checking of the prescription with bar coding or similar technology, as it takes up time the pharmacist can be using to work with patients. Some states have changed their laws, whereas others have not.

Safety Note: Checking the final product dispensed against a computer generated label, rather than the prescription has been shown to be highly dangerous in court cases where patients have been harmed by dispensing errors. If the prescription is entered into the patient's profile incorrectly and without a check, the label will be wrong.

MEDICATION DELIVERY AND PATIENT COUNSELING

Ideally, it should be the pharmacist who delivers the medication to the patient, not the pharmacy technician or clerk. In addition, under OBRA 90 and good pharmacy practice, pharmacists, not technicians or clerks, *must* make an offer to counsel all Medicaid patients about their medication. All state boards of pharmacy consider doing one thing for one class of patient and not doing it for another class to be unethical. Thus, all state boards of pharmacy have passed regulations that pharmacists must offer to counsel *all* patients.

An international study about community pharmacists counseling patients about their medication found wide variability with prevalence ranging from 8% to 100%. Of the nine studies reviewed from the United States, the mean pharmacist counseling rate was 64.5% (range of 40% to 95%).[39] One caveat is that this study was published in 2009 (the latest that could be found) and the U.S. studies quoted were from 1994 to 2005. All the studies were convenience samples asking pharmacist how much they counsel patients, rather than observation by an independent observer. Therefore, the actual pharmacist counseling rate remains elusive.

It is doubtful that a verbal offer to counsel a patient by a pharmacist (as required by OBRA 90) is very high. *Note:* if you are interested in pharmacy practice research as a student or pharmacy faculty member, this would be a good project that more than likely can be funded.

Most patients do not understand the law that requires pharmacists to offer to counsel patients about their medication. In a study in the four types of community pharmacy locations, patients were asked if they were requested to sign something before they received their medication.[40] When asked what they were signing, 30% (of 80 patients at eight different sites)

said that it was to document that they picked up the medication; 21% were unsure; 18% said they did this for insurance reasons; and 6% said it was because certain drugs require a signature. Twenty percent were never asked to sign anything, and only 5% knew they were signing to document that they were offered counseling by the pharmacist.

A study in 2016 discovered that patients and community pharmacists have a low level of satisfaction with medication counseling.[41] Though pharmacists were more satisfied (47.3%) with medication counseling than patients (34.0%), their major reason for dissatisfaction was lack of time. The major reason for patient dissatisfaction was insufficient time spent on counseling.

The three "Cs" of effective patient counseling are communication, comprehension, and adherence.[42]

Communication: To communicate effectively with patients, pharmacists need to remove any barriers to good communication, be good listeners, and use open-ended questions.

Comprehension: To counsel patients properly, pharmacists should select only a few key counseling points and verify that patients understand what they need to know.

Adherence: Unless counseled, most patients will not take their medication exactly as prescribed. It is important to stress how often to take the medication and what may happen if the patient does not take it as prescribed.

Increasing medication adherence to 80% or more is associated with less healthcare utilization (i.e. hospitalization, emergency room, and physician visits), and it has been shown that pharmacists can increase adherence significantly.[43,44]

Pharmacists in the *Indian Health Service* of the U.S. Public Health Service have developed a standardized, and effective process for counseling patients.[45] Three prime questions form the foundation for the medication consultation: (1) What did your doctor tell you the medication is for? (2) How did your doctor tell you to take the medication? (3) What information did your doctor tell you to expect? Each question probes the patient's knowledge of a specific area of understanding needed to self-medicate. The pharmacist is able to reinforce what information patients already know and counsel them on important aspects of the medication they don't know.

WHOSE JOB IS IT?

In community pharmacy practice, well-trained (and it is hoped certified) pharmacy technicians should be performing all of the traditional and technical functions: entering data, preparing the medication, compounding, affixing the label, and ringing up the sale. Community pharmacists should be asking: How much of my day is spent doing these technical and clerical functions? It should be little, if any.

Instead, pharmacists should be greeting each patient, accepting and clarifying the information on the prescription, and asking about allergies. The pharmacist should be the one who clarifies all prescription issues with the prescriber and checks the accuracy of the drug and medication label to be dispensed to the patient. But, it is also the pharmacist's function (not that of the technician or clerk) to counsel the patients about their medication. How often should community pharmacists be counseling patients? Ideally, for all new medication, and for the first refill to see how well the medication is performing, and if the patient is having any difficulty with the medication.

Ideally, the pharmacy technicians should be the ones entering medication order information into the computer and preparing and labeling the medication.

AVOIDING ERRORS IN THE DISPENSING PROCESS

The first principle of pharmacy practice is *primum non nocere*, or "*first, do no harm*." Pharmacists are trained and pride themselves on accuracy. However, medication preparation, labeling, and dispensing errors occur every day. There are two kinds of medication errors: potential (errors that are caught before they reach the patients) and real (those that reach the patient). It is important that both types are properly documented when they occur. Additionally, there should be notes along with what changes will be made to prevent them from occurring again, as part of the pharmacy's *continuing quality improvement program.*

How often do medication errors occur in the pharmacy? It depends on the environment and the definition of an error. Is a misspelled patient's name an error? Is lack of refill information an error? Or is just dispensing the wrong drug, wrong dose, or wrong directions an error? In community pharmacy, the error rate has been found to be about 1.7%.[46,47] One well-designed study found 19% of doses in error, and 7% of these were deemed potentially harmful.[48]

Mail-order pharmacy error rates are substantially less due to the use of extensive automation. One study revealed a potential error rate in a highly automated mail-service pharmacy of 0.075%.[49] However, pharmacists working in mail-order pharmacies cite a typical performance rate standard of 1 potential error per 10,000. The number reaching the patient is rarely known.

Dangerous Medication Errors

The most dangerous medication errors are those involved when a patient receives the wrong drug, the wrong dose, when the frequency of taking the medication is incorrect, or when a drug interaction or contraindication occurs. All of these can result in significant harm to the patient. Errors such as dispensing the wrong form of the drug (a tablet instead of a liquid), misspelling the patient's name, and not labeling the container with the drug name and number of refills are also errors, but these will seldom result in patient harm.

Between 1989 and 2016, claims for pharmacy malpractice for one insurance company were as follows: wrong drug, 50%; wrong strength, 26%; wrong directions, 8.5%; lack of drug review, 8.5%; counseling, 2%; and lack/poor counseling 1.5%.[50]

Reasons for Medication Errors

Errors usually occur because of human failing, but also often occur because of flaws in the *medication use process*: the prescribing, dispensing, administration, and monitoring of medication. Errors are usually not just the result of physicians, nurses, and pharmacists making an error, but of good people working in a bad system. Pharmacists have built safety net systems to catch errors, however, as work volume increases, or someone bypasses a certain step in the process, these safety nets may not catch the error in time.

Errors versus Mistakes

Medication errors are based on a knowledge deficit or a performance deficit. *Knowledge deficit errors* are also called *mistakes*. In the case of a mistake, the person committing the error does not possess the knowledge to avoid the error. For example, if a pharmacist dispensed an overdose of a medication and did not know that amount of medication was an overdose, this is classified as a knowledge deficit error or a mistake. *Performance deficit errors* are also called *slips*, as the person committing the error knew better but did not perform as expected. Inattentiveness or distractions often cause slips.

Safety Note: The author advocates a *safety zone* – a 2' x 2' marked area on the floor—where only the pharmacist goes when checking terminally dispensed medication, and there

is to be absolutely no interruption while the pharmacist is there. Being in the safety zone, the pharmacist recognizes the importance of what he or she is doing.

Some of the major contributors to errors are: (a) not reading labels, (b) the oral prescribing of medication, (c) being too busy, and (d) sloppy handwriting.

Not reading labels

Not *actively* reading the label is perhaps the number one cause of errors. The problem is often compounded by the way manufacturers label their drugs. Many drugs are labeled similarly. Many drugs look similar to other drugs of the company (same shape container, same color label, same label format, same print) except for a small detail such as the drug name or the strength. Many drug names look similar, for example, quinine and quinidine, prednisone and prednisolone, vincristine, and vinblastine. Enhanced lettering like *tallman lettering* may help.[51] Instead of hydroxyzine HCl, the labeling would be hydrOXYzine HCl to distinguish the drug from hydralazine HCl (HydrALAzine HCl).

The rule for checking dispensing by the pharmacist is to read the label at least three times: when the drug is retrieved from storage, before it is counted or measured, and just before it is dispensed. Some pharmacists use a fourth check when the drug is put back into storage.

Oral prescriptions or orders

It is common for physicians to prescribe medication verbally over the telephone. It is also common practice for physicians to allow their nurses to communicate a prescription over the telephone to a pharmacist or pharmacy intern. Although verbal orders are legal, they can be dangerous if not handled carefully.

The first consideration when handling *verbal orders* is to make sure the caller is legitimate. Do you recognize the voice as a physician or the nurse of the physician? Second, each part of the prescription must be put into writing immediately: the physician's name, the patient's name, the drug, its strength and dosage form, the amount, the directions, and the number of refills. Third, it is critical that the details of the prescription, as heard, are repeated to the sender with a request for confirmation.

This procedure, sometimes called *echoing*, is an important safety practice that can catch errors, especially for drugs that sound alike. Examples of sound-alike drugs are Lodine and codeine, Lopid and Slo-Bid, and Preven and Preveon. This practice confirms the dose and how often the medication is to be taken, which are two factors that can contribute, if incorrect, to significant morbidity or mortality.

Being too busy

There is no question that being busy contributes to medication errors. All pharmacies have their busy times and their slow times. During the busy times, everyone in the pharmacy works harder to be efficient and not to have patients wait too long for their medication. It is during these busy times that errors have an increased likelihood of occurring because of distractions and cutting important steps to save time in procedures designed to prevent errors. Thus, the busier the pharmacy gets, the more diligent everyone needs to be. The occasional busy time in the pharmacy is understandable, and not often predictable.

Sloppy handwriting

For handwritten prescriptions, sloppy handwriting by prescribers contributes to errors in prescriptions, but only if the pharmacist tries to guess what is written. Pharmacists have a duty to call the prescriber when in doubt about what the prescription says. Avoidance of this problem is an exclusive requirement for *e-prescribing* and *computerized prescriber order entry* (CPOE).

Not Enough Help

There is no excuse for pharmacists to have to work without enough help or the resources to practice safely.[52] Employers who emphasize speed or achieving quotas above safety through their conversations, supervision, or by using incentives are a danger to patients, the pharmacist, and the profession. Pharmacists, bound by their *code of ethics* and state board of pharmacy rules and regulations, are obligated to bring unsafe working conditions that may jeopardize patient safety to the attention of their employers. If these conditions do not improve, it would be wise for the pharmacist to seek other employment and to consider bringing the unsafe conditions to the attention of their state board of pharmacy.

COMMUNITY PHARMACY SERVICES

Community pharmacies provide various services for patients. These services can be divided into traditional services and newer, innovative services.

Traditional Services

Most people are familiar with the traditional community pharmacy services offered to patients: prescriptions, *over-the-counter* (OTC) drugs, and perhaps home delivery. The pharmacy services may also provide medications for nursing homes, and some pharmacists prepare intravenous products for home health care patients.[53] If the pharmacy is in a full-service store, greeting cards, cosmetics, magazines, and other sundry items may be available. The heart and soul of each community pharmacy is the prescription service and the OTCs.

Prescription Services

Not every pharmacy will choose to stock every drug. This is a physical challenge because it takes space and is fiscally unwise to do. Drugs are expensive, and each day a drug remains on the shelf unsold increases inventory cost. Most pharmacies choose to stock the most popular drugs. In 2016 the top 10 drugs by prescription volume were: Rituxan, Humira, Avastin, Januvia, Advair, Revlimid, Lantus, Enbrel, Remicade, and Atropla.[54] Most pharmacies can obtain any drug within 1 day from a drug wholesaler if they need it or within an hour if they borrow it from another pharmacy.

Some pharmacies will make a business decision not to compound prescriptions (many corporate community pharmacies), whereas others (several independent community pharmacies) will elect to make compounding a high priority or even a specialty.

Over-the-Counter Drugs

The pharmacist is uniquely qualified to advise patients about OTC medications. From a business perspective, OTCs are an important source of income.

Patients seeking OTC drugs as the answer to their health concerns offer a unique opportunity for pharmacists to display their knowledge and caring attitude. Properly counseling patients who seek OTC drugs involves several steps:[55]

1. Assess the patient's physical complaint, symptoms, and medical condition.
2. Determine whether the condition is self-limiting or needs medical intervention.
3. Advise the patient on the proper course of action, that is, no treatment with drug therapy, self-treatment with nonprescription products, or referral to a physician or other health care provider.

If self-treatment with one or more nonprescription drug is appropriate, the pharmacist should

- Assist in product selection.
- Assess patient risk factors.
- Counsel the patient regarding proper use of the OTC drug.
- Note the use of the drug in the patient's profile.
- If possible, provide follow-up.
- Discourage the use of ineffective, fraudulent, and "quack" remedies
- Prevent delays in seeking appropriate medical attention.
- Assess whether a nonprescription drug is masking the symptoms of a more serious condition.

Patients have the highest awareness of cold remedies, vitamins, and dental products and are usually satisfied with the selection and pricing of these items.[16]

Newer Services

Providing immunizations, health screenings (blood pressure, cholesterol, and osteoporosis), smoking cessation programs, and analysis of weight and body fat, are now fairly routine, as is the provision of *medication therapy management* (MTM). Here are some new emerging services in community practice.

Participation in Medical Homes: The *medical home* is not a physical location, but rather a fundamental rethinking of the way care should be delivered.[56] The reasoning is that patients should have a home where their care is coordinated, and that home should include a pharmacist. Through this model, pharmacists can provide pharmaceutical care and MTM and can manage chronic therapy through *collaborative practice agreements* with primary care physicians. Reimbursement for pharmacist *cognitive services* (CSs) will propel these services.

Helping with Transitions in Care: Lapses in care happens when the patient moves from one level of care to another (i.e., from the hospital to home; from intensive care to a general medical surgical unit; from the ER to the hospital, etc.). One lapse that occurs quite often is that the medication orders get fouled up. Pharmacists can have technicians perform *medication reconciliation* to make sure the patient's needed medication is correct during transition.

Medication Synchronization: NCPA says a recent process called *medication synchronization*—synching refills so they are all due at the same time—results in more adherent patients (86%), improved patient satisfaction (73%), more prescriptions filled (63%), streamlined workflow (70%), and better inventory control (64%).[57]

Payment for Community Pharmacy Care

For pharmacists to be paid for the CSs, which are those services not associated with a product, they must show that what they do is value added.[58] Options for getting paid include collecting money from the patient, billing the patient's insurance company, and billing the patient's employer. Most pharmacies that seek payment bill for CSs bill the patient's insurance company. *Note:* More detailed information on pharmacist billings for cognitive services can be found in Chapter 7, "Pharmaceutical Care."

COMMUNITY PHARMACIST SATISFACTION

A 2014 survey found the following:[59]

- Seventy-five percent of pharmacists in independent community pharmacy settings expressed satisfaction with their jobs, compared to 46 percent (from 59% in 2000) in chains, and 49 percent (from 61% in 2000) in mass merchandisers.
- In regard to workload, 46 percent of chain pharmacists and 51% of mass merchant pharmacists said their current pharmacy workload had a "negative" or "very negative" impact on the quality of care provided to patients. Only 13 percent of independent pharmacists agreed with that statement.
- The major concern for independent pharmacists (38%) in terms of job stress, was "doing excessive paperwork." Pharmacists in chain and mass merchant settings said, "having to meet quotas" and "not being staffed with an adequate number of technicians" were sources of high levels of stress.

No information on pharmacist satisfaction could be found for pharmacists working in mail-order pharmacies.

POSITIONS FOR PHARMACISTS IN COMMUNITY PHARMACY

Various positions are available for pharmacists in community pharmacy: pharmacy interns, community pharmacy residents, staff pharmacists, store-level and district managers, corporate management, and pharmacy ownership.

Pharmacy Interns

The first possibility is a *pharmacy intern*. A pharmacy intern must be a pharmacy student registered by the state board of pharmacy in the state of employment. Pharmacy interns must work under the direct supervision of a licensed pharmacist.

Community Pharmacy Residents

New pharmacy graduates may want to do a 1-year *community pharmacy residency*. These programs teach the resident how to manage a community pharmacy and how to provide and bill for innovative pharmacy care services. The resident learns by doing, but is closely mentored by a preceptor.[60] If the community pharmacy residency program is accredited, a residency project is required, and the results presented at a regional residency conference.

Most people feel a 1-year residency is like gaining 2–3 years of practical experience and boosts the resident's confidence to practice. It also has been shown that those choosing to do a pharmacy residency often get the best career opportunities, and many go on to be leaders in the profession.

Staff Pharmacists

Most new graduates who don't complete a community pharmacy residency will start by working as an entry-level pharmacist, but at an attractive wage based on supply and demand. Some like the role of a staff pharmacist and continue working in that capacity, whereas others want to advance into management.

Store-Level and District Managers

Once experience is gained at the staff pharmacist level, some pharmacists will move up to supervisory or management positions within a pharmacy. These positions pay more and require more skill in managing resources and people. They also are more stressful. The next step after this is a position as district manager over many stores.

Corporate Management

Some pharmacists move into the management structure of their corporation. These can be high-level positions that offer opportunities to improve how pharmacy is practiced within the company. For this to happen, many pharmacists seek additional training in management, and some earn a Master of Business Administration (MBA) degree from a school of business.

Pharmacy Ownership

Some pharmacists may want to own their own pharmacy. Currently, it is wise to have a good understanding of what this entails before purchasing a store. It is recommended that pharmacy students take an elective course in pharmacy ownership while in pharmacy school if this is something the student thinks he or she may want to do some day. Also, staff pharmacists who think they might like to be pharmacy owners should consult with a community pharmacy consultant or a faculty member specializing in community pharmacy ownership before purchasing a store.

Future of Community Pharmacy Practice

No one knows for sure what community pharmacy practice will be like in the future; however, there are some trends that will help shape this future.

- *Rising prescription volume:* Prescription volume is projected to rise dramatically owing in part to the aging population.
- *Not enough help:* Based on satisfaction surveys and interviews with pharmacists, the number one concern is not enough help so they have time to practice patient-centered care, especially in commercially owned pharmacies.
- *Technology and automation:* For pharmacy to dispense all the prescriptions that will be generated through 2035, and for community pharmacists to practice pharmaceutical care, there will need to be more use of pharmacy technicians, technology, and automation.[61]
- *Pharmacogenomics:* We are entering the era of designing custom-made dosage forms for patients based on genetic profiles of patients. Will community pharmacists be a part of this new development?
- *Payment for achieving positive patient outcomes:* It is hoped that by 2025, community pharmacists will be known more for their role in helping patients achieve positive outcomes from improved drug therapy than for providing the medication.
- *Provider status:* Will *provider status* be given to pharmacists, or is it an elusive and unneeded quest? Will it be the savior of community pharmacy practice and the profession? Time will tell.
- *Achieving the dream of pharmaceutical care:* It will take more pharmacist autonomy and standing firm for patient care over commercial interest to achieve the dream of pharmaceutical care for all.[62]

SUMMARY

Community pharmacy is the heart and soul of pharmacy practice. About 60% of pharmacy graduates work in one of four types of community pharmacy practice sites after graduation. Each type of practice site has its pros and cons as a place to practice pharmacy. Based on the aging population and increased use of medication to improve health, community pharmacy practice will continue to grow rapidly. To meet this growth and to practice pharmaceutical care, pharmacies will need to use more pharmacy technicians, use more automation, and make sure pharmacists only do pharmacist-only functions. It is hoped that by the year 2025, community pharmacists are known more for the care and counseling they provide than for providing medication.

DISCUSSION QUESTIONS AND EXERCISES

1. Based on what you know and have read thus far, record what you feel are the pros and cons of practicing pharmacy in a
   a. Community pharmacy
   b. Chain store pharmacy
   c. Mass merchandiser pharmacy
   d. Food store pharmacy
2. Based on what you know and have read thus far, what do you feel are the pros and cons of owning your own pharmacy?
3. List three things community pharmacists can do to improve patient satisfaction and three things they can do to improve patient safety.
4. Make an appointment to interview a pharmacist who is
   a. An owner of a community pharmacy
   b. Working in a chain store pharmacy
   c. Working in a mass merchandiser pharmacy
   d. Working in a supermarket pharmacy

   Note: Ask about their job satisfaction and the amount of pharmaceutical care being delivered. How often do they have face-to-face contact and meaningful dialogue with patients?
5. List three ways community pharmacists can improve patient satisfaction, in order of priority, and explain why you think these methods will work.

CHALLENGES

1. Residencies in community pharmacy are relatively new. For extra credit, and with the permission of your professor, write a concise report about community pharmacy residencies. Include what they are, how many there are, how many residents are in these programs, and the advantages and disadvantages of doing this type of residency from the student's viewpoint, rather than point of view of the profession.
2. One of the most critical issues in dispensing a prescription order is the frequent inability to read the prescriber's directions. Some medical schools have gone so far as to require mandatory courses in handwriting. Some experts think the answer lies in computerized origination of the prescription. For extra credit, and with the permission of your professor, prepare a concise paper probing the complex dimensions of solving this problem for the nation.

3. Pharmacy is often criticized because pharmacists spend an inordinate amount of time on technical functions—counting, pouring, labeling, and so on. For extra credit, and with the permission of your professor, construct methods that purport to minimize the negative social consequences with professional performance of this more restricted and yet prominent role of the pharmacist.

WEBSITES OF INTEREST

Department for Professional Employees: Fact sheet 2016. Pharmacists and pharmacy technicians: Facts and Figures: http://dpeaflcio.org/programs-publications/issue-fact-sheets/pharmacists-and-pharmacy-technicians-facts-and-figures/

Food Marketing Institute: http://www.fmi.org/

Grocery store pharmacy jobs: http://www.rxrecruiters.com/grocery-store-pharmacy-jobs.htm

National Association of Chain Drug Stores: http://www.nacds.org

National Community Pharmacists Association: http://www.ncpanet.org/

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9 Health System Pharmacy

INTRODUCTION

The healthcare team (physicians, nurses, pharmacists, and other healthcare workers) is most evident in organized healthcare systems such as hospitals, health plans, and clinics. Hospitals, the most dominant member of health systems, are also where the newest drugs, some of which are still under investigation, are used. Because of this, hospitals are exciting places for pharmacists to work.

This chapter explores the hospital, the patient, the healthcare team, and what it is like to practice pharmacy inside a typical hospital. It covers pharmacy's mission within a hospital: the control of drugs, proper use of drugs, avoiding medication misadventures, and education and training. The roles of the pharmacist and other members of the pharmacy department and how they are evolving are also covered. The chapter concludes by discussing some trends that may shape the future of pharmacy practice in health systems.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Define the term *health system.*
- Provide a brief history of hospitals.
- Discuss the types of hospitals and how they vary.
- Explain how hospitals are accredited.
- Explain how hospitals are organized.
- Discuss the feelings of a typical hospitalized patient.
- Explain the mission of the hospital pharmacy department.
- Discuss how hospital pharmacies accomplish their mission.
- Discuss how hospital pharmacists fit into the healthcare team.
- Explain how medications are managed in a hospital.
- Discuss the difference between a CPO and a DOP.
- Explain how most hospital pharmacy departments are organized.
- Explain the terms 340B and antimicrobial stewardship.
- Contrast the roles of a hospital pharmacist with that of a community pharmacist.
- Discuss future trends of pharmacy practice in hospitals.

HEALTH SYSTEMS

A *health system* can be defined as all the healthcare delivered in a country. However, in the United States, health systems are organized healthcare settings, such as hospitals, clinics, and even health plans and primary care offices, often linked together by ownership or partnership. There are two dominant employers of pharmacists in organized healthcare settings: hospitals and health plans such as *health maintenance organizations* (HMOs). However, a new feature—the *patient-centered medical home* (PCMH)—is emerging under the *accountable*

care organization (ACO) model of care, and these are ideal places for pharmacists to work. PCMHs need to be in an ACO with a hospital.

HOSPITALS

Hospitals have changed from small beginnings to becoming major healthcare centers of excellence.

How Hospitals Started

In ancient times, hospitals were shelters for travelers and pilgrims.[1] Hospitals were places for Christian travelers in the Holy Land during the early Christian era. In Europe, during the 1600s, "poorhouses" were established to provide food and shelter for the downtrodden. In the early years of the United States, hospitals were infirmaries for the poor. In the late 1700s and early 1800s, hospitals were charitable places for the ill. It was not until the late 1800s and early 1900s that hospitals became safe and effective treatment centers. During the 1930s and 1940s, hospitals became known for their diagnostic skill, new treatment methods, and special care.

Modern Hospitals

Today's modern hospital is a sophisticated, high-technology center for the diagnosis and treatment of general or specific medical conditions—both acute and chronic. An *acute illness* is a medical condition that needs immediate attention; if properly treated, it is self-limiting. A *chronic illness* is one of long duration, which can sometimes last a lifetime. The *eight major chronic illnesses* treated today are asthma, hypertension, diabetes, arthritis, obesity, depression, congestive heart failure, and hypercholesterolemia.

Besides diagnosing and treating these illnesses, hospitals also diagnose and treat rare and unusual conditions, perform surgery if needed, and educate patients about their health and how to manage and improve their *quality of life.*

Types of Hospitals

There are three types of hospitals: general (about 87%), specialty (about 10%), and rehabilitation (about 3%).[2]

- *General hospitals* have emergency rooms, x-ray departments, and surgical suites, and they care for general medicine and surgical patients.
- *Specialty hospitals* care for special populations of patients, such as pediatric, geriatric, or psychiatric patients. These have specialized equipment and healthcare providers with specialized expertise.
- *Rehabilitation hospitals* specialize in rehabilitating patients with orthopedic (bone and joint) or central nervous disorders.

Hospital Ownership

Hospitals are classified by who owns them. They can be privately owned or publicly owned (city, county, state, or federal). They can be *for profit* or *not for profit*. All public hospitals are nonprofit. Many private hospitals are run by religious organizations and are not for profit, whereas other private hospitals are for profit.

Hospital Size

Sixty percent of hospitals have fewer than 200 beds. In addition, the number of beds in hospitals has been dropping due to a major shift from acute to ambulatory care and declining lengths of hospital stays. These shifts are driven mostly by the need to reduce costs.

Hospital Type

In 2015, there were 5564 hospitals in the United States. Of these, 4862 were community hospitals.[2]

Hospital Statistics

Table 9.1 compares the statistics[3] for hospitals in 2000, 2005, 2008, and 2012. The number of hospitals, the total number of beds, the total admissions, and the average daily census all dropped during this time frame, while outpatient and emergency visits increased as did the costs. Although these numbers indicate that there are fewer patients in hospitals, those admitted are sicker. At the same time, there has been a shift to treating more outpatients. Outpatient care is much less costly than inpatient care.

Internal Organization

The typical hospital is organized into two distinct, but related, parts: the medical staff structure and the hospital structure.

Medical Staff Structure

The medical staff (the physicians) are either private or on staff (a hospital employee, such as hospitalists, or other contracted physician services), and have their own rules and regulations (bylaws), their own officers (president, vice-president, treasurer, and secretary), and a governing board (executive committee). The medical staff is organized by departments, such as medicine, pediatrics, and radiology, and each department has a chief (e.g., the chief of surgery). The medical staff also has an extensive set of committees in the hospital to help get its work done. Some examples of committees important to pharmacy are the pharmacy and therapeutics (P&T) committee, patient care committee, and ambulatory care committee.

TABLE 9.1
U.S. Hospitals Statistics

	2000	2005	2008	2012
Total hospitals	5810	5756	5815	5723
Total beds (1000s)	984	947	951	921
Average daily census (1000s)	650	656	649	600
Emergency visits (million)	106.9	118.9	126.7	137.3
Total expenses (billions of dollars)	$395.4	$570.5	$690.0	$829.7

Source: ProQuest. *Proquest Statistical Abstract of the United States 2015.* Issued December 2014. Table 181. Hospitals—Summary Characteristics: 2000 to 2012. Lanham, MD: Berman press.

Administrative Structure

Hospital employees other than physicians work in various departments of the hospital. The chief executive officer (CEO), the chief operating officer (COO) or president, the chief financial officer (CFO), the chief nursing officer (CNO), the chief technology officer (CTO), and various vice presidents of the hospital work in hospital administration. Reporting to the various vice presidents are the directors of various hospital departments, for example, pharmacy, nursing, laboratory, and anesthesia.

PATIENTS

Patients entering the hospital, either as outpatients or as inpatients, come to this experience from different points of view. Some patients look forward to finding answers to their health problems. Others are afraid the experience will be a bad one, in that they may discover they have a major illness or a poor prognosis. Some may be afraid of surgery. Others come trusting healthcare professionals, whereas others are leery of these professionals. Some have language or cultural barriers. Some are afraid the cost of hospitalization will ruin them financially, whereas others are afraid a medical error will harm them.

Hospitals can be busy and confusing places for patients. Because of this confusion and respect for healthcare professionals, many patients turn themselves over to the healthcare team rather than become a partner in their own healthcare. Patients have rights and need to be members of the healthcare team. Patients also need to understand their health situation, know their rights and duties, understand their alternatives, look for something that may not be correct, and continually work to improve their health.

Pharmacists need to understand the patient, who is usually not feeling well and is seeking better health. The pharmacist should work with patients using their knowledge and a caring attitude. The patient–pharmacist covenant goes like this: “If you help me [the patient] make the best use of my medications, I will give you [the pharmacist] my respect, trust, and cooperation.”

However, being successful at this covenant is not always easy because every patient has a different set of circumstances and comes from a different background. The pharmacist must start with the facts, ask probing questions, be understanding, and show a caring attitude. Success usually comes with experience; however, the fundamental principles of respect for human dignity and feeling the patient’s vulnerability lie at the core of a fruitful pharmacist–patient relationship. Yet, the short length of hospital stays (down from 7.8 days in 1970 to 4.5 days in 2014) for most patients makes it difficult for the hospital pharmacist to implement the covenant relationship.

HEALTHCARE TEAM

The healthcare team is never more obvious and visible than it is in the hospital. Physicians, nurses, pharmacists, dieticians, laboratory personnel, and radiology (x-ray) personnel, to name a few, work together for the good of the patient. The healthcare team runs smoothly when each person on the team understands and respects the roles of other members of the team, communicates well, and always has the patient’s best interest at the center of their attention. Including the patient in his or her care makes the team function even better.

How the pharmacist fits into the healthcare team is changing for the better. In the past, pharmacists were relied on to make sure the right drug was given to the right patient at the

right time. This is still a key role for pharmacy from a drug distribution standpoint. However, to dispense the first part—the correct drug—the pharmacist needs to know the patient's diagnoses and help select the best drug for that patient. To do this, the pharmacist needs to be on the patient care unit after the patient has been evaluated and diagnosed, and when the drug is being selected.

The pharmacist also needs to advise the nurse about the important job of administering medication. It is also the role of the pharmacist to be the patient's adviser when it comes to medication.

The goal should be that most patients say "yes" when asked whether they talked with a pharmacist during their hospital stay. It is even better if the patient remembers the pharmacist's name. Unfortunately, many patients in hospitals do not realize there are pharmacists working there.[4]

PHARMACY DEPARTMENT

The pharmacy department is considered an important department within every hospital. Whether it is viewed as a hospital department or a clinical department varies from hospital to hospital, and this is often dependent on how the pharmacy department views itself.

Mission of Pharmacy

The mission of most pharmacy departments in hospitals is the safe, effective, timely, and cost-effective use of drugs. It involves control of drugs, overseeing the drug use process (purchase, storage, dispensing, prescribing, administering, charting, utilization review) to ensure appropriate use and avoid medication misadventures. It also includes education and training.

A Business within a Business

In a sense, the pharmacy department is a business within a business (the hospital), and this needs to be evident to the pharmacy and hospital administration. Drugs have become big business in hospitals and because of their complexity and rising cost, drugs are an ever increasing proportion of the overall hospital budget. This is not the case for the "usual cast of characters" (dietary, lab, radiology, central supply). Pharmacy can have a major impact on the hospital, as drugs are the fastest growing expense line, a major source of revenue, the primary treatment modality for most patients, and the largest contributor to errors.

Pharmacy is far more than an ancillary support service, and should not be viewed and managed by hospital administration as a commodity, as increasing hospital drug cost is tied to increased or poor utilization as much or more than price increases. Because of the importance of drugs in hospitals, the head of the pharmacy should be part of the leadership of the hospital and be designated Chief Pharmacy Officer (CPO), rather than the Director of Pharmacy (DOP).

Control of Drugs

The pharmacy, by law and the *Joint Commission on Accreditation of Healthcare Organizations* (JCAHO) standards, is responsible for the control of medication throughout the hospital facility. The director of pharmacy is held accountable for this control. Control involves more than keeping supplies secure.[5] Control includes knowing where all the drugs are stored, that there is enough (not too much or too little), and that all drug products are in-date.

Purchasing

The pharmacy is responsible for purchasing the best therapeutic agents at the lowest cost. To do this, there must be a formulary to let the pharmacy know what drugs to purchase, and purchase agreements with drug wholesalers and manufacturers that today are handled almost exclusive by a purchasing group representing a consortium of hospitals to which the hospital belongs. The more purchasing power, the lower the cost.

340 B Drugs—The 340B Drug Pricing Program allows certain hospitals and other healthcare providers ("covered entities") to obtain discounted prices on "covered outpatient drugs" (from drug manufacturers). Manufacturers must offer substantial 340B discounts to covered entities to have their drugs covered under Medicaid.

The U.S. Health Resources and Services Administration (HRSA), which manages the program, estimates that covered entities saved $3.8 billion on outpatient drugs during the program in fiscal year 2013. According to HRSA, the intent of the 340B program is to allow certain providers to stretch scarce federal resources as far as possible to provide more care to more patients. One group estimated that, on average, hospitals in the 340B program receive a minimum discount of 22.5% of the average sales price for drugs paid under the outpatient prospective payment system.[6]

Inventory Control

It is the sole responsibility of the CPO or DOP to control all drugs used within the institution. This includes routine drugs, investigational drugs, samples, and narcotics and controlled substances. This responsibility comes by way of law (Federal and State) and standards (JCAHO and State Health Department). The name on the pharmacy permits and narcotic licenses is that of the CPO or DOP, not CEO, COO, or the CMO. The COP/DOP is solely responsible for control of all drugs purchased for the organization.

Drug control starts with stringent inventory control. Stringent inventory control means keeping accurate records of what is used and how often it is used. Drugs must be stored properly in areas with correct temperatures and light. Narcotics and other controlled substances must be stored properly. Schedule II controlled substances (substances with high addiction and abuse potential) must be stored under lock and key. Schedule III–V controlled substances are either spread throughout the stock or also kept under lock and key (see Chapter 4, "The Drug Use Process"). Strict inventory and security requirements need to be followed for these drugs both in the pharmacy and when they are used on the patient care units.

Drug Samples

Other drugs needing strict control are *drug samples*. Drug samples are small quantities of drugs provided by drug manufacturers to physicians for starting a patient on a new drug to see how it works or if there are adverse effects before writing a prescription. Because physicians often see ambulatory patients in hospital clinics, samples sometimes show up there. Because the CPO/DOP must exercise control, the JCAHO states that there must be a hospital policy for drug samples. The policy of many hospitals is not to use them.

Investigational Drugs

Another category of drugs that needs strict inventory control is *investigational drugs*. These drugs are used in clinical research trials where some patients receive the active (investigational) drug, whereas other patients receive a look-alike, inactive drug (placebo). The pharmacy keeps records of which patient receives which drugs.

Narcotics and Controlled Substances

Controlling narcotics and controlled substances is complex and beyond the scope of this book, which is to provide an overview. Discussion of the policies and procedures for control of these substances is best left to the classroom and on-site training.

Overseeing the Drug Use Process

There is a well-defined process to decide how drugs are used in the hospital:

- *Policies and procedures:* The pharmacy drafts policies and procedures on the important steps in the drug use process (prescribing, preparation, dispensing, and administrating) for discussion by the P&T committee. The CPO/DOP is usually the secretary of this committee, and there is usually a nurse and a hospital administrator on this committee along with several members of the medical staff. The drug use policies and procedures are discussed, changed, and approved for use by the committee. They are usually revised annually.
- *Documenting medication use and allergies:* When admitted to the hospital, patients are asked which medications they take regularly and if they have allergies to the medication. The answers to these questions are documented in the patient's record (paper or *electronic medical record* [EMR]) and sent to the pharmacy electronically or now rarely by a copy (carbonless [NCR] paper) of the information.
- *Prescribing and transmission of orders:* If the hospital is using a paper system for ordering (now rare), a JCAHO standard states that the pharmacy must review a copy of what the physician has ordered; thus, transcriptions (rewriting orders) by nursing personnel are not permissible. There are various methods orders written manually arrive at the pharmacy: courier, fax, pneumatic tube, or electronically (the best way). In 2013, 93.9% of hospitals had *electronic health records* (EHRs), and 65.2% had *computerized-prescriber-order-*entry (CPOE) systems with *clinical decision support* (CDS).[7]
- *Receipt of medication orders:* In most cases, the pharmacy receives an electronic medication order that is sent to a patient's electronic pharmacy profile. In hospitals that do not use computerized records, there are two manual medication records for each patient—the pharmacy patient profile and nursing's *medication administration record* (MAR). They should be identical. The best procedure for checking a patient's unit dose drawer is for the pharmacist to check the contents of the drawer against the nursing MAR rather than the pharmacy patient profile from which the drawer was dispensed. If the drawer is not correct, it means one of three things happened: (1) the drawer was dispensed incorrectly, (2) there was a computer entry error made in the pharmacy, or (3) there was a transcription error made between the physician's order and the nursing MAR. Which error occurred? The answer can be found by checking the physician's order in the patient's record.
- *Drug preparation and distribution:* The ASHP has national *standards* (what should be done) for pharmacists to follow to prepare and distribute drugs in hospitals properly. The use of these standards is critical in protecting patients and helping the pharmacy service to be up to date on what it is doing.

Three primary systems are used for distributing drugs in hospitals and other organized healthcare settings: floor stock, unit dose, and centralized intravenous (IV) additives.

Floor Stock

Medication can be stored on the patient care units in the form of *floor stock*; however, this is not recommended. If this is done, medication should be limited in order to avoid errors and using outdated drugs. Floor stock, if stored in places such as shelves or drawers (on the nursing unit) offers more opportunity for error; there is no system of double checks and balances to avoid mistakes. The nurse can take out what she or he thinks is needed, and give it directly to the patient. Thankfully, 97% of hospitals now use *automated dispensing machines* (ADMs) located on the patient units.[8] These devices dispense medication, but only when the nurse uses proper procedure and the request is consistent with the patient's medication profile. *Note:* See Chapter 6, "Pharmacy Informatics and Automation").

Unit Dose

An alternative method of drug distribution, and one that is far superior to uncontrolled floor stock is called *unit dose*. A unit dose is a single dose of packaged and labeled medication dispensed from the pharmacy that is ready to be given to the patient, which means that no further dosage preparation, calculation, or manipulation is required.

The earliest attempts at unit dose drug distribution were documented nearly 40 years ago in community hospitals in Long Beach, California and Rochester, Minnesota.[9] Unit dose systems are safer than uncontrolled floor stock because there is less opportunity for error, and there is a built-in system of checks and balances.

In the unit dose system of medication distribution, there are two medication drawers for each patient. One drawer is always in the pharmacy being dispensed, whereas the other is always on the patient care unit for use by the nurse to give medication to that patient. Each drawer is usually divided into two sections—one for regularly scheduled medication, and the other for as-needed (prn; *pro re nata*) medication. The pharmacy places enough medication for the patient for the next shift (7 a.m. to 3 p.m., 3 p.m. to 11 p.m., or 11 p.m. to 7 a.m.) or for the next 24-hour period. At the end of the shift or 24-hour period, the drawers are exchanged.

The built-in system of checks and balances in the unit dose system is based on three sets of medication records: the doctor's orders in the patient's record, the patient's pharmacy profile, and the nursing *medication administration record*.

Intravenous Admixtures

The third drug distribution system is *intravenous admixtures*. Intravenous additives are drugs added to intravenous solutions. These are administered to patients intravenously (into their vein) and must be *sterile* (free of any germs that can cause infection—bacteria, viruses, and fungi). The technique of adding medication to intravenous solutions should be done carefully and under ideal conditions. In the past, nurses prepared the intravenous solution on the patient care unit, which is a place full of germs. If this is still allowed in the hospital, there must be a policy on how nurses should do this.

American Society of Health-System Pharmacists (ASHP) and JCAHO standards state that intravenous admixtures should be prepared in the pharmacy using aseptic (germ-free) technique and a laminar flow hood. Most hospital pharmacies have a complete, comprehensive intravenous admixture program. A *laminar flow hood* is an aseptic work area with positive-pressure airflow that filters the air. Pharmacists and pharmacy technicians are trained to prepare intravenous admixtures properly, and they should be recertified on how to do this.

Once the intravenous additives are prepared, preferably by a *certified pharmacy technician* rather than a pharmacist, they are checked by a pharmacist. When an intravenous

admixture is contaminated during preparation, the bacteria grow exponentially with time and temperature. Therefore, intravenous admixtures should be prepared just before they are needed and refrigerated between the time they are prepared and the time they are used. Distributing intravenous admixtures to the patient care units is usually done by a courier or a pneumatic tube system.

Note: The unit dose system of drug distribution is still used in hospitals struggling to afford ADMs.

Sterile Compounding

Sometimes physicians request injectable medication that is not available commercially, so hospital pharmacists must make the injections from scratch. This takes patience and expertise. Calculations need to be made carefully, and like intravenous admixtures, the injectable medication must be prepared in a laminar flow hood or clean room using an aseptic (sterile) technique. The U.S. Pharmacopeia (USP) has standards (Chapters 797 and 800) for preparing sterile preparations that must be followed. In 2014, 65% of hospitals reported having a cleanroom compliant with USP Chapter 797.[8]

Decentralized Pharmacies

Drug preparation and distribution can be done from a large central pharmacy or from smaller, decentralized satellite pharmacies. Decentralized pharmacies are located in strategic locations in the hospital and serve several patient care units. Central pharmacies are more efficient, require less inventory, and need fewer personnel. The advantages of decentralized, satellite pharmacies are faster, more personalized service and more opportunity for staff pharmacists to deliver pharmaceutical care on the floors. The trend is toward centralized pharmacies and decentralized pharmacists.

Drug Administration

Drugs are administered to inpatients by registered nurses (RNs) or in some states by licensed practical nurses (LPNs) who have taken a course in medication administration. The MAR serves as a reminder to the nurses of when medication is to be given to the patient. In hospitals using general nursing care procedures, there may be a medication nurse who is responsible for administering all the medication on a patient care unit for one shift. In *primary care nursing*, one nurse performs all duties for four to six patients, including the administration of medication.

After the first dose of medication is administered, which should be as soon as possible after the order is written, it is usually scheduled according to the standard dosing schedule of the hospital. For example, all medication ordered “every 6 hours” is usually administered at 6 a.m., 12 noon, 6 p.m., and 12 midnight. A medication ordered four times a day (q.i.d) is usually administered at 10 a.m., 2 p.m., 6 p.m., and 10 p.m.

The important questions to ask before administering medication are as follows: (1) Is this the correct patient? (Check the patient’s armband ID.) (2) Is this the correct medication? (3) Is the dose correct? (4) Is this the correct dosage form? (5) Is it the correct time to give the medication? Fortunately, the correct medication for the patient in the correct dose and in the correct dosage form should be in the patient’s unit dose drawer or dispensed from a ADM. However, the nurse still needs to be careful about administering the correct medication.

Once the medication is administered, the nurse must “chart,” or record, the medication administered to the patient by documenting what was given, how much, and when.

This is done on the MAR or automatically using bar-coding that reads the unit dose before it is administered.

Ensuring Rational Drug Use

Achieving rational drug therapy (the appropriate use of drugs) in the hospital is the goal of every pharmacy department and the medical staff. Achieving this goal is difficult, as is overcoming several challenges that make rational therapy less possible.

Challenges to Rational Therapeutics

The first challenge to rational therapeutics is the modest education and training on pharmacology and rational drug therapy that physicians receive in medical school. Second, because of the number of new drugs approved for use each year by the *U.S. Food and Drug Administration* (FDA), there is "information overload." Third, drug companies market information about their drug products that emphasize the benefits of the medication. The drug companies are skillful in stating the best features of their drug products to increase sales. Fourth, there is a large gap between what clinical studies show and what works (evidence-based medicine) and how the medication is used in everyday practice.

An example of the gap between what is known and what is done is how peptic ulcer disease is treated. For years, peptic ulcers were thought to be caused by stress and aggravated by spicy foods. The long-standing treatment of peptic ulcers was the use of antacids, and, more recently, H2 antagonists such as cimetidine. We know today that most peptic ulcers are associated with the presence of the bacterium *Helicobacter pylori* and therefore should be treated with antibiotics. Still today, some patients are being treated the old way. This is what happens when physicians are too busy to keep up to date with the medical literature. This is where pharmacists can be the most helpful.

Pharmacy's Input into Rational Therapeutics

The challenges to achieving rational therapeutics represent a real opportunity for pharmacists and pharmaceutical care. Pharmacy educators and some practitioners started noticing these opportunities in the mid- to late 1960s. This spawned the *clinical pharmacy* movement.

Clinical pharmacy was first practiced by a handful of pharmacists in a few hospitals, mostly on the West Coast. With expanded education in the areas of pathophysiology, pharmacokinetics, laboratory medicine, therapeutics, and clinical pharmacy, new pharmacy graduates and pharmacy residents began to work directly with physicians, mainly the house staff (medical residents), to improve drug therapy. Acceptance of the pharmacist in this new clinical role was slow but moved forward methodically.

A 2015 ASHP survey found that pharmacists in hospitals are monitoring the therapy of at least 75% of patients 57.8% of the time (versus only 20.3% in 2000), and 31.4% of hospitals have pharmacists practicing in ambulatory or primary care clinics.[10]

Anticoagulation Management

The most common clinical pharmacy service offered to outpatients in 2013 was anticoagulation management (63.5%).[7] Pharmacists delivering this service commonly work under a *collaborative practice agreement* (CPA) with physicians that allow the pharmacist, working under a protocol, to monitor and change the patient's therapy when needed without obtaining approval every step of the way.

Antimicrobial Stewardship

The poor prescribing and use of *antimicrobial agents* (antibiotics and other anti-infective agents) promotes *antibiotics resistance*—the ability of micro-organisms to adjust and avoid being killed by antibiotics. Some believe the misuse of antibiotics may be as bad as this[11]:

- Optimal agent used ≈ 80%
- Correct dose used ≈ 80%
- Narrow spectrum antibiotic used when cultures available/patient stable ≈ 10%–20%
- Optimal duration of therapy used ≈ 30%
- The likelihood that all sequential steps are optimal ≈ 4.5%

These inappropriate uses can result in an excessive *length of stay* (LOS), which one study found to be 6.4–12.7 days with an excess cost ($18,588–$29,069).[12]

To combat this problem, pharmacists and others have devised an approach called *antimicrobial stewardship* (AMS). AMS is often defined as a systematic approach to the use of antimicrobial agents to achieve optimal outcomes, as close to 100% of the time as possible. This means using the correct agent, at the correct dose, with the correct route of administration and for the appropriate duration, to cure or prevent infection, while minimizing toxicity and emerging resistance.

Pharmacists have been major drivers and participants in AMS programs, and many have rewarding practices in this area. AMS programs with pharmacist leadership and participation have been shown to reduce inappropriate therapy, LOS, antimicrobial resistance, and cost.[13]

Drug Formulary and Pharmacy & Therapeutics Committee

Rational therapeutics begins with having an effective *drug formulary*, which is a compilation of pharmaceutical agents (and often related products) authorized or recommended for prescriber selection and patient use in a given healthcare environment.[14,15] The drugs selected for the hospital formulary must be effective, safe, and cost-effective. By narrowing the list of drugs, the hospital can obtain quantity discounts, thus lowering the price of drugs for patients.

The primary goals of a formulary fall under one or more of the following: (1) therapeutic objectives designed to improve patient health outcomes by means of certifying *drugs of choice,* (2) economic objectives aimed primarily at limiting purchases for drug products (cost control), and (3) realizing certain administrative ends, such as ideal inventory control or easing claim processing.

Formularies may be used as a compulsory control over drugs that may be prescribed (often accompanied by a protocol for requesting a non-formulary drug product) or as a voluntary guideline under a companion quality assurance program called a *drug utilization review* (DUR) or a *drug usage evaluation* (DUE). Although many physicians contend that, by itself, a formulary restricts their ability to order any marketed pharmaceutical product, the major substantive issue is that formularies may make therapeutic goals less desirable than other objectives.[15]

The selection of the *drugs of choice* to be listed in the formulary is done by a *Pharmacy & Therapeutics (P&T) Committee.* This committee composed mainly of physicians, with representation from nursing and pharmacy. The director of pharmacy is usually the secretary of the committee.

A drug under review is compared to similar drugs in the formulary. A drug being considered for formulary status must be better than a drug that is currently used (or equal and cheaper) and, if it is better, will either replace the older agent or be given a trial period to see

how it performs. After the trial period, a final decision is made about which of the drugs will have formulary status.

The pharmacy is responsible for writing the *P&T background* (the evaluation) of a drug being requested for formulary status. Formulary requests usually come from members of the medical staff, who must state the reasons a drug is being requested. P&T backgrounds are extensive, comparative evaluations based on the clinical studies and pharmacoeconomic evaluations (cost effectiveness) published in the medical and pharmacy literature.

In addition to approving drugs, the committee approves the policies and procedures for prescribing, dispensing, administering, and documenting the use of the drugs.

Other important committees of the medical staff to which pharmacists can contribute are the patient care and the ambulatory care committees. These committees often deal with issues of interest to the pharmacists.

Leading Drugs

Although the formulary for each hospital will have different drugs, many of the drugs will be the same based on their efficacy, side-effect profile, and cost. The top ten drugs (by spending) in hospitals during 2015 were acetaminophen, nitroprusside, isoproterenol, neostigmine methylsulfate, glycpyrrolate, pegaspargase, vasopressin, calcitonin (salmon), glucagon, and phytonadione.[16]

Pharmaceutical Care

Hospital pharmacists have led the way to the clinical practice of pharmacy. The hospital is the ideal environment to practice pharmaceutical care and for pharmacy students to learn about disease and treatment. Every hospital is at a different stage of development of offering pharmaceutical care. Some are not offering pharmaceutical care at all, some are middling, while others are far advanced.

Pharmaceutical care in hospitals revolves around ensuring ideal drug therapy. As shown in Figure 9.1, *quality drug therapy* is safe, effective, timely, and cost-effective. From a pharmaceutical care prospective, ideal drug therapy must be delivered so that the patient knows that the pharmacist is involved and cares. If ideal drug therapy is evidence based, then it is also rational.

For pharmacists to help deliver ideal drug therapy, they must be involved in prescribing, dispensing, administering, and monitoring the drugs used in the hospital, which is a big job. The basis for this involvement is *evidence-based medicine*—therapy based on published clinical studies and used following the drug use policies and procedures approved by the P&T committee.

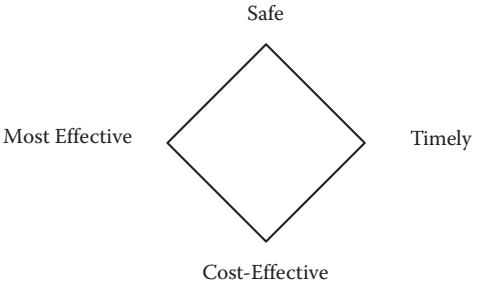

FIGURE 9.1 Quality drug therapy.

Historically, pharmacists approached the clinical use of drugs by carrying out various clinical pharmacy functions. Clinical pharmacy residents and clinical pharmacists (usually those with the doctor of pharmacy degree and having completed a pharmacy residency) in the mid- to late 1960s started working with willing physicians to help improve drug therapy for patients.

Certain useful clinical roles emerged from these pioneer clinical pharmacists. One role was to provide useful drug information and input to the drug therapy of specific populations of patients—those with pain, cancer, or needing intravenous nutrition—that was called previously *hyperalimentation*, but now called *total parenteral nutrition* (TPN). About the same time, it was discovered that the pharmacist could also be useful during a cardiac arrest, which occurs when the patient's heart stops and is sometimes called a *code blue*. The pharmacist's role on the cardiac arrest team is to draw up the drugs, make sure they are given in the correct order and in the correct dosage, and record which drugs were given and when.

A breakthrough for clinical involvement by the pharmacist working in a hospital was monitoring drugs that have therapeutic plasma levels close to their toxic plasma levels. These drugs are usually effective, but they need to be used cautiously because of their potential toxicity. Because of pharmacists' educational background in *biopharmaceutics* and *pharmacokinetics*, they are suited to working out the mathematical modeling needed to dose these drugs scientifically and safely. Pioneer clinical pharmacists in academic medical centers and community hospitals not only proved pharmacists could dose and oversee these drugs better than most physicians, but several have started billing and are receiving hospital reimbursement for this service.

Pharmacists in some hospitals are able to prescribe drugs to patients under a written protocol or a *collaborative drug therapy* management agreement that comprises guidelines of the medical staff. Since 1995, the Department of Veterans Affairs (VA) has allowed *clinical pharmacy specialists* an expanded scope of practice with independent prescribing privileges through a formal credentialing process.[17] An interesting commentary on the evolution of ambulatory clinical pharmacy practice has been written.[18]

WHAT ARE THE CLINICAL GOALS?

It is important in ambulatory pharmacy practice to keep in mind what's important.

Focusing on Patients Needing the Most Help

Philosophically, all patients deserve pharmaceutical care. Pharmacists should review the drug therapy of every patient. However, until there are enough pharmacy technicians, enough pharmacy automation, and enough pharmacists to do this, criteria are needed to select which patients will receive pharmaceutical care. Under the clinical pharmacy model, patients were usually selected based on the clinical pharmacy specialist's judgment. This resulted in mixed results and a haphazard approach to care.

In many hospitals today, pharmacists are members of *patient-focused teams*—teams of clinical practitioners from medicine, nursing, pharmacy, and other health disciplines that focus on special populations of patients for improving the patient's outcomes, health status, satisfaction, quality of life, and cost of care.

With limited resources, it is best to select categories of patients to be monitored. This should be coordinated to meet the needs of the hospital, as chosen by the P&T committee and based on the most common or most significant *medication-related problems* in the hospital. The P&T committee may have information through its DUE program that certain

categories of drugs are not being used ideally. Thus, these drugs are the ones pharmacists need to monitor until there is improvement. Some hospital P&T committees may want to focus on treatment failures, patients with reduced renal function, patients 65 years of age or older, or patients taking antibiotics (an excellent choice) or prescribed more than a certain number of drugs.

Avoiding Medication Misadventures

Although it is important for pharmacists to be a part of making sure that patients receive the most appropriate drug, it is also important they focus on preventing or minimizing the adverse effects of drugs, that is, *drug misadventures*. Drug or medication misadventures are defined as significant negative effects of drugs.[19,20] Medication misadventures reveal themselves in the form of adverse drug reactions, medication errors, drug interactions, and allergic drug reactions. Definitions and explanations of these mechanisms of medication misadventures are provided in Chapter 4, "The Drug Use Process," and the extent and cost of medication misadventures are provided in Chapter 7, "Pharmaceutical Care."

Some drugs cause more mortality, life-threats, and disability than others.[21–24] These *high-alert drugs* vary by practice setting: acute care, ambulatory care, or long-term care.[25] The *Institute for Safe Medication Practice* (ISMP) high-alert drugs for acute care practice include subcutaneous epinephrine, IV epoprostenol, insulin U-500, magnesium sulfate injection, oral methotrexate (non-oncologic use), oxytocin, nitroprusside, concentrated potassium chloride for injection, potassium phosphates injection, IV promethazine, and IV or intraosseous vasopressin.[25]

Avoiding Medication Errors

When a medication error occurs in the hospital, it is a JCAHO requirement that an *incident report* be completed by the person who discovers the error. This report contains all the facts about the error without placing blame. All incident reports go to the risk manager. If the incident report involves medication, a copy should also go to the person in charge of quality assurance in the pharmacy.

In most hospitals, medication incident reports are investigated further, and a summary report is produced by the pharmacy for review by the P&T committee. It is important that this summary report include (a) clinical significance—how it affected the patient; (b) whether the event could have been prevented; and (c) how it could have been prevented.

JCAHO now requires health organizations to take added steps if the event is a *sentinel event*. A sentinel event is an adverse event that ends in death or is a *near-death event*, which is an event that could have ended in a tragic outcome. For sentinel events, the healthcare organization must show that it has performed a *root cause analysis* (RCA) of the event. Once the RCA is complete, the healthcare organization must document what changes have been made to prevent a similar instance in the future.

If the adverse event was serious (ended in death); was life-threatening (presented a real risk of dying); resulted in hospitalization (first or prolonged), disability (significant, persistent, or permanent), or a congenital anomaly; or needed intervention to prevent permanent harm or damage, the FDA would like to have the event reported. These reports are voluntary, but important, and can be filed by anyone (including patients) to the *MedWatch* program of the FDA.

Many medication errors are preventable, and many are preventable by pharmacists. Common causes of medication errors include (a) use of abbreviations, (b) not reading labels, (c) sound-alike drug names, (d) look-alike names, and (e) sloppy handwriting. The pharmacy department drafts and monitors medication policies and procedures that improve drug safety in the hospital for the P&T committee. One example of an important drug safety policy concerns abbreviations. There are now well over 32,000 medical abbreviations, acronyms, and symbols.[26]

A study at a large urban teaching hospital showed that the presence of a pharmacist on rounds as a full member of the patient care team in a medical ICU could substantially lower the rate of prescribing errors.[27] The results of this study have been validated many times since. Besides preventing medication errors, pharmacists can also reduce other adverse drug events (ADEs) such as drug interactions, adverse drug reactions, and allergic drug reactions.

PRACTICE MODELS

Pharmacy practice in hospitals and organized healthcare settings has evolved.[28] Prior to 1960, pharmacy practice in hospitals was heavily focused on the distribution of medications and somewhat on compounding and manufacturing of medication products not available from pharmaceutical companies. Then, in the late 1960s, some hospitals associated with colleges of pharmacy started having pharmacists work full time on patient care units, attending rounds, assessing and monitoring drug therapy, and teaching students. This was the start of *clinical pharmacy*. Later, a philosophical argument ensued. Should there be two categories of pharmacists: a generalist (primarily focused on drug distribution) and a specialist (primarily focused on clinical)?

In the 1980s, the practice of pharmaceutical care took root in many hospitals; the patient, rather than the prescriber became the focus of many hospital pharmacists' care. The profession (and its evolution) has embraced an integrated practice model rather than separation of the two roles.

In 2010, ASHP started a *Pharmacy Practice Model Initiative* (PPMI) that is now called the *Practice Advancement Initiative* (PAI), which outlines a plan to advance pharmacy practice by 2020. More information on the PAI is available in Chapter 7, "Pharmaceutical Care."[29]

Predictions for a future practice model include the following:[28]

- Healthcare will be more team oriented and demand more of pharmacists.
- Medication preparation and distribution will be more centralized and automated.
- The vast majority of pharmacists will spend their time in direct patient care, with information technology providing the necessary interconnectivity.
- There will be a trained, certified, and potentially licensed technician workforce.
- There will be a better definition and standardization of the direct pharmacy care services provided to patients.
- Allocation of healthcare resources will be driven heavily by metrics.
- Every patient will receive a comprehensive multidisciplinary, assessable, and transferable pharmacotherapy plan.
- The public will expect additional requirements for credentialing.
- In the community, most pharmaceutical care will be provided by pharmacists located in interdisciplinary clinics.
- Collaborative practice will evolve to include pharmacist-independent prescribing as part of coordinated healthcare teams in hospitals and clinics.

EDUCATION AND TRAINING

Another important part of hospital pharmacy practice is education and training. Every pharmacist is taught that part of being a pharmacist is teaching others about pharmacy, drugs, drug therapy, and in general, health:

Pharmacy: The pharmacist can help educate and train pharmacy students, pharmacy interns, pharmacy residents, and other pharmacists. There is special joy in helping others learn about pharmacy, and it is a way of paying back the profession. After all, if you are a seasoned pharmacist, someone helped you to learn when you were at the beginning of your career.

Medicine: Pharmacists also help train medical students, medical interns and residents, and attending physicians. Almost any physician can tell you a story about how a pharmacist taught him or her something about a drug or drug therapy.

Nursing: Many pharmacists train nursing students on the practical aspects of drugs, how to administer drugs, and how to monitor the effects of the drug. Some pharmacists also teach some of the coursework (such as pharmacology) in nursing schools.

Patients: Of course, all pharmacists are involved in helping patients learn about their medication. It is also important to teach patients about pharmacy and about being a pharmacist.

PHARMACY STAFF

Hospital pharmacies are organized in different ways. A typical organizational chart in a moderate-size hospital is shown in Figure 9.2. Most hospital pharmacies have pharmacists, managers, supervisors, pharmacy technicians, and other supportive personnel such as clerks and secretaries.

Pharmacists

Pharmacy Managers

Pharmacy managers include: the CPO or DOP and associate and assistant directors. Supervisors report to assistant or associate directors, who report to the CPO/DOP. In large pharmacy departments, there may also be an associate director of pharmacy position between the assistant directors and the director. Some pharmacy managers have added education and training beyond a degree in pharmacy. Many have completed a hospital or administrative pharmacy residency, and some have also completed a master's degree in business administration (MBA) or in hospital or healthcare administration.

All hospitals deserve a CPO rather than a DOP. Because of the magnitude of medication management in a hospital, the high cost of drugs, the number of drug misadventures, and the number of people having a role in medication management, each hospital should have a CPO who is part of the hospital's C-Suite—the Chief Executive Officer (CEO), the Chief Operations Officer (COO), the Chief Medical Officer (CMO), the Chief Financial Officer (CFO), and the Chief Nursing Officer (CNO). Being at the table of these leaders is important for pharmacy.

The CPO or DOP (when there is no CPO) is accountable to hospital administration for the department. They set the vision and direction for the department—where the department should be at a time in the future. The director is also responsible for the morale and teamwork within the department.[30]

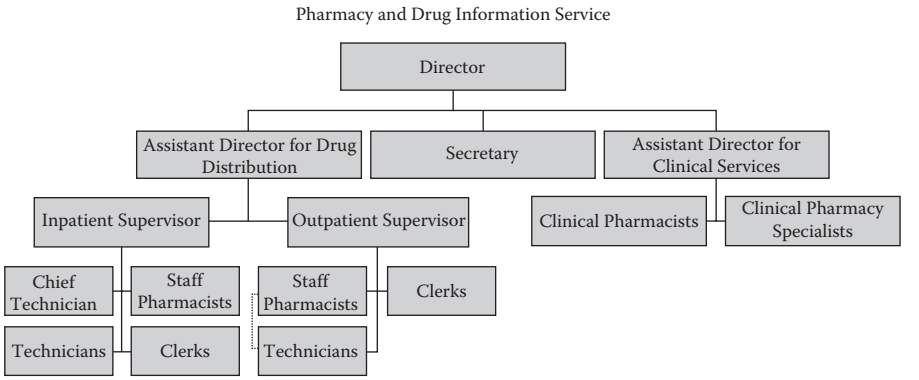

FIGURE 9.2 Typical organization of a moderate-size hospital pharmacy department.

The pharmacy managers do the planning and help move the pharmacy program forward. They also are the ones who often work outside the department with other departments on behalf of the pharmacy. In short, they try to achieve the vision set forth by the director.

Pharmacy Supervisors

Pharmacy supervisors oversee the pharmacists and the pharmacy technicians or chief pharmacy technician. They see that the work gets done, and they are responsible for the quality of work. Supervisors must be able to handle people well and motivate and counsel pharmacists and pharmacy technicians. Supervisors hire personnel, recommend raises and terminations, schedule employees, and interact with the supervisors of other departments.

Staff Pharmacists and Clinical Pharmacists

There are two categories of pharmacists who are not managers or supervisors. There are *staff pharmacists* and *clinical pharmacists*, although the line between these positions is starting to blur because of pharmaceutical care and integrated practice models.

Some staff pharmacists have a Doctor of Pharmacy degree, and some (less and less) have a Bachelor of Science (BS) in pharmacy degree. Despite the difference in education, if the work is the same, so is the pay. A survey discovered that staff pharmacists spent the majority of time performing medication review (32.6%), followed by communication, non-clinical tasks, supply, medication discussion and in-transit. They were interrupted 3.5 times per hour and spent 4.4% of observed time multi-tasking.[31]

There may be two types of clinical pharmacists in the hospital: a *clinical pharmacy generalist* and a *clinical pharmacy specialist*. The clinical pharmacy generalist or clinical pharmacist probably will have a doctor of pharmacy degree and will have completed a pharmacy residency. These pharmacists follow a patient's therapy and progress using the principles of pharmaceutical care. The clinical pharmacy specialist will usually have a doctor of pharmacy degree and will have completed a residency in a specialty area (e.g., critical care, ambulatory care, adult medicine) and will follow special populations of patients or those patients with complex medication-related problems.

Some hospitals have *career ladders*; advancement programs that place pharmacists on a continuum—new graduate pharmacist, staff pharmacist, clinical pharmacist, and clinical pharmacy specialist. In some hospitals, these positions are listed as pharmacist I, II, III, and IV. Each level has different job functions, responsibilities, and pay. Pharmacists can advance from one level to the next with more training, experience, and good job evaluations.

Most hospital pharmacists are happy with their jobs, and many would not work elsewhere. However, the rising workload has some pharmacists doing more drug distribution than clinical work.

What hospital pharmacists need to have a more clinical practice is: more administrative support, more automation, additional pharmacy staff, and perhaps more *outsourcing*—contracting to prepare drugs and intravenous solutions outside the hospital.

Pharmacy Supportive Personnel

Pharmacy supportive personnel include pharmacy technicians, pharmacy clerks or aides, and secretaries.

Pharmacy technicians: Hospital pharmacies could not get along without pharmacy technicians. Employing good pharmacy technicians is the backbone of any pharmacy service. Pharmacists could not get the work done without them, and they allow the pharmacist to be able to practice clinically. See Chapter 5, "Pharmacy Supportive Personnel." Just like pharmacists, many hospitals have career ladder advancement programs for pharmacy technicians. An example of a continuum for the career ladder is technician trainee, technician I, technician II, and chief technician. The advancement through the ladder is based on more training, certification, experience, and job evaluations. There is movement toward requiring all pharmacy technicians who work in a hospital to be certified.

Pharmacy clerks or aides: Pharmacy clerks or aides usually have no formal training in pharmacy and often learn on the job. Pharmacy clerks do routine functions in the pharmacy and do not prepare medication. Typical functions of a pharmacy clerk are to unpack medication orders, restock shelves, perform routine clerical functions, and deliver medication.

Pharmacy secretaries: Every hospital pharmacy needs a good secretary or two. Pharmacy secretaries need special skills in understanding drug names and pharmacy terminology. They also need to understand the role of pharmacy in the hospital and know how to interact effectively with other departments.

ACCREDITATION

Hospitals receive *accreditation*—confirmation that they meet certain minimum standards of care—from the JCAHO. It is a nonprofit, nongovernmental organization that inspects hospitals every 2 to 4 years. Some of the standards concern the pharmacy and the medication use process in the hospital. Three surveyors complete the survey over a 2 to 3-day period. Although hospital accreditation is strictly voluntary, some governmental reimbursement (such as Medicare and Medicaid) is tied to JCAHO accreditation. However, hospitals not accredited may comply with federal conditions of participation and still qualify for Medicaid and Medicare.

Achieving accreditation, passing state health department and board of pharmacy inspections is one of the most important aspects of hospital pharmacy, and the CPO or DOP is accountable for making sure this happens.[32]

JCAHO accreditation is a nationwide seal of approval that indicates that a hospital meets high-performance standards. Pharmacy services in hospitals must meet JCAHO standards for the pharmacy service, some medical staff standards involving the formulary, P&T committees, and policies and procedures involving the drug use process.

In addition, the pharmacy must help the hospital meet the national patient safety goals of JCAHO that relate to medication and the medication use system (MUS) (see http://www.jointcommission.org/standards-information/npsgs.aspx). Examples include having a list of do-not-use abbreviations and ensuring the continuity of care when patients move from one setting to another (e.g., from home to the hospital and from the hospital to a nursing home). This last requirement means that there must be a process of checking to make sure no doses of medication the patient is taking are missed or the dose, dosage schedule, or route of administration are changed without authorization of the prescriber.

IMPROVING PRACTICE

The 2015 ASHP initiative to improve the practice of pharmacy in health systems included six goals:[33]

1. Increase the extent to which pharmacists help individual hospital inpatients achieve the best use of medications.
2. Increase the extent to which health system pharmacists help individual non-hospitalized patients achieve the best use of medications.
3. Increase the extent to which health system pharmacists actively apply evidence-based methods to the improvement of medication therapy.
4. Increase the extent to which pharmacy departments in health systems have a significant role in improving the safety of medication use.
5. Increase the extent to which health systems apply technology effectively to improve the safety of medication use.
6. Increase the extent to which pharmacy departments in health systems engage in public health initiatives on behalf of their communities.

Progress on the 2015 goals are measured annually and may be seen at the ASHP website (http://www.ashp.org).

JOB SATISFACTION

Most pharmacists working in hospitals like what they are doing. Job satisfaction among pharmacists working in hospitals correlates highly with both intrinsic (motivators) and extrinsic (hygiene) factors. Factors such as autonomy, supervisor, management culture, and job role are important. Although not specific to hospital pharmacy, a 2015 survey found 35% of pharmacists describe themselves as satisfied with their current positions, while 24.5% are very satisfied and another 13.7% would classify themselves as extremely satisfied. Only about a quarter are somewhat dissatisfied or extremely dissatisfied with their positions.[34]

SUMMARY

Hospital pharmacists pride themselves and have been recognized for controlling the drug use process in hospitals. Hospital pharmacists have continuously implemented new policies and procedures and technology to speed the distribution of drugs and make the drug use process safer. Hospital pharmacists are now turning their attention to improving the clinical, humanistic, and economic outcomes of patients from drug therapy through collaborative practice. Pharmacists in organized healthcare settings will be increasingly recognized for helping develop drug therapy that is more rational, more evidence based, ideal, and delivered with care.

DISCUSSION QUESTIONS AND EXERCISES

1. Make an appointment to tour a pharmacy in a medium (100–300 beds) or large (more than 300 beds) hospital.
2. While you are there, interview a
   a. Staff hospital pharmacist
   b. Clinical pharmacist
   c. Pharmacy resident (postgraduate year 1 [PGY1] or PGY2), if available
3. How does hospital pharmacy differ from community pharmacy in terms of the following?
   a. Types of patients
   b. Types of medication
   c. Amount of patient contact
   d. Interaction with other healthcare personnel like doctors and nurses
   e. The knowledge the pharmacist needs to practice competently
4. Based on what you know and have read thus far, what do you feel are the pros and cons of being a pharmacist in a hospital?

CHALLENGES

1. Hospital pharmacies specialize in compounding individualized sterile preparations for patients. In doing so, pharmacists must be well trained, use sterile techniques, and follow USP procedures. For extra credit, and with the permission of your professor, read general Chapter 797 in the USP and prepare a concise summary report on what hospital pharmacies must do to be compliant with USP standards when compounding sterile preparations.
2. Many hospital pharmacists are still tied to a drug preparation-and-distribution system but would like to deliver pharmaceutical care most of their day. For extra credit, and with the permission of your professor, prepare a brief report on your perfect job as a clinically oriented hospital pharmacist. What mechanisms would allow you time to spend with patients? What assurances are in place to make sure drug preparation and distribution would be error free? Describe your perfect day.
3. For extra credit, and with the permission of your instructor, write a concise (< four pages in Word, double spaced) position paper on why all hospitals should have a CPO, rather than a DOP.

WEBSITES OF INTEREST

American Hospital Association: http://www.aha.org
American Society of Health-Systems Pharmacists: http://www.ashp.org
JCAHO: https://www.jointcommission.org

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10 Managed Care Pharmacy

INTRODUCTION

Managed care encompasses a range of programs, organizational structures, and financial incentives designed to better integrate health insurance and healthcare delivery to more effectively "manage" the delivery of healthcare to patients.[1] Managed care tries to achieve lower costs, increased quality, and improved efficiency. It is estimated that 90% of insured Americans are now enrolled in healthcare plans with some form of managed care.

Pharmacists in managed healthcare organizations are responsible for delivering prescription drug benefits to over 200 million Americans. Pharmacists employed within managed care organizations (MCOs) are responsible for a broad and diversified range of clinical, quality-oriented medication management services to ensure that patients within a population receive the appropriate medication therapy at the appropriate time.[2]

This chapter introduces the reader to concepts and opportunities for pharmacists to practice in managed care. It will also address the various roles and functions pharmacists play in managed care.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Describe challenges in U.S. healthcare spending.
- Define managed care.
- Explain how managed care works.
- Describe how managed care pays providers.
- Describe the different types of managed care organizations.
- Explain the role of standards and managed care accreditation.
- Define managed care pharmacy.
- Explain pharmacy benefit management and design.
- Explain the following terms:
  - Formulary
  - Pharmacy and Therapeutics Committee
  - Utilization management
  - Specialty drugs
  - Medication therapy management
  - Drug utilization review
  - Health outcomes and research
- Explain how information technology impacts managed care pharmacy.
- Summarize disease management.
- Discuss roles of pharmacists in managed care pharmacy.

U.S. HEALTHCARE SPENDING

Total U.S. healthcare spending increased 5.8% and reached $3.2 trillion in 2015, or $9,990 per person.[3] From 2009 through 2013, health spending growth accelerated 5.3% in 2014

and 5.8% in 2015. The faster growth in 2014 and 2015 occurred as the *Affordable Care Act* (ACA) expanded health insurance coverage for individuals through Marketplace Health Insurance Plans and the Medicaid program.

Individual households, private businesses, and federal, state, and local governments are the main sponsors of healthcare spending and are responsible for financing the nation's healthcare bill. In 2015 the federal government accounted for the largest share of spending (29%), followed by households (28%), private businesses (20%), and state and local governments.[4]

Prescription drugs account for approximately 10% of national healthcare costs. Prescription drug spending jumped in 2014 because of new brands, higher prices for existing drugs and fewer patent expirations. In 2015, spending on prescription drugs outpaced all other health-related spending.

In recent years, a new class of medications, commonly referred to as *specialty drugs* have driven up pharmacy costs, but at the same time provided innovative treatments for diseases with limited or no treatment options. Spending on specialty medicines has nearly doubled in the past five years, contributing more than two-thirds of overall medicine spending growth between 2010 and 2015.[5]

WHAT IS MANAGED CARE?

In practical terms, managed care means care and cost managed by those who pay for it, including the employer, insurers, health plans, and the government. Before managed care, access to care was not managed, and the cost, availability, and delivery of care was controlled by those who provided it; that is, physicians, other healthcare providers, and healthcare facilities.

All MCOs contract with doctors, hospitals, clinics, and other healthcare providers such as pharmacies, labs, x-ray centers, and medical equipment vendors. This group of contracted healthcare providers is known as the health plan's *network*. In some types of managed care plans, you may be required to receive all your healthcare services from a network provider. In other managed care plans, you may be able to receive care from providers who are not part of the network, but you will pay a larger share of the cost to receive those services.

HOW MANAGED CARE WORKS

Managed care plans typically cover a wide range of health services such as preventive care and immunizations for adults and children, general checkups, diagnosis, and treatment of illnesses (including necessary tests, doctors' visits, prescription medications, and hospital care), and complete prenatal (pregnancy) and newborn care. Additionally, most managed care plans offer some services for the diagnosis and treatment of mental health conditions and substance abuse problems.

HOW DO PROVIDERS GET PAID BY MANAGED CARE?

Here is a summary of how providers receive payment under managed care arrangements.[6]

Salaries: The provider is paid a fixed amount, regardless of the number of patients or the services delivered.

Capitation: In *capitation*, the provider is paid a fixed amount per member enrolled, regardless of the number of services delivered to that member.

Bundled Payment: Under *bundled payments*, the provider is paid a fixed amount for a defined group of services, regardless of the volume of services delivered.

Fee-for-Service: In *fee-for-service* (FFS), the provider is paid for each service provided, just like in traditional care. The difference is rates are contractually set.

Value-Based*: Value-based payment adjustments are available to reward excellence in healthcare delivery or share savings (or even losses) through reimbursement methodology*.

TYPES OF MANAGED CARE ORGANIZATIONS

There are several different types of MCOs.

HMO—Health Maintenance Organization

An HMO provides, offers, or arranges for coverage of designated health services needed by members for a fixed, prepaid premium. HMOs offer prepaid, comprehensive health coverage for both hospital and physician services. The HMO is paid monthly premiums or capitated rates by the payers, which include employers, insurance companies, government agencies, and other groups representing covered lives.

There are six basic HMO models: (1) group model, (2) hybrid model, (3) individual practice association, (4) network model, (5) point-of-service model, and (6) staff model. An HMO contracts with healthcare providers, for example, physicians, hospitals, and other health professionals. The members of an HMO are required to use participating or approved providers for all health services and generally all services will need to meet further approval (referrals) by the HMO through its utilization program.

1. *Group Model:* In the *group-model HMO*, the HMO contracts with a physician group, which is paid a fixed amount per patient to provide specific services. The administration of the group practice then decides how the HMO payments are distributed to each participating physician. This type of HMO is usually located in a hospital or clinic setting and may include a pharmacy. These physicians usually do not have any *fee-for-service* (FFS) patients.
2. *Hybrid Model:* The *hybrid model HMO* is a combination of at least two managed care organizational models that are merged into a single health plan. Since its features do not uniformly fit one model, it is called a hybrid.
3. *Independent Practice Association (IPA) Model:* The *independent practice association* contracts with independent physicians who work in their own private practices and see FFS patients as well as HMO enrollees. Physicians belonging to the IPA guarantee that the care needed by each patient that they are responsible for will fall under a certain amount of money. They guarantee this by allowing the HMO to withhold an amount of their payments (usually about 20% per year).

   If, at the end of the year, the physician's cost for treatment falls under this set amount, then the physician receives his entire "withhold fund." If the opposite is true, the HMO can then withhold any part of this amount, at its discretion, from the fund. Essentially, the physician is put "at risk" for keeping down the treatment cost. This is the key to the HMO's financial viability.

4. *Network Model:* The *network model HMO* contracts with more than one physician group and may contract with single or multi-specialty groups as well as hospitals and other healthcare providers. The health plan contracts with multiple physician groups to deliver healthcare to members. This is generally limited to large single or multi-specialty groups. Distinguished from group model plans that contract with a single medical group, IPAs contract through an intermediary, and direct contract model plans that contract with individual physicians in the community.
5. *Point-of-Service (POS) Model:* Sometimes referred to as an "open-ended" HMO, the *point-of-service model* is one in which the patient can receive care either by physicians contracted with the HMO or by those not contracted. Physicians not contracted with the HMO who see an HMO patient are paid according to the services performed. The patient is incentivized to use contracted providers through the fuller coverage offered for contracted care.
6. *Staff Model:* The *staff model HMO* is the purest form of managed care. All the physicians in a staff-model HMO are in a centralized site, in which all clinical and perhaps inpatient services and pharmacy services are offered. The HMO holds the tightest management reigns in this setting, because none of the physicians traditionally practice on an independent FFS basis. Physicians are more likely to be employees of the HMO in this setting, because they are not in a private or group practice.

PPO—Preferred Provider Organization

A *preferred provider organization* (PPO) is a managed care organization where physicians are paid on a FFS schedule that is discounted, usually about 10–20% below normal fees. PPOs are often formed as a competitive reaction to HMOs by physicians who contract out with insurance companies, employers, or third-party administrators. A patient can use a physician outside of the PPO providers, but he or she will have to pay a greater portion of the fee.

EPO—Exclusive Provider Organization

The *exclusive provider organization* (EPO) is a form of a preferred provider organization in which patients must visit a caregiver who is on its panel of providers. If a visit to an outside provider is made, the EPO will offer limited or no coverage for the office or hospital visit.

CDHP—Consumer Directed Health Plan

The *consumer directed health* plan allows beneficiaries more direct control over medical decisions and costs. Typically, this type of plan consists of several tiers—a health spending account funded by the employer that can be rolled over from year to year.

Generally, a "defined contribution," such as a specific dollar amount, is placed in this account by the employer for the employee. The deductible is funded by the employee and used after the health spending account is exhausted; and health insurance is triggered after the deductible is met. Employees also may fund medical reimbursement accounts to pay for their share of expenses.

Accountable Care Organizations (ACO)

An *Accountable Care Organization* (ACO) is a formally organized entity, consisting of physicians, hospitals, and other relevant health service professionals who have elected to join.[7] ACOs are responsible through contracts with payers for providing a broad set of healthcare services to their patients. This entity is accountable for organizing and aligning healthcare services to deliver seamless, coordinated care whether the ACO is contained within a single corporate structure or is an organized network of independent but associated healthcare professionals.

The impetus is to change the way providers are paid. Instead of getting paid for each service ACOs reward providers that can manage chronic disease and meet certain quality measures, including reducing hospital admissions and emergency room visits. If the quality of care improves and costs are constrained, the systems can share in the savings.[7]

THE ROLE OF STANDARDS

Shortly after MCOs were established, several employer groups and some MCOs in the northeastern United States began discussing the possibility of developing a set of measurements that employers and patients could use to compare managed care plans. Today, the *Health Employer Data and Information Set* (HEDIS) is a set of managed care performance standards that can be used to compare managed care plans and to conduct health outcomes research.[8]

The HEDIS performance measures include such items as clinical quality, access to care, patient satisfaction, membership characteristics, use, and organizational and financial information. The guidelines are provided by the National Committee on Quality Assurance (NCQA). Large employers often require HEDIS information from MCOs as a condition of contracting. Comparisons of MCOs are available from the NCQA, and these are updated each year from new HEDIS reports.[9]

The Centers for Medicare & Medicaid Services (CMS) uses a five-star quality rating system to measure Medicare beneficiaries' experience with their health plans and the healthcare system. It also applies to Medicare Advantage plans that cover both health services and prescription drugs (MA-PD).

MANAGED CARE ORGANIZATION ACCREDITATION

There are three organizations that accredit managed care plans: (1) the NCQA, (2) the Utilization Review Accreditation Commission (URAC), and (3) the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). To be accredited by one of these organization a MCO must demonstrate that they meet agreed upon standards of quality. Accreditation is voluntary but is often required to participate in some government healthcare programs and is often used as a marketing tool.

MANAGED CARE PHARMACY

Managed care pharmacy focuses on managing medication specific outcomes in a way that drives down the total cost of care and improves the overall well-being of the patient.[10] Managed care pharmacy organizations cover populations of people. Pharmacists in managed care pharmacy can impact the care of millions of patients. They strive to provide the highest quality drug therapy management for the members in a plan, while considering the economic implications for the entire group of patients.

CONCEPTS IN MANAGED CARE PHARMACY

Pharmacy Benefit Manager

Pharmacy benefit managers (PBMs) are companies that administer drug benefit programs for employers and health insurance carriers. As of 2015, the top three PBMs were Express Scripts, CVS Caremark, and OptumRx.[11] Due to consolidations in the marketplace, these PBMS control over 70% of the U.S. prescription market. PBMs contract with MCOs; employer groups; unions; Medicaid and Medicare managed care plans; and federal, state, and local governments to provide managed prescription benefits.

The role of PBMs is to "aggregate the buying power of healthcare plans, government programs and employer groups by negotiating discounted purchase prices with retail pharmacies, purchasing drugs at discounted prices for delivery by mail, and separately securing rebates on brand pharmaceuticals from manufacturers."[12]

PBMs design prescription benefit plans, have networks of contracted pharmacies to fill prescriptions, provide mail order pharmacy services, and process pharmacy claims for their customers. PBMs may also offer medication adherence programs, specialty pharmacy services, and pharmacy care management.

Prescription Benefit Design

The prescription benefit should be designed to meet the medical, educational, economic, and physical needs of most beneficiaries enrolled in the plan. MCOs and benefit purchasers work together to develop a benefit that should provide the following:

- Cover medications that are effective in treating patients by improving significant clinical outcomes and reducing overall medical costs.
- Encourage prescribers to select medications that are in accordance with an evidence-based practice of medicine.
- Preserve appropriate access to pharmacies while enhancing an employer's ability to leverage volume, safety, and price.
- Monitor and encourage patient adherence with drug therapies.
- Maintain and use patient-medication records to prevent unnecessary and potentially harmful drug interactions and other problems.
- Monitor employee drug usage for over- and under-utilization.
- Promote prudent utilization of pharmaceuticals by plan members with benefit designs that provide a mixture of incentives and disincentives to facilitate access and support cost and quality-effective choices.

Drug Benefit Plans

Drug benefit plans typically require a patient to pay a certain amount of out-of-pocket expenses for their prescription drugs. Cost-sharing options can include copayments, coinsurance, deductibles, or a combination of these. A cost share amount is established in the plan design for major categories of drugs such as brand, generic, or formulary classification. The amount may be a flat dollar amount or a percentage of the total cost of the prescription.

Most drug benefit plans classify drugs on their formularies into groups called "tiers" and establish different levels of cost-sharing for each tier. Lower tiers may have a fixed dollar copayment, but higher tiers increasingly use a percentage of drug cost to determine a patient's cost share.

Generic substitution is the dispensing of the generic or multi-source product in place of the original brand name drug. Most drug benefit plans mandate or provide an incentive to use generic substitution as a cost control mechanism. The U.S. Food and Drug Administration approves generic products.

Formularies

A *drug formulary* is a continually updated list of prescription medications that represents the current clinical judgment of providers who are experts in the diagnosis and treatment of disease.[12] The overall goal of a formulary is to develop a list of the safest, most effective medications that will produce the desired goals of therapy at the most reasonable cost to the healthcare system.[13]

Formulary decisions have an impact on all components of the healthcare delivery system. In the face of the escalating number and complexity of drug products, rising drug prices and direct-to-consumer advertising, the formulary management process provides the managed healthcare system with the ability to objectively differentiate between superior and marginal medications.

Studies show that choice of the most appropriate drug results in fewer treatment failures, reduced hospitalizations, and enhanced patient adherence to the treatment plan, fewer adverse side effects, and better overall outcomes.

A formulary system includes the methodology an organization uses to evaluate clinical and medical literature and the approach for selecting medications for different diseases, conditions, and patients. Policies and procedures for the procuring, dispensing, administering and appropriate utilization of medications are also included in the system.[14]

Formulary systems often contain additional prescribing guidelines and clinical information that assist healthcare professionals to select high quality, affordable medications for patients. Finally, for quality assurance purposes, managed healthcare systems that use formularies have policies in place to give physicians and patients access to non-formulary drugs when medically necessary.

Formulary management systems are routinely used by health plans, pharmacy benefit management companies (PBMs), hospitals and government agencies, including the Veterans Health Administration, Department of Defense, and Medicare and Medicaid programs. Formularies have evolved into a tool for assuring the selection of medications demonstrated to be safe, effective, and affordable while maintaining or improving quality patient care.[14]

Pharmacy and Therapeutics Committees and Formularies

The medications and related products listed on a formulary are determined by a *pharmacy and therapeutics committee* (P&T) or an equivalent entity. P&T committees are comprised of primary care and specialty physicians, pharmacists, and other professionals in the healthcare field. Often P&T committees include nurses, legal experts, and administrators. P&T committee members should be independent of the benefit plan sponsor and required to reveal any conflicts of interest. Some managed care organizations choose to keep the identity of P&T committee members confidential so that outside influence is avoided.

The P&T committee is responsible for developing, managing, updating and approving the formulary. The P&T committee also reviews and approves formulary system policies on utilization and access to medications. Utilization management strategies such as quantity limits, step therapy and prior authorization criteria may be reviewed and approved by P&T committees.

P&T committees evaluate medications after Food and Drug Administration (FDA) approval. Due to the multiplicity of medications on the market and the continuous introduction of new medications, a formulary must be a dynamic and continually revised listing. In order to keep a formulary current, the P&T committee meets regularly to review newly released drugs and/or classes of drugs. The P&T committee reviews some or all the following:

- Medical and clinical literature including clinical trials and treatment guidelines, comparative effectiveness reports, pharmacoeconomic studies and outcomes, FDA-approved prescribing information and related FDA information including safety data
- Relevant information on use of medications by patients and experience with specific medications
- Current therapeutic use and access guidelines and the need for revised or new guidelines
- Economic data, such as total healthcare costs, including drug costs
- Healthcare provider recommendations

P&T committees compare medications by therapeutic classifications or on similarities in clinical use. When two or more medications produce similar effectiveness and safety results in patients, then business elements like cost, supplier services, ease of delivery or other unique properties of the agents are considered when determining which agent to include on the formulary.

In many organizations, the P&T committee only performs clinical analyses. If two or more medications are determined to be clinically equivalent, then the finance department will determine formulary inclusion or exclusion. The overall goal is to develop a list of the safest, most effective medications that will produce the desired goals of therapy at the most reasonable cost to the healthcare system.

Utilization Management

Utilization management is the process of evaluating the necessity, appropriateness, and efficiency of healthcare services against established guidelines and criteria. Common utilization management programs include prior authorization, step therapy, and quantity limits.

Prior Authorization (PA): This requires prior approval to allow the MCO or evaluate the appropriateness of use against a set of medication use criteria. This process is coordinated with the pharmacist, prescriber, and patient.

Step Therapy: These are treatment guidelines used to recommend a specific drug therapy beginning with the most cost-effective or safest alternative. More expensive drugs or those with known safety risks are only approved when the patient fails to respond to or does not tolerate the first-line therapy.

Quantity Limits: These are limits on the number of pills or dosages of a prescription drug that will be covered, either per claim or per unit of time. Quantity limits typically reflect FDA-approved dosing guidelines and safety information.

Overseeing Specialty Drug Use

Specialty drugs are typically large, protein-based molecules, produced through a biotechnology process. They are differentiated from other more common medications that are

manufactured through synthetic processes or are extracted from biological sources. Early specialty pharmacy products treated complex conditions affecting distinct disease populations, such as multiple sclerosis, cancer, pulmonary hypertension, hemophilia, and hepatitis C.

Newer products may be targeted to more common chronic diseases requiring maintenance therapy, such as rheumatoid arthritis, high cholesterol, and asthma. MCOs may vary as to the medications they classify as specialty pharmaceuticals, but the consistent link is that specialty pharmaceuticals demand more attention and management. *Specialty drugs* may also require expertise in handling such as refrigeration or sterile conditions for mixing doses.

Medication Therapy Management

On January 1, 2006, the government started paying for the prescriptions of Medicare beneficiaries. This *Part D Medicare* benefit could be offered by managed care plans as a standalone benefit called a *prescription drug program* (PDP) or as part of a comprehensive medical benefit. Part D Medicare regulations require plans to have a *medication therapy management program* (MTMP) for "targeted beneficiaries" (those who have multiple chronic diseases, are taking multiple Part D medications, and are likely to incur annual costs exceeding a level predetermined by the Center for Medicare and Medicaid Services [CMS]). The rule states that pharmacists may be reimbursed from the plan for providing these services.

MTM programs are not limited to just the Medicare population. Increasing numbers of MCOs are providing MTM services to commercially insured populations.

Drug Utilization Review

Drug utilization review (DUR) is defined as an authorized, structured, ongoing review of prescribing, dispensing, and use of medication. Other terms considered synonymous with DUR include *drug use evaluation* (DUE), *medication use evaluation* (MUE), and *medication use management* (MUM). DUR encompasses a drug review against predetermined criteria that results in changes to drug therapy when these criteria are not met. It involves a comprehensive review of patient's prescription and medication data before, during and after dispensing to ensure appropriate medication decision-making and positive patient outcomes.

As a quality assurance measure, DUR programs provide corrective action, prescriber feedback and further evaluations. NCQA, CMS and many other government agencies mandate that drug reviews be performed to ensure appropriate drug therapy.

Managed healthcare systems and pharmacy benefit management companies (PBMs) have the responsibility of managing the medication use of anywhere from a few hundred thousand to millions of patients. DUR programs play a key role in helping these organizations understand, interpret, and improve the prescribing, administration and use of medications. This is often accomplished by using DUR programs to provide prescribers with feedback on their performance and prescribing behaviors as compared to pre-set criteria or treatment protocols.

Monitoring Drug Use

Pharmacists typically oversee DUR activities. There are three ways to do this: [15]

1. *Prospective:* Evaluation of a patient's drug therapy before medication is dispensed
2. *Concurrent:* Ongoing monitoring of drug therapy during the course of treatment
3. *Retrospective:* Review of drug therapy after the patient has received the medication

Steps in Conducting a Drug Use Evaluation

Most authorities agree the following six steps are essential when conducting any quality-related DUR program:[15]

1. *Identify or determine optimal use.* An organization's established criteria compares optimal use with actual use. The criteria should focus on relevant outcomes within a delineated scope for DUR and identify the relevant drugs to be monitored for optimal use in advance. For example, if the use of a drug class prescribed to treat a patient with diabetes is being evaluated, then standards should be determined to identify all drugs within the drug class and evaluate each drug's effectiveness, such as a decrease in blood glucose or A1c (glycosylated hemoglobin) levels within normal limits.
2. *Measure actual use.* This step is where data are gathered to measure the actual use of medications. These data can be obtained from medical and prescription records or electronic claim forms. It may require the organization to build an algorithm to identify all members who fit the criteria.
3. *Evaluate.* Acceptable thresholds (percentage of patients meeting the indicator) should be determined prior to the comparison. This step involves applying the algorithm, identifying members who meet the DUR criteria and the comparison between optimal or appropriate and actual use. During this process, the evaluator determines causes for any discrepancies and whether findings are expected. In this process, patterns or aberrations can be identified and interpreted.
4. *Intervene.* This is the step where corrective action is implemented. Action should be targeted to areas of concern such as prescribing patterns, medication misadventures, and quality of drug therapy or economic consideration.
5. *Report the DUR findings.* The final step is to report these findings to the appropriate team within the organization (e.g., the P&T) and/or individual prescribers when appropriate.
6. *Evaluate the DUR program.* This step assesses the effectiveness of the DUR program. Efforts should be made to evaluate the outcomes and document reasons for positive and negative results. Implementing appropriate changes to the DUR program and continued observation should be undertaken.

Education of Providers and Members

It is important for MCOs to educate and work with their members (patients) and their providers (primarily physicians, pharmacists, and hospitals) to assure the provision of high-quality, cost-effective care.

Member education: Pharmacy benefits, formularies and utilization management requirements may be very confusing to members. MCOs typically provide pharmacy education to their members on their website, through routine newsletters and through customer service representatives. Often the MCO will have pharmacists available to answer members' questions on availability of generic alternatives, more cost-effective drug therapy options, drug interactions, and adverse drug reactions (ADRs).

Provider education: Provider education is targeted toward prescribers and pharmacists. MCOs may build performance profiles of each provider physician and each provider pharmacy. These performance profiles, sometimes called *report cards*, are mailed

to the provider or the provider is visited by a healthcare professional to review the provider profile and identify opportunities for improvement. In a prescriber visit, the lead reviewer often is a managed care pharmacist. These visits are sometimes called *academic detailing* or *counter-detailing*.

Academic or counter-detailing is based on unbiased, *evidence-based medicine*, as opposed to the detailing provided to physicians and pharmacists by sales representatives of pharmaceutical companies. The person doing the academic detailing shares the performance of the provider with the provider along with comparable information. The actual performance may be compared with the provider's peers or against certain *benchmark measures*, which is the ideal or a standard.

Some items, often selected for provider education, are the use of generic drugs, compliance with the formulary, responses to computer alerts, and use of therapeutic interchange, which is approval to substitute one brand of drug for another. MCOs use this information to select physicians for academic detailing. MCOs may also use this information to review network pharmacy performance to assist in determining which pharmacies will participate in the network.

Health Outcomes Research and Value

Health outcomes research is a type of research that measures results of various medical treatments and/or interventions in patient populations.[16] The purpose of outcomes research per the Patient Centered Outcomes Research Institute (PCORI) is to assist patients, clinicians, purchasers, and policy makers in making informed health decisions by advancing quality and relevance of evidence. The *Agency for Healthcare Research and Quality* (AHRQ) defines the purpose of outcomes research as a tool to provide evidence about benefits, risks, and results of treatments so clinicians and patients can make more informed decisions.

The process involves identifying, measuring, and evaluating effects of care provided to patients. Results of outcomes research, which consider clinical, economic, and humanistic outcomes, can guide healthcare decision makers in selecting the most effective treatment and/or procedural strategy or to improve on current treatments and medical interventions.

Outcomes research can be economic (pharmacoeconomics), clinical (comparative clinical effectiveness research), or humanistic (health-related quality of life). Pharmacoeconomics is "the scientific discipline that assesses the overall value of pharmaceutical healthcare products, services, and programs." The costs associated with economic evaluation methods are derived from many different sources and include both direct and indirect costs, some of which are difficult to measure. These might include medical, pharmacy, patient productivity, and level of activity costs, to name a few.

Comparative clinical effectiveness research is research evaluating and comparing health outcomes and clinical effectiveness, risks and benefits of two or more medical treatments, services or items. Health-related quality of life, typically used to measure the effects of chronic illness, treatments, and disabilities, is a multi-dimensional concept that focuses on the impact that health status has on the quality of life.

Pharmacists are important contributors in conducting outcomes research processes with roles in the following areas:

1. Identifying topic areas for outcomes evaluation
2. Evaluating the published literature

3. Designing evaluations
4. Analyzing and assessing results
5. Identifying and executing intervention strategies
6. Monitoring the results of those strategies
7. Presenting results
8. Repeating the evaluation process

There is an enhanced focus on deciphering the inherent value of new products. Some health organizations want more rigorous and comprehensive assessment of value when considering the adoption of new health technologies, including new medications. These provide guidance to healthcare decision makers and patients regarding important considerations related to the value of health technologies.[17]

DELIVERING MANAGED CARE PHARMACY SERVICES

Health Information Technology

Health information technology (HIT) plays a major part in the ongoing success of managed care pharmacy programs.[18] Initiatives such as electronic prescribing, electronic health records, and integrated pharmacy information systems enhance the pharmacist's ability to identify medication issues and institute appropriate interventions.

In 2010, nine pharmacy professional organizations formed the *Pharmacy HIT Collaborative*. In the following year, the collaborative published "The Roadmap for Pharmacy Health Information Technology Integration in U.S. Healthcare," which outlined goals, objectives, and strategies pharmacy as an industry should follow. Medication therapy management programs, transitions of care, medication reconciliation as well as initiatives around pharmacy fraud and abuse will all be enhanced with greater health information available to managed care pharmacists.[18]

Pharmacy Networks

MCOs develop networks of pharmacies (retail, mail order, and specialty) to provide consumers convenient access to prescriptions at discounted rates. MCOs also monitor prescription safety across all of the network pharmacies, alerting pharmacists to potential drug interactions, even if a consumer uses multiple pharmacies. Network pharmacies compete on service, convenience, and quality to attract consumers within a plan.

Many MCOs develop preferred pharmacy networks for their members as a way of providing additional options and cost savings without any diminishment of quality or patient access.[19] Preferred pharmacy networks represent another important innovation and tool developed by managed care pharmacy, and, if effectively implemented, there is strong data that indicates it reduces the high cost of prescription drug coverage.

Preferred pharmacy networks are created by MCOs by enlisting pharmacies within the existing network that may be willing to contract at a lower reimbursement rate than other pharmacies. Enrollees that choose—at their option—to utilize these "preferred pharmacies" can save money at the point of sale in the form of lower copayments or coinsurance.

Additional savings are also shared with the MCO, which enables them to stabilize future premiums. While non-preferred network pharmacies are still in the pharmacy network, they do not offer covered drugs at the same lower cost-sharing level as those within the preferred

pharmacy network. They still, however, allow members to get their prescription medications filled at a reduced cost as a network pharmacy.[19]

Disease State Management

Disease management is the concept of reducing healthcare costs and improving quality of life for individuals with chronic conditions by preventing or minimizing the effects of the disease through integrated care.[20] Disease management programs are designed to improve the health of persons with chronic conditions and reduce associated costs from avoidable complications by identifying and treating chronic conditions more quickly and more effectively, thus slowing the progression of those diseases. Disease management is a proactive, multidisciplinary, systematic approach to healthcare delivery that

- Includes all members with a chronic disease
- Supports the provider–patient relationship and plan of care
- Optimizes patient care through prevention and proactive interventions based on evidence-based guidelines
- Incorporates patient self-management
- Continuously evaluates health status
- Measures outcomes
- Strives to improve overall health and quality of life and lower cost of care

Components of disease management programs include the following:

- Population identification processes
  - Programs designed to target individuals with specific diseases
  - Chronic and costly conditions
- Evidence-based practice guidelines
- Collaborative practice involvement
  - Multidisciplinary teams that may include physicians, pharmacists, nurses, dieticians, and psychologists
- Risk identification and matching interventions to need
- Patient self-management education
  - Self-management may include behavior modification, support groups, and primary prevention
- Process and outcomes measurement and evaluation
  - A method for the measurement of outcomes may include heath care service use, expenditures, and patient satisfaction
- Tracking and monitoring systems
  - Routine reporting and feedback loops that include patients and providers
  - Appropriate use of information technology

Care coordination is one of the primary concerns of healthcare payers and providers. Individuals with chronic conditions require appropriate management and interventions to ensure optimal health outcomes. Disease management programs should emphasize the prevention of exacerbations and complications using evidence-based practice guidelines and patient empowerment strategies, while evaluating clinical, economic, and humanistic outcomes to improve overall health and quality of life for patients.

CAREERS IN MANAGED CARE PHARMACY

Over 18,000 pharmacists work for health plans and pharmacy benefit management companies. Managed care pharmacists may also work for integrated health delivery systems, pharmaceutical manufacturers, and academic institutions. The *Academy of Managed Care Pharmacy* (AMCP) is an excellent resource on managed care pharmacy practice. Managed care pharmacy professionals—including pharmacists, physicians, and nurses—perform many functions. Among other things, they

- Design pharmacy benefits for health plans.
- Monitor the safety and effectiveness of new drugs on the market.
- Develop and implement evidence-based clinical programs and MTM programs and services.
- Use medication therapy management practices to ensure patients receive the most appropriate therapy.
- Develop and implement programs to improve medication adherence.
- Ensure that "medical-necessity" guidelines for the pharmacy benefits are consistent with evidence-based medicine and that exceptions are based on sound medical judgment.
- Communicate and collaborate with patients, prescribers, and pharmacists.
- Provide ongoing patient education and care coordination of medication therapy.
- Use various evidence-based tools and incentives to keep the costs of prescription drugs under control.

The growth of specialty drugs, the expansion of MTM under the Medicare program, healthcare reform and growth of pay-for-value reimbursement programs will expand the clinical practice opportunities for pharmacists in managed care pharmacy.

AMCP offers managed-care pharmacy internships for students wishing to learn more about managed care pharmacy. In addition, ASHP, in collaboration with AMCP, accredits PGY-1 Managed Care Pharmacy Residency programs for pharmacist graduates looking for additional managed care pharmacy training.

SUMMARY

With the continued focus on containing healthcare costs in the U.S. health system and improving health outcomes, managed care will continue to play an important role in assuring that high quality healthcare is delivered through efficient and cost-effective providers. The specialty drug market will further challenge employers, health plans and consumers with extremely high-cost drugs. Yet, if used for the appropriate patient, specialty drugs provide treatments for many diseases for which there have not been therapies available.

Managed care pharmacists will continue to play an important role in the management of medications in many different types of settings. Whether providing MTM services for a Medicare Part D patient or developing formulary programs for an employer group pharmacy benefit, managed care pharmacists will continue to advocate for the use of the right drug for the right patient at the right time.

DISCUSSION QUESTIONS AND EXERCISES

You are the formulary manager for a large health plan that has both commercial and Medicare Part D members (patients). The FDA approved a new specialty pharmacy product to treat moderate to severe rheumatoid arthritis. It has a novel mechanism of action compared to other drugs available to treat rheumatoid arthritis, but is 20% more expensive.

1. What is your strategy to evaluate this new specialty drug for a presentation at the Pharmacy and Therapeutics Committee?
2. What type(s) of utilization management criteria could be considered for this new specialty drug?
3. What type of DUR program could you implement to monitor use of this new medication?
4. What types of education would you recommend for members (patients) and prescribers?
5. How would you incorporate these patients into your Medicare MTM program?
6. What types of education would you recommend for patients, prescribers, and pharmacies in your network?

CHALLENGES

1. Some people think managed care is a mixed blessing. For extra credit, and with the permission of your professor, prepare a concise report discussing the pros and cons of managed care from the point of view of the patient, physician, and pharmacist (community and MCO).
2. Part of the Part D Medicare regulations call for plans for MTMPs. For extra credit, and with the permission of your professor, investigate and document how one of these programs works.

WEBSITES OF INTEREST

American Academy of Managed Care Pharmacy: http://www.amcp.org
American Journal of Managed Care: http://www.ajmc.com
HEDIS & Performance measurement: http://www.ncqa.org/hedis quality-measurement
Managed Care Digest: http://www.managedcaredigest.com
National Committee for Quality Assurance: http://www.ncqa.org
International Society for Pharmacoeconomics and Outcomes Research (*ISPOR*): https://www.ispor.org

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11 Home Health and Hospice Care Pharmacy

INTRODUCTION

Today, patients often receive care and treatment at home rather than in an organized healthcare setting. This is called *home healthcare*. Home healthcare provides the patient with familiar surroundings, and an environment surrounded by family, and it saves money on healthcare costs.

Most home healthcare patients are still moderately ill and need the attention of health professionals who help them with their care. They often need medication carefully prepared by a pharmacist using special techniques.

This chapter is about home healthcare and the role of the pharmacist in the care of patients at home and in hospice. It begins with the development of home healthcare and discusses what home healthcare is and how it is provided. Common pharmacy services provided to home healthcare patients and what it is like being a home healthcare pharmacist are covered. The important roles pharmacists play in helping patients with their transitions of care, and caring for patients in hospice are also discussed.

LEARNING OBJECTIVES

After participating in this learning session, you should be able to:

- Define home healthcare.
- State why home healthcare has become important.
- Explain how a typical home care agency is set up.
- Explain how home care is provided.
- Explain the role of the home healthcare pharmacist.
- Explain what it is like to practice home care pharmacy.
- Discuss the rewards of home care pharmacy.
- Explain hospice care.
- Discuss the role of the pharmacist in hospice care.
- Explain the need for pharmacists to help transition patients from one level of care to another.

BACKGROUND

Home healthcare, sometimes called *home health* or *home care,* is defined by the U.S. Department of Health and Human Services (HHS) as "that component of a continuum of comprehensive healthcare whereby health services are provided to individuals and families in their place of residence for the purpose of promoting, maintaining, and restoring health or of maximizing the level of independence, while minimizing illness."[1] Many home healthcare patients need medication infusion therapy (the American Society of Health-System Pharmacists [ASHP] has issued guidelines on home infusion pharmacy services).[2]

Patients used to stay in the hospital much longer than they do now. For example, it was not unusual for a patient suffering a heart attack (a myocardial infarction) to be in the hospital for several weeks. New mothers used to stay in the hospital 5–7 days after delivery. Today, a patient experiencing a myocardial infarction (without complications) will usually stay in the hospital less than a week, and a new mother may stay only a day or two after delivery. In hospitals in the United States, the average *length of stay* (LOS) dropped from 7.8 days in 1970 to 4.5 days in 2014.[3]

The primary reason for this drop in LOS is cost. Hospital reimbursement has dropped because of a capitation (a fixed rate of reimbursement based on diagnosis) system of reimbursement for many patients (e.g., Medicare) and the negotiating power of managed care (see Chapter 10, "Managed Care Pharmacy").

The main concern about sending patients home from the hospital earlier is whether patients are clinically and physically ready to be sent home. One way to help ensure that patients will have care through their recuperation is for them to receive home healthcare. In addition, some patients, rather than going to a hospital, can be cared for in their home. Hospital pharmacists can help physicians identify which patients may be candidates for home therapy.

Home health patients often need complex intravenous medications that were previously only provided in hospitals. Pharmacists have been employed in home healthcare agencies to prepare drug infusions—drugs slowly administered into a vein—for patients at home.

Hospice care provides medical service, emotional support, and spiritual resources for people who are in the last stages of a terminal illness. Pharmacists provide valuable services for these patients.

STATISTICS

In 1986, there were only 5,250 home care agencies in the United States.[4] In 2014, there were 12,400.[5] According to the CDC, 80% of home care agencies are for-profit.

> Men aged 65 years and over use home healthcare at a lower rate than women. Among home healthcare patients 65 years and over, women were more likely to be 85 years and over while men were more likely to be married and receive home healthcare as post-acute care. Women 65 years and over who received home healthcare were less likely than males to receive wound care and physical therapy, and more likely to receive homemaker services. Among home healthcare patients who were 65 years and over, cancer was more prevalent among men, and essential hypertension was more common among women.[6]

HOME CARE AGENCIES

Home healthcare agencies provide services to ill, disabled, and infirm people in their homes. The home healthcare agency may be located within another health facility but must be licensed by the state, accredited by a national body (usually the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]), and certified by Medicaid and Medicare. Home care agencies must provide nursing care and at least one therapeutic service to patients, and services must be provided under the direction of a physician.[7]

Home healthcare involves providing nursing care, equipment, and treatment for the patient. Nursing care must be provided by or under the direction of a registered nurse. Medicare categorizes home care agencies as Part A or Part B agencies or both. Nursing services are provided under Part A, and equipment and treatment are provided under Part B.

Pharmacy services, treatment, and equipment are provided to patients through Part B home care agencies. Pharmacies provide infusion services and *home medical equipment* (HME). Pharmacy services for home care can be provided by a hospital-based home care agency, a free-standing home care agency, or a specially equipped community pharmacy. The infusion part of the business is the most profitable.

Home Infusions

Infusion therapy is the administration of medication dripped through a needle or catheter in the patient's bloodstream. Home infusion has been proven to be a safe and effective alternative to inpatient care for many diseases, if done correctly.[8]

Rapid growth in the home infusion business has occurred because the cost is typically $200 a day, compared to $1,500 a day in a hospital. Home infusion therapy in 2015 was a $13 billion market and is expected to grow substantially over the next 10 years.[9]

Stand-alone *ambulatory infusion centers* (AICs) specialize in providing infusion therapy and nursing care to noninstitutionalized patients, and patients not treated at home in a center that provides high-quality, low-cost care. Patients come to the AIC for part of a day, then return home after they receive their care, or they come to the center to pick up their home infusions or supplies. This idea is thought to be more efficient and takes less home care staffing to manage.

An emerging market for nonhospital infusion services is long-term care. During 2013–2014, there were 15,600 nursing homes in the country providing a total of 1,663,300 certified beds[10] (see Chapter 12, "Long-Term Care Pharmacy").

PROVIDING HOME CARE

Much has been made of integration in healthcare, although the idea is simple. Freestanding home care agencies offer a single product line such as private duty nursing, home medical equipment (HME), or infusion therapy. There are also home care agencies that provide more than one product, with the most common being nursing care and infusion therapy. However, only a *healthcare system* can provide integrated care: emergency care, chronic care, ambulatory care, home care, and long-term care.

Receiving home care from a healthcare system offers several advantages. First, patients' records are more easily available to all healthcare providers, and there is less duplication of services provided. Second, the continuity of care is better, and the care is more efficient and less time consuming for the patient.

Patient Eligibility

To be eligible to be reimbursed for home care, the patient must: (1) be confined to the home, (2) need skilled services, (3) be under the care of a physician, (4) receive services under a plan of care established and reviewed by a physician, and (5) have had a face-to-face encounter with a physician or allowed non-physician practitioner.[11]

The David Jayne Medicare Homebound Modernization Act (2003) expanded eligibility from strictly residents confined at home to any individual who: (a) has been certified by a physician as having a permanent and severe condition that will not improve and that requires the individual to receive assistance from another individual with at least three of five activities of daily living for the rest of the individual's life, and (b) requires one or more described

home health services to achieve a functional condition giving the individual the ability to leave the home.

Standard Treatment

A standard protocol for treating home care patients includes an initial visit, continuing nursing visits, home health aide visits (for non-nursing chores), physical therapy, HME, and drug infusions and treatment.

Home Care Patients

Most patients receiving home care are elderly and many are undernourished.

Services commonly used by home healthcare patients aged 65 years and over included: skilled nursing services (84%), physical therapy (40%), assistance with activities of daily living (ADLs) (37%), homemaker services (17%), occupational therapy (14%), wound care (14%), and dietary counseling (14%).[4] Among home healthcare patients, women were more likely than men to have hypertension and were almost twice as likely to have osteoarthritis, whereas men were nearly twice as likely to have malignant neoplasms.

Accreditation

Home care and hospice agencies are accredited by the *Joint Commission on Accreditation of Health Organizations*. Under JCAHO, pharmacy services providing home infusion have their own standards. The standards for providing pharmacy services for home care patients are more progressive and may exceed standards for hospital pharmacies for providing pharmaceutical care.

The JCAHO standards are a basic road map to ensure patient safety and positive patient outcomes. Most home care pharmacy services have written policies on how to provide quality care. It is recommended that these policies be patterned after the JCAHO standards, and that these standards be incorporated into the daily practice of the pharmacists providing service to home care patients. The pharmacy always has to be ready for a JCAHO visit.

Also, JCAHO has consolidated accreditation of long-term care pharmacy services and free-standing (pharmacy-based) ambulatory infusion services with its home care pharmacy accreditation program.[12]

HOME HEALTHCARE PHARMACY SERVICES

Great satisfaction can come from providing pharmacy services for home care patients.[13] The pharmacist plays a vital role for these patients, as most patients need complex intravenous pharmaceuticals that must be carefully compounded. Home services can be provided from a hospital pharmacy, a free-standing infusion service, or a community pharmacy, all of which need to be specially equipped.

Total Parenteral and Enteral Nutrition

Many patients sent home may be undernourished or do not receive proper nourishment. It is critical that the pharmacists and pharmacy technicians are well trained on how to prepare these

life-maintaining specialty solutions, the most complex of which is called *total parenteral nutrition* (TPN). TPN is an intravenous solution containing all the needed nutrition (proteins, carbohydrates, fats, vitamins, and minerals) to sustain life. From the standpoint of calories, it is like putting a complete meal in an intravenous container. Patients need this when they cannot eat and are unable to absorb nutrients from their gastrointestinal (GI) tract.

A TPN solution needs to be carefully prepared to ensure accurate content and in such a way that it remains sterile (germ free) because it is infused into the patient's vein. Important guidelines on implementing safe practices for parenteral nutrition formulations have been published by the American Society for Parenteral and Enteral Nutrition (ASPEN).[14]

Enteral nutrition is a term used to describe complete and specialty nutrient mixtures that can be prepared and administered orally or nasally through a feeding tube in patients who have a gastrointestinal tract that can absorb the nutrients. These mixtures have to be prepared using the *aseptic technique* to prepare a sterile product.

Pharmaceutical Care

Largely because of the JCAHO home care and hospice standards, home healthcare and hospice pharmacists do not have a choice about clinical practice and practicing pharmaceutical care. The JCAHO standards demand that the pharmacist know the laboratory results for each patient, and that the pharmacist practice with the entire team caring for the patient. It also means identifying, classifying, and resolving home care patients' *medication-related problems* (MRPs). One study found of 232 MRPs in home care patients, 28% concerned suboptimal therapy and 24% were unnecessary drugs.[15]

Another study found the five most common medications implicated in MRPs in home care patients were: (1) acetaminophen, (2) albuterol, (3) omeprazole, (4) insulin (glargine and aspart), and (5) aspirin.[16]

Home Medical Equipment

Home care pharmacies often provide *home medical equipment* (HME) for patients. HME has replaced the older term *durable medical equipment* (DME). Examples of HME include aids for daily living, hospital equipment for the home, ostomy aids and supplies, incontinent supplies, self-monitoring equipment, ambulatory aids such as walkers and wheelchairs, dressings, and prostheses. The HME pharmacy business can be rewarding if done properly.[17]

THE PHARMACIST'S ROLE IN HOME HEALTHCARE

The role of the pharmacist in home healthcare is important. The ASHP guidelines for pharmacists providing home infusion services covers seven responsibilities:[2]

1. Day-to-day supervision of dispensing sterile preparations and delivery activities
2. Drug information provided to nurses, physicians, patients, and caregivers
3. Clinical monitoring, care planning, and assessment of home infusion patients
4. Maintaining a professional image and demeanor in both appearance and actions
5. Maximizing work efficiency and patient safety through the use of technology
6. Maintaining confidentiality of patient and proprietary information
7. Utilizing support personnel effectively

It is typical for a home healthcare pharmacy to provide service to 50–80 patients.[18] Services usually include preparing infusion products and providing medications and HME. It also includes providing pharmaceutical care. Typical time allocation for pharmacists providing these services are: 22% for patient care services; 19% in dispensing and patient counseling; 18% in management activity; 8% in medication preparation; and 8% in health professional counseling.[18]

In the home care pharmacy, pharmacists are required (by JCAHO) to maintain medication profiles, written care plans, and communication notes. The care plan should identify actual or potential patient problems or needs. The pharmacist also documents the patient's goals of therapy and progress toward those goals. Also, JCAHO expects home healthcare pharmacists to identify, resolve, and prevent medication-related problems. A useful community pharmacy model on how to provide pharmaceutical care for home healthcare patients has been developed.

Pharmacy technicians are the key to freeing up the home care pharmacist to work directly with patients. Pharmacy technicians can also become experts in preparing the various infusion preparations needed by home care patients.

Competency in Home Care

Pharmacists working in home care need to be experts in infusion therapy, understand the home care patient, and have good pharmaceutical care skills. A competency assessment for the home care pharmacist was developed several years ago and is still viable today.[19] The instrument tests the following skills: communication, completion of initial pharmacy assessment and reassessment, obtaining a medication profile, taking a medical history, screening for nutrition, assessing laboratory data, developing a patient care plan, and checking the pharmaceutical preparation.

Summary

Home care services and the scope of home infusion therapy prepared by pharmacists will continue to expand. This expansion will be based on changing patient needs and increased comfort levels among physicians. This trend will be fueled by the increasing number of elderly patients, but its success will be determined by satisfactory payments by third-party payers and managed care. Pharmacists are valuable team members who provide care to home care patients.

THE PHARMACIST'S ROLE IN HOSPICE CARE

Some home healthcare agencies and hospices provide compassionate care and pharmacy services to terminally ill patients. For a patient to be eligible for hospice care under Medicare, death must be imminent within six months. Patients who are considering hospice must agree to have all curative efforts stopped and to focus on palliative efforts alone.

In a hospice program, the dying patient has rights that are respected. These rights include

- The right to enjoy the best quality of life possible
- The right to die with dignity, as the patient perceives dignity
- The right to participate in his or her own care, his or her remaining life span, dying, and the event of death
- The right to remain a viable family member in an environment of choice

Hospice care can be provided in many settings that include the home, in a certified facility, or as part of a hospital or nursing home care. Some pharmacists work with other healthcare providers (physicians and nurses) to provide pain management and other therapies for terminal patients. This practice is called *collaborative drug therapy management* (CDTM).

Many patients in hospice care have cancer, and pharmacists with training in caring for these patients can be very helpful.[20] Controlling pain is one of the central goals of end-of-life care, and hospice requires a completely new level of care by pharmacists. It takes more time to take care of a hospice patient. Pain control for the patient with cancer in the home care setting can also be challenging and rewarding for the pharmacist.

Care for these patients involves *palliation*—to ease without curing the underlying condition. It is about making the patient as comfortable as possible.[21]

Pharmacists who do get involved in hospice often say that it is the most gratifying practice they have experienced. For those interested in this practice area, ASHP has an informative "Statement on the Pharmacist's Role in Hospice and Palliative Care."[22]

For further information, contact the *Society of Palliative Care Pharmacists* at http://www.palliativepharmacist.org/site_home.cfm.

Summary

Hospice pharmacists specializing in pain management are important members of hospice teams. They make a difference for end-of-life patients.

HELPING WITH TRANSITIONS IN CARE

Transition of care is defined as "the movement of patients between healthcare locations, providers, or difference levels of care within the same location as their conditions or care needs change."[23]

Besides helping manage medication, pharmacists can help patients in other ways. For example, as pharmacists become familiar with a patient's treatment regimens, they also gain a sense of when the patient may be ready for a transition in care, either to a more or less intense care. This sense may occur to the pharmacist before it occurs to other practitioners (prescribers and nurses). Thus, the clinical hospital pharmacist may know when a patient would be better served by care in a lower cost setting such as the patient's home, or in a nursing facility.

Likewise, a clinical hospital pharmacist can help physicians recognize the right time to move a patient into hospice care. Often this occurs much too late in the process and pharmacists can help ensure the patient receives the right level of optimal care.

CAREER OPPORTUNITIES

Employment opportunities in home care include positions with hospital-based programs, private home care companies, and some community pharmacies that specialize in providing medication and infusion services for patients. Home care offers pharmacists three types of positions: management, clinical practice, and pharmacy operations.

Positions as a hospice pharmacist are available and there is a need for pharmacists who specialize in pain management and how to care for patients who are at the end-of-life stage. The more training you have in these areas the more valuable you become. Thus, residency training is needed to be the best at these functions.

REWARDS AND SATISFACTION

Observation and personal testimonies suggest that practicing home care pharmacy is rewarding. Satisfaction comes from working with ill patients, many of whom are elderly, to preserve or improve their health and quality of life. Home and hospice care pharmacy requires pharmacists to practice pharmaceutical care. Home patients have many special needs, including parenteral antibiotics, chemotherapy, pain management, and caregivers who are understanding. Pharmacists can become experts in many of these therapies.

If you would like to read about a day in the life of a home care pharmacist or hospice pharmacist, a good guide is available.[24]

DISCUSSION QUESTIONS AND EXERCISES

1. Home care pharmacies prepare intravenous additive infusions for patients. What is an intravenous infusion?
2. Home care pharmacies prepare TPN infusions for patients. How does TPN differ from other intravenous additive infusions?
3. Intravenous infusions must be aseptically prepared. What constitutes aseptic preparation?
4. Are there certain intravenous additive infusions that should not be prepared by pharmacy technicians? By certified pharmacy technicians?
5. All intravenous products prepared by pharmacy technicians must be checked by a pharmacist—the ingredients, the amount of the ingredients, and the label. If a pharmacist was not present when the intravenous product was prepared, how will the pharmacist know how much of each ingredient was used?
6. Pharmacists have two primary roles when working in home care: (1) oversight of the drug preparation, and (2) dispensing process and monitoring patients for appropriate drug therapy. Which role would you prefer and why?
7. Home care pharmacy practice may include pain management and hospice care. Is this something that interests you? Why or why not?
8. Make an appointment to tour a home care pharmacy and interview a home care pharmacist.
9. What do you feel are the pros and cons of being a home care or hospice pharmacist?
10. Based on what you know and have read so far, is working as a home care pharmacist something you would like to do? Why or why not?

CHALLENGES

1. The role of home care pharmacists is much more clinical than that of pharmacists in most other settings. For extra credit, and with the permission of your professor, prepare a concise report comparing and contrasting the roles of the average pharmacist in home care and the average pharmacist in a hospital. Explain differences and provide arguments and mechanisms on how the clinical role of the hospital pharmacist might look more like the role of pharmacists in home care.
2. The public's perception of pharmacy is formed largely from what it sees in community pharmacies. That perception reveals not only trust but also technical expertise, rather than clinical expertise like that seen in home care pharmacy. For extra credit, and with the permission of your professor, prepare a concise report

comparing and contrasting the roles of the average pharmacist in home care and the average pharmacist in community pharmacy. Explain differences and advance arguments and mechanisms on how the clinical role of the community pharmacist might look more like the role of a pharmacist in home care.

3. Visiting a hospice where a pharmacist practices is a valuable experience for a student. For extra credit, and with the permission of your instructor, locate a hospice program where there is a pharmacist and set up an appointment to visit. Spend at least 2 hours there and prepare a concise report of your experience that includes the pros and cons of being a hospice pharmacist.

WEBSITES OF INTEREST

American Society for Parenteral and Enteral Nutrition: http://www.nutritioncare.org
JCAHO Home Health Standards: http://www.jointcommission.org/Standards_information/standards.aspx
National Association for Home Care and Hospice: http://www.nahc.org
National Home Infusion Association: http://www.nhia.org

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12 Long-Term Care Pharmacy

INTRODUCTION

According to the *World Health Organization* (WHO), "the number of people aged 65 or older is projected to grow from an estimated 524 million in 2010 to nearly 1.5 billion in 2050."[1] In the United States, the major impact of an increasingly aging population on the healthcare system will be felt in 2030.[2] Much of the impact will be in long-term care of patients.

Long-term care (LTC) "covers a diverse array of services provided over a sustained period of time to people of all ages, but mostly elderly patients with chronic conditions and functional limitations."[3] The needs of long-term care patients range from help in performing daily activities to total care. Many providers in various settings, such as people's homes, assisted living facilities, and nursing homes, take care of these needs.

Long-term care pharmacy has become a specialty area of pharmacy practice. A pharmacist with a special interest in caring for long-term care patients has the title *consultant pharmacist*. There is much to consultant pharmacy, and this area of practice is exciting and rewarding because you can make a difference for patients who need the expertise of a pharmacist.

This chapter explores long-term care and the role pharmacists play in this important area of healthcare. It begins by describing long-term care patients and their medication-related problems. Next, the chapter describes the various types of environments and standards for long-term care. The central focus of the chapter is on the role of consultant pharmacists in long-term care. The chapter concludes with a description of the satisfaction and rewards of having a career in long-term care.

LEARNING OBJECTIVES

Following this learning session, you should be able to:

- Define the term *long-term care*.
- Explain the goals of LTC.
- Discuss how the population is aging.
- Explain some of the therapeutic issues of long-term patients.
- Discuss the different types of LTC facilities.
- Explain what consultant pharmacy practice is like.
- Discuss some services provided by consultant pharmacists.
- Explain, briefly, the role of the consultant pharmacist in antimicrobial stewardship.
- Discuss the kinds of growth expected in long-term care.
- Explain consultant pharmacy practice.
- Discuss the satisfaction level of consultant pharmacists.

THE AGING POPULATION

Patients of any age may need long-term care. Patients experiencing the disabling effects of chronic disease and those experiencing the long-term disabling effects of accidents may need long-term care whether at home or in an extended care facility such as a nursing home. However, most long-term care patients are elderly (65 years of age or older).

The Elderly

As explained in the introduction, the growth in the number of elderly in the United States is increasing at a historical rate. In 2006, there were 38 million seniors—about one in seven people. That number will rise to 75 million by 2030.[4]

Goals of Long-Term Care

The goals of long-term care involve the restoration or maintenance of health and function. Care is centered on allowing maximum patient autonomy and minimizing complications and dependency. The type and extent of care depend on the patient's health status, support, and potential for recovery.

Diseases

The elderly, as a group, experience chronic diseases as they get older. Figure 12.1 shows the disease prevalence of the population who are 65 years and older. Chronic diseases are consistent with aging, but can be managed with proper diagnosis, treatment, and monitoring. Pharmacists can help make sure long-term care patients are managed properly.

Drug Therapy in the Elderly

Medication needs to be carefully prescribed in the elderly because of the large variation in how patients respond to therapy. The sources of this variation include the presence of multiple chronic diseases, or comorbidity, physiological changes (decreasing organ functioning) that go with aging, and the wide properties of drugs used to treat diseases of the elderly. For some reason, there can also be an enhanced drug effect in older people.

Comorbidity

The presence of more than one disease can complicate diagnosis and treatment. Nearly 40% of the elderly have arthritis plus another serious health condition.[5] One study showed that

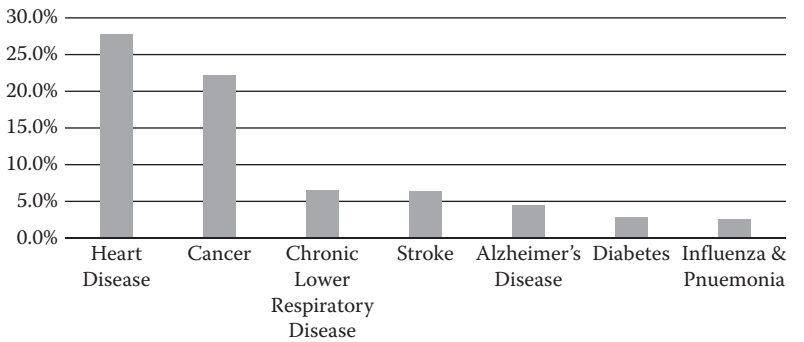

FIGURE 12.1 Chronic conditions leading to death in U.S. adults aged 65 or older in 2007–2009. (From CDC, National Center for Health Statistics. National Vital Statistics System. The state of aging and health in America 2013. https://www.cdc.gov/aging/pdf/state-aging-health-in-america-2013.pdf. Accessed March 23, 2017.)

people over 55 years had an average of 2.68 chronic conditions.[6] Sorting out what is going on in the patient can be difficult, and individualizing therapy is a necessity.

When comorbidity is present, there is also the possibility of drug–disease interaction, which occurs when a drug used for one condition worsens another condition. An example of this is when beta blockers (such as propranolol) are used to treat a heart condition in a patient who also has respiratory problems. Although the drug will help the heart condition, it may reduce breathing in a patient already experiencing breathing problems. In addition, the presence of certain diseases together may dramatically reduce the effectiveness of some drugs. The predictability of how a drug will work decreases as the number of coexisting diseases increases.

There are several strategies for pharmacists to use when helping manage comorbidities in patients.[7]

Physiological Changes

It is well documented that the elderly vary in how their bodies handle drugs more so than younger people. Age-related physiological change affects how drugs are absorbed, distributed, metabolized, and excreted from the body. Each of these four pharmacokinetic features can affect the active drug in the blood and at the site of action. Too much of a drug can cause an overdose, and too little of a drug could cause the disease or condition to be undertreated.

Drug absorption can be altered in the aging patient because of reduced gastric acidity, increased gastric emptying time, and reduced intestinal blood flow. Thus, the rate and extent of drug absorption can be altered.

Some drugs distribute to lean body tissue, whereas others distribute to fat. As a person ages, there is less lean body mass and more fatty tissue. There is also less total body water and less serum albumin. Using normal adult doses, without consideration of the lean body mass and total body water, can commonly result in too much or, less commonly, too little drug distributed to the site of action.

Most drugs are lipid-soluble (dissolve in fat) drugs that are absorbed in the small intestine and pass through lipid membranes to the site of action. The drug then leaves the site and is available for metabolism, usually being transformed from a lipid-soluble drug to a water-soluble drug, which needs to be excreted into the urine by the kidney. Metabolism is dependent on blood flow (reduced in older patients) through the liver (size also reduced) and the presence of certain liver enzymes. As people age, both of these functions can be altered, resulting in the drug being metabolized either too quickly or too slowly. If the drug is still administered at the same rate, it can build up in the bloodstream and cause toxicity or be reduced and be less effective.

Most drugs are eliminated from the body by the kidneys. Reduced renal (kidney) function and blood flow occurs with age, and this reduction is predictable. In elderly patients, kidney function may be reduced by as much as 50% by age 75 years.[5]

Enhanced Effects

When compared with younger people, the elderly are more likely to experience an enhanced, atypical response to their medication.[5] Organ systems can become more sensitive to the effects of certain drugs with age. This is especially true for drugs affecting the *central nervous system* (CNS), such as narcotic analgesics and tranquilizers.

Medication-Related Problems

Because of comorbidities, physiological changes, and enhanced drug effects, the elderly experience more medication-related problems (see Chapter 7, "Pharmaceutical Care") than those in other age groups.[7] Investigators have described the prevalence, types, and effects of adverse drug events (ADEs) in patients 65 years old or older taking multiple (five or more) medications.[8] Thirty-five percent of patients reported having at least one ADE within the previous year. Various medications were involved, but the ADEs were mostly associated with cardiovascular (33%) and CNS agents (29%).

Here are a few more senior pharmacy facts:[9]

- Older adults comprise 13% of the population, but account for 34% of all prescription medicine use and 30% of all over-the-counter (OTC) drug use.
- Four out of five older adults live with one or more chronic condition.
- Many older adults take multiple medicines at the same time. A recent survey of 17,000 Medicare beneficiaries found that two out of five patients reported taking five or more prescription medicines.
- Older adults are at increased risk of serious adverse drug events, including falls, depression, confusion, hallucinations, and malnutrition, which are important causes of illness, hospitalization, and death among these patients.
- Almost 40% of seniors are unable to read prescription labels, and 67% are unable to understand information given to them.

Polypharmacy

Polypharmacy is the act or practice of prescribing too many medications or is a prescription made up of many medicines or ingredients. Twice as many medications are prescribed to patients over 65 years of age compared to younger patients.[10] Seniors use approximately 30% of all prescription medications, along with an unknown percentage of nonprescription medications.

A study showed that one-third of seniors take medications prescribed by two or more physicians.[11] More than one-quarter of seniors (28%) had been to at least three physicians in the prior 6 months. One-third of older adults take eight or more medications.

LONG-TERM CARE FACILITIES

There are several types of long-term care (LTC) facilities: nursing homes, assisted living facilities, and continuing care retirement communities (CCRCs).

Nursing Homes

The best-known type of LTC facility is the nursing home, which largely came about as a result of the Social Security Act of 1935. In nursing homes, patients (*residents* is the preferred term) cannot do one or more of the normal activities of daily living: ambulating, eating, bathing, dressing, or toileting.[12]

Nursing homes provide intense services and have various healthcare workers, including physicians, nurses, dieticians, physical therapists, respiratory therapists, social workers, and

consultant pharmacists. Low-income residents are eligible for Medicaid, and this helps pay for nursing home expenses.

Assisted Living

There are two less-intense levels of community-based LTC, generally called *assisted living*.

Independent living: The first level of community-based LTC is a relatively new idea called *independent living*. These facilities allow residents to do as much as possible for themselves yet provide support and backup. Such facilities often provide assistance in taking medication, housekeeping, eating, and doing laundry. They also have attractive cultural and recreational facilities. The cost is borne by the resident or is provided through estate planning.

Intermediate care: An emerging level of LTC between independent living and nursing homes is called *intermediate care*. This level of care is less intense than nursing home care but more intense than independent living. More services are offered than in assisted living, and the care allows the resident to remain as independent as possible before progressing to nursing home care. For example, impairment may occur in one or more basic measures of function.

Continuing Care Retirement Community

The *Continuing Retirement Community Care* (CCRC) provides individuals a continuum of care that is needed as they move through the last part of their lives. A CCRC usually provides for all levels of care, from independent living through nursing home care. Some CCRCs also provide acute, Alzheimer's, and hospice care.

Statistics

In 2013, there were 15,663 nursing homes with an occupancy rate of 80.8% (1.4 million patients), a slight decline since 2010.[13] The decline is most likely attributed to the increased focus of nursing homes on patients with greater disability and post–acute care needs and a preference for alternatives to nursing home care.

However, the number of individuals using paid long-term care services in any setting (e.g., home, residential care such as assisted living, or skilled nursing facilities) is closer to 13 million. This number is estimated to rise to 27 million by 2050.[14]

Quality of Care

Local, state, and national policy makers have questioned the quality of LTC. The public, including the families of residents of LTC facilities, especially nursing homes, have also questioned the quality. Concerns about the quality of care and treatment of residents persist despite some improvements in these facilities in recent years.

The Institute of Medicine (IOM), with the support of the Robert Wood Johnson Foundation, launched a study, *Improving the Quality of Long-Term Care*.[15] This study is a follow-up to one completed earlier. In general, the IOM found that the quality of care in nursing

homes had improved since 1987. They also found that the quality of life for nursing home residents had shown some improvement, but to a lesser extent.

The IOM offered 14 recommendations in the following areas:

- Provide access to appropriate services (1)
- Provide quality assurance through appropriate oversight (5)
- Strengthen the workforce (5)
- Build organizational capacity (1)
- Address reimbursement issues (2)

State standards exist for assisted living facilities; however, the IOM said these standards are variable. For nursing homes, there are both federal and state regulations to protect the quality of care. To monitor and assess adherence with these regulations, state agencies perform on-site surveys. After surveying a facility, state surveyors decide whether the facility has met each standard.

Unfortunately, the quality of care in nursing homes has not improved minimally since the IOM report. For example, one study of the 10 largest nursing home chains received more deficiencies from regulators than from other nursing homes.[16] This study also discovered that for-profit facilities had fewer nurse "staffing hours." Almost two-thirds of nursing homes are for profit.

The American Geriatrics Society has a position statement on measuring the quality of care for nursing home residents.[17] In addition, the quality of care in the nation's nursing homes may get a boost from a quality improvement initiative from the Centers for Medicare & Medicaid Services (CMS).[18]

Financing Long-Term Care

Long-term care does not come cheap. Here are the average monthly cost figures for 2016:[19]

- Nursing home care
  - Semi-private room $6,844
  - Private room $7,698
- Assisted living $3,628
- Adult day healthcare $1,473
- Home healthcare
  - Homemaker services $3,813
  - Home health aide $3,861

Unfortunately, most people lack insurance to protect themselves from the potentially catastrophic financial demands of such vital services. An article titled, "Financing Health Care for an Aging Population," stated that the United States has a broken financing system that so far is unable to cope with an aging population.[20] Although seniors received help when the Medicare prescription benefit started in 2006, no solution is on the radar for helping to finance long-term care for seniors.

CONSULTANT PHARMACY PRACTICE

Pharmacists specializing in LTC pharmacy are called *consultant pharmacists* because the relationship between the facility or agency and the pharmacist is contractual (rather than that of employee–employer). A term for pharmacists with specialized knowledge in geriatrics, geriatric pharmacotherapy, and the unique needs of the senior population is *senior care pharmacist*.

Settings

Consultant pharmacists work in various settings:

- An independent or chain store pharmacy that provides limited LTC services
- Stand-alone LTC pharmacies
- Pharmacies that provide no drugs but consult on the proper procedures and therapies in the facility
- Pharmacies located in nursing homes

There are increasing numbers of consultant pharmacists making their living by working for assisted living facilities and skilled nursing facilities on a full-time basis. They have a contract with the pharmacy provider or with the facilities themselves. Major LTC pharmacy companies include Omnicare/CVS, PharMerica, and Guardian.

Federal Laws

Federal law mandates consultant pharmacy services to nursing homes. Nursing homes, to qualify for Medicaid, must have the drugs of all residents reviewed by a pharmacist at least once a month. Today, this is the only clinical pharmacy service recognized by federal law.

Managed Care

Increasingly, managed care plans are starting to look at long-term benefit plans for their enrollees. It is important that these plans include a long-term pharmacy benefit plan. There are various arrangements (from fee for service to full capitation) under which consultant pharmacists can provide services to patients using a managed care plan (see Chapter 10, "Managed Care Pharmacy").

Creed and Standards of Practice

The *American Society of Consultant Pharmacists* (ASCP) has developed a creed and progressive standards. The creed says—as medication therapy experts, consultant and senior care pharmacists:

- Hold their patients' interest above all others.
- Take responsibility for their patients' medication-related needs.
- Ensure that their patients' medications are the most appropriate, the most effective, the safest possible, and are used correctly.
- Identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy.

Many of the ASCP standards incorporate pharmaceutical care into the daily routine of each practicing consultant pharmacist. These standards of practice have helped standardize and improve pharmacy services to extended care facilities and have raised the pharmacist's clinical practice.

Accreditation

Accreditation of LTC pharmacy comes from the Joint Commission on Accreditation of Healthcare Organizations.[21] The standards are progressive, especially concerning the pharmacist's clinical practice.[22] Consultant pharmacists have done a wonderful job in meeting the standards.

Services

Services pharmacists provide to LTC facilities can be divided into provider services (at the pharmacy) and consultant services (onsite—clinical). These services can be combined or provided individually.

Provider Services

Provider (pharmacy) services are supplied at various levels depending on the needs of the LTC facility. The most basic service is dispensing medications to the residents of the facility. Many of the services are listed in Table 12.1.[23]

Many of these services can be automated, which has the following benefits: (a) improved efficiency, (b) improved accuracy, (c) reduction of medication errors, (d) automated charting of medication, (e) automated billing of medication, and (f) freeing the pharmacist to provide more patient-focused care.[24]

Consultant Services

The services listed in Table 12.1 were for a pharmacy service that provides services to a nursing home facility. Consultant services refer to the clinical on-site-services provided by a consultant (clinical pharmacist). Consultant pharmacy services range from the federally mandated *medication regimen review* (MRR) to performing geriatric research. Some of the many

TABLE 12.1
Selected Provider (Pharmacy) Functions

Drug distribution
Drug delivery (routine and emergency)
Drug packaging and labeling
Medication reordering
Auditing for controlled medications
Emergency medication supply
Monitoring of proper storage of medication
Forms and reports
Patient profile
Medication administration
Physician order forms
Automatic stop orders
Treatment records
Patient care plans
Drug utilization review
Billing statements
Policy and procedure development
Drug information
Durable medical equipment
Medical/surgical supplies
Enteral products
Intravenous services
Education and training
Medication error detection

consultant pharmacy services are listed in Table 12.2. The extent of involvement and variety of services offered depends on the consultant pharmacist's interest, motivation, formal training or experience, work environment, and reimbursement for services.

Reviewing Drug Therapy

The three methods of reviewing drug therapy in consultant pharmacy practice for quality are medication regimen review (MRR), drug use review (DUR), and drug use evaluation (DUE).

Medication Regimen Review

At the heart of consultant pharmacy services is MRR.[25,26] A consultant pharmacist must review a resident's medications at least every 30 days. Doing this improves therapy, reduces medication-related morbidity and mortality, and reduces costs, achieving quality drug therapy.

The best way to undertake MRR and to achieve quality drug therapy is to have a well-functioning interdisciplinary team, with each team member focusing on the same goal. The effect of such a team was measured.[27] The team comprised of a geriatric physician, geriatrics medical fellow, nurse practitioner, medical resident, clinical pharmacist, geriatric pharmacy resident, social worker, rehabilitation therapist, dentist, and nursing staff. Although the number of drugs (some added and some discontinued) did not change over a 4-month period, there was a significant decrease in the number of unnecessary medications.

MRR is performed *concurrently*, which means while the patient is taking the medication. Thus, recommendations to change therapy can have an immediate effect on the quality of drug therapy. For this, the pharmacist reviews the resident's medical history, prognosis, treatments, orders, laboratory tests, medication history, and care plan. The pharmacist then focuses on the treatment goals set up for the patient by an interdisciplinary team, of which the pharmacist is a member.

The pharmacist's attention is then turned to the appropriateness of therapy and uses and identifying medication-related problems, as developed under the pharmaceutical care model of delivery care (see Chapter 7, "Pharmaceutical Care").

TABLE 12.2
Selected Consultant Pharmacist Activities

Medication therapy management
Medication regimen review (MRR)
Chronic disease state management
Patient and caregiver counseling
Therapeutic drug monitoring
Fall prevention
Formulary management
Provider in-services
Antimicrobial stewardship
Quality assurance measures
Medication use evaluation
Immunizations

Source: American Society of Consultant Pharmacists. What do consultant pharmacists do? https://www.ascp.com/page/whatisacp. Accessed March 23, 2017.

Commercially available software is helpful to pharmacists in performing MRR. The software helps capture the data, tracking various kinds of medication, producing reports, making recommendations, and capturing recommendation outcomes.[28]

Consultant pharmacists look for specific problems when doing a MRR. For example, there is a national or regional average for the number of prescriptions the average elderly person takes each month. Patients who take more than the average number of prescriptions may be taking unnecessary therapy. National and regional figures are also available for the number of medication administration errors found monthly by other consultant pharmacists. Such *benchmarks* can be useful.

Other useful signs to be looking for are as follows: (a) multiple orders for the same drug for the same patient; (b) drugs administered after *stop orders* (automatic stops on medication); (c) prn (from the Latin *pro re nata*—medication ordered as needed) drugs administered each day for more than 30 days; (d) drug interactions; (e) wrong dosage of laxatives, tranquilizers, analgesics, antipsychotics, or antidepressants; and (f) failure to order diagnostic tests during chronic therapy.[29]

Another finding is that LTC residents are sometimes undertreated for conditions such as pain, depression, and osteoporosis. Various software programs incorporate disease state management programs to help consultant pharmacists identify problems and improve patient outcomes.

An important function of consultant pharmacists during the MRR process is to identify, resolve, and prevent *adverse drug events*. A study determined that in residents of eight community nursing homes experienced 1.89 ADEs every 100 months and 0.65 potential ADEs (those that may have caused harm but did not do so because of chance or because they were detected) every 100 months.[30] Of the ADEs, one was fatal, 6% were life threatening or serious, and 56% were significant.

Out of 515 ADEs, 72% of fatal, life-threatening, or serious events, and 34% of significant ADEs were prevented. Errors resulting in preventable ADEs occurred most often at the stages of prescribing and ordering. Psychoactive medications (antipsychotics, antidepressants, and sedatives and hypnotics) and anticoagulants were the most common drugs associated with preventable ADEs.

Some common ADEs in the elderly may tip off the consultant pharmacist that the resident is experiencing trouble with his or her medication. These include confusion, depression, no appetite, weakness, drowsiness, ataxia, forgetfulness, tremor, constipation, dizziness, diarrhea, or urinary retention.

The Beers List (Potentially Inappropriate Drugs for Elderly)

Aging affects organs that metabolize drugs (the liver) and excrete drugs (the kidneys), and may affect respiration and central nervous system (CNS) functioning. Some of therapeutic categories that have potential for harm in the elderly include CNS drugs (tranquilizers, antidepressants, opioids, sedatives, and hypnotics), some cardiovascular agents, and skeletal muscle relaxants. Individual drugs in each potentially unsafe therapeutic category for older adults can be seen by consulting the listing in the manuscript.[31] This list is used by the Agency for Healthcare Administration (AHCA) surveyors during their annual inspection of skilled nursing facilities (SNFs).

Drug Use Review

MRR is performed on one patient at a time, and the consultant pharmacist's recommendations are provided to the patient's physician. *Drug use review* (DUR) is the process of

reviewing drug therapy on a broader basis, that is, on a drug used in many patients or by many physicians. DURs supply trend information. Once a drug is selected for review, criteria on how the drug should ideally be used are developed. Pharmacists usually perform this function. The review can take place retrospectively by reviewing the records of patients who have received the drug in the past or concurrently—on patients still taking the drug. A table of results of how the drug is being used in the facility versus the ideal way the drug should be used is developed for review by the *pharmacy and therapeutics committee* (P&T) or presented to the physicians at an education meeting or through a newsletter.

Drug Use Evaluation

Drug use evaluation (DUE) is a process of reviewing drug therapy that is even broader than DUR. In DUE, a disease is selected to see how it is being treated; thus, the process reviews the use of many drugs.

The importance of MRR, DUR, and DUE is that medication-related problems are identified and solutions are put in place to help the patient (MRR) or many patients (DUR and DUE). Consultant pharmacists are to be congratulated on the fine job they are doing. A study showed that consultant pharmacists were able to reduce or stop the use of 43% of unacceptable medications.[32]

Another study of 3464 interventions made by consultant pharmacists found that 85.7% of the interventions requested a response by the physician (14.3% were informational). Of the interventions seeking a response, physicians accepted the advice of the pharmacist 68% of the time.[33] The most common interventions were for unnecessary medication, laboratory monitoring, and more laboratory checking.

Consultant pharmacists provide value to LTC facilities and their residents. A study discovered most LTC facilities pay $3.28 for each resident each month for consultant pharmacist services (range was $3.14 to $4.04).[34] The savings generated by discontinuation of unnecessary drugs as recommended by the pharmacist more than pays for these services.

One of the methods pharmacists have developed to reduce unnecessary medication is the use of the *stop order*, which is not an order at all, but rather a policy developed by the P&T committee to stop the use of certain drugs after a certain time unless the physician reorders the medication. The beauty of a stop order policy is that it reminds physicians to review the active orders routinely for a patient.

The downside is that certain important medications may be stopped when the physician does not want them stopped, which is why physicians are given several warnings by the pharmacy before the medication is stopped. However, in LTC facilities, physicians may only see their patients once a month and miss the stop order warning. This is where the consultant pharmacist's MRR should help.

An example of a LTC stop order policy looks like this: antibiotics, 7 days; anti-emetics, 4 days; antihistamines, 7 days; cold preparations, 5 days; all other medication, 30 days.

Antimicrobial Stewardship

The never-ending march of *antimicrobial resistance* is a major threat to worldwide health. Fortunately, there is a strategy to slow down, and in some instances, reduce antimicrobial resistance. *Antimicrobial stewardship* is a systematic approach to the use of antimicrobial agents to achieve optimal outcomes, as close to 100% of the time as possible. This means using the correct agent, at the correct dose, with the correct route of administration, and

for the appropriate duration, to cure or prevent infection, while minimizing toxicity and emerging resistance.[35,36]

Pharmacists have been at the forefront of the antimicrobial stewardship effort and are key members of the antimicrobial stewardship team, but up until 2016, only in the hospital. In 2016, the *Center for Medicare and Medicaid Services* (CMS) issued final new rules for long-term care that includes the requirement for antimicrobial stewardship.[37] The new requirements will be rolled out in three phases, and antimicrobial stewardship is in phase 2 which was expected to be implemented by November 27, 2017.

The following is the major thrust of the new requirements for antibiotic stewardship in nursing homes:

- Requiring facilities to develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program and designate at least one Infection Preventionist (IP).
- Review of antimicrobial therapy by the consultant pharmacist during their monthly MRR.
- The use of antibiotic use protocols and systems for monitoring antibiotic use and recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

Opportunity: Pharmacists can make a big difference for patients if they pursue these new requirements diligently.

Drug Safety

Since the enlightening report by the IOM, "To Err Is Human," there has been a stepped-up effort by consultant pharmacists to improve medication safety.[38] Although concern about overmedicating nursing home patients with CNS agents continues, other medication-related problems also exist. The ASCP published a list of the top 10 drug interactions in long-term care.[39] These dangerous interactions are as follows:

1. Warfarin–NSAIDs
2. Warfarin–sulfa drugs
3. Warfarin–macrolides
4. Warfarin–quinolones
5. Warfarin–phenytoin
6. ACE (angiotensin-converting enzyme) inhibitors–potassium supplements
7. ACE inhibitors–spironolactone
8. Digoxin–amiodarone
9. Digoxin–verapamil
10. Theophylline–quinolones

Note that the NSAID class does not include COX-2 (cyclo-oxygenase 2) inhibitors. Quinolones that interact include ciprofloxacin, enoxacin, norfloxacin, and ofloxacin.

GROWTH IN LONG-TERM CARE

The elderly population is growing dramatically. It is estimated that the greatest impact will be felt between 2020 and 2030. Patients in nursing homes are expected to get there quicker

and be sicker. This is already starting to happen. Because of declining reimbursement for hospitals, patients are being discharged sooner. In about 1966, the average nursing home patient took 3 to 10 medications a day or an average of 3.8 drugs.[40] In 1996, the nursing home patient took an average of 6.3 different medications a day. Today, that number is much higher.

GROWTH IN CONSULTANT PHARMACY PRACTICE

George F. Archambault, who first coined the phrase *consultant pharmacist* in the 1950s, probably never imagined the growth of consultant pharmacy practice since that time. This growth has occurred because of the growing number of elderly, whose numbers are projected by 2030 to exceed 70 million. The growth in consultant pharmacy practice also has to do with the dedication and enthusiasm of many hard-working consultant pharmacists and their professional organization, the ASCP.

CERTIFICATION

Through the ASCP, pharmacists can obtain certification in the practice of *geriatric pharmacy*. Those pharmacists passing the examination are allowed to use the designation CGP (certified geriatric pharmacist). The certification is good for 5 years and can be renewed by taking specific continuing education credits or retaking the examination.

REWARDS AND SATISFACTION

Despite the regulation of LTC, consultant pharmacists have focused on the right things and have documented their successes. Consultant pharmacists have been able to combine the clinical aspects of hospital pharmacy practice with the business challenges of community pharmacy. Consultant pharmacists like working with physicians and other healthcare professionals, feel like they have a direct impact on patient well-being, have autonomy, and like the rewards.

Consultant pharmacists also like the variety in their daily routine: monitoring the dispensing process, counseling physicians, performing pharmacokinetics, reviewing therapy, counseling patients, and committee work. The less-appealing aspects of consultant pharmacy are conflicts with management and other healthcare professionals, dealing with those who do not adapt to change, and the travel associated with monthly MRRs.

The new requirement to perform antibiotic stewardship will be challenging, but will also freshen up consultant pharmacy practice from its current everyday routine.

FUTURE OF CONSULTANT PHARMACY PRACTICE

Changes in the nursing home survey process have started to focus on quality. Surveyors use 24 quality indicators when selecting a sample of residents to review. The quality indicators help consultant pharmacists provide better services to patients. Also, the arrival of the Medicare nursing facility prospective payment system created a financial reason for all decisions. Thus, consultant pharmacists must now consider costs during their MRRs. The cost of drug therapy now includes the cost of *therapeutic failures* and *medication-related problems*, not just the cost of the medication, distribution, and use. There will also be more focus on reviewing the use of antibiotics and psychotropic medication, not only in nursing homes, but also in assisted living facilities.

SUMMARY

The U.S. population is getting older. By 2030, there will be 70 million Americans 65 years old or older. With this growth in population has been the growth in LTC and consultant pharmacy practice. Consultant pharmacists are a dedicated and motivated group of healthcare professionals who are focusing on what is important: quality drug therapy and improved health outcomes in LTC residents. Their job combines clinical and business skills and offers various functions throughout the workday. They also are on the leading edge of pharmaceutical care, and have provided leadership to the profession of pharmacy in thinking about automation. An excellent overview is available.[41]

DISCUSSION QUESTIONS AND EXERCISES

1. How do you feel about working with elderly patients?
2. It is federally mandated that the medication regimen of all patients in nursing homes in the United States be reviewed by a pharmacist every 30 days and recommendations made to the prescribing physician. Is this something that interests you? Why or why not?
3. During MRR, you (the pharmacist) discover a drug being prescribed for a patient that, according to Food and Drug Administration (FDA) labeling, is absolutely contraindicated in the patient and thus poses a potential danger to the patient.
   a. What would you do?
   b. What would you do if the prescribing physician still wants to use the drug?
4. You note that you and other LTC pharmacists provide many MRR recommendations to one physician versus other physicians, and that this physician rarely accepts the pharmacists' recommendations.
   a. Should you do anything about this?
   b. If yes, what would you do?
5. Patients in LTC facilities often receive too many central nervous system (CNS) depressants or experience exaggerated effects from these agents. What are the signs and symptoms of too much CNS depression?
6. Make an appointment to interview an LTC pharmacist.
7. What do you see as the pros and cons of being an LTC pharmacist?
8. Based on what you know and what you have read thus far, is LTC pharmacy something you are interested in doing? Why or why not?

CHALLENGES

1. The prevalence of polypharmacy is higher among those 65 years of age or older. For extra credit, and with the permission of your professor, research and prepare a concise report titled, "The Problems and Solutions to Polypharmacy in the United States."
2. The Medicare Modernization Act, which authorized payment by Medicare for Part D prescription expenses, affects many LTC residents. For extra credit, and with the permission of your professor, research and prepare a concise report titled, "The Effect of the Part D Medicare Benefits on LTC Residents."

WEBSITES OF INTEREST

American Geriatrics Society: http://www.americangeriatrics.org
American Society of Consultant Pharmacists: http://www.ascp.com
Commission for Certification in Geriatric Pharmacy: http://www.ccgp.org

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13 Government Pharmacy

INTRODUCTION

One of the advantages of being a pharmacist is the variety of places to work. One of those places is within the government. Unfortunately, pharmacist positions in the government do not have the visibility and recognition they deserve, yet are vital to the nation's overall health.

This chapter is about the opportunities pharmacists have and the kinds of work pharmacists do in government service. It discusses the U.S. Public Health Service (PHS) and the various areas pharmacists can work within the PHS, for example, the Indian Health Service (IHS), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and federal prisons.

Pharmacists work in federal hospitals such as the National Institutes of Health (NIH), the Environmental Protection Agency (EPA), the Agency for Toxic Substances and Disease Registry (ATSDR), the Agency for Healthcare Research and Quality (AHRQ), and the Health Care Financing Agency (HCFA).

This chapter also discusses how pharmacists work and provide service within the Veterans Affairs (VA) hospitals, the Drug Enforcement Administration (DEA), and the Department of Defense (DOD; the Army, Navy, and Air Force).

The chapter concludes with discussion of opportunities in state government and the rewards and satisfactions of working for the government.

LEARNING OBJECTIVES

After participating in this learning session, you should be able to:

- Explain the term "public health."
- Discuss the role of pharmacists in public health.
- Identify the eight agencies where pharmacists work in the PHS.
- Explain the mission of the PHS.
- Explain opportunities for pharmacists within the DOD.
- Explain opportunities for pharmacists within the VA.

U.S. PUBLIC HEALTH SERVICE

President John Adams set up the PHS on July 16, 1798 to provide care and relief for sick and disabled navigators.[1] Since this beginning, the PHS has protected and advanced the health of our nation and has contributed to the delivery of health-care worldwide.

The U.S. PHS is a part of the U.S. Department of Health and Human Services (HHS).[2] The PHS has 13 agencies: the CDC, the ATSDR, the NIH, the FDA, Substance Abuse and Mental Health Services Administration (SAMHSA), Health Resources and Services Administration (HRSA), the AHRQ, the IHS, Centers for Medicare & Medicaid Services (CMS), Office of the Assistant Secretary of Health (OASH), Office of the Secretary (OS), Office of the

Assistant Secretary for Preparedness and Response, and the Program Support Center (PSC).[2] Pharmacists are employed in most of these agencies.

The mission of the PHS Commissioned Corps is to protect, promote, and advance the health and safety of our Nation. As America's uniformed service of public health professionals, the Commissioned Corps achieves its mission through

- Rapid and effective response to public health needs
- Leadership and excellence in public health practices
- Advancement of public health science

There are more than 6,500 Commissioned Corps officers and over 45,000 civil service employees in the PHS.

The Role of the Pharmacist in Public Health

All pharmacists have a public health-care role, whether they work for the PHS or not. Both the *American Pharmacist Association* and the *American Society of Health System Pharmacists* have statements on the role of pharmacist in public health.[3,4] No matter the work location, all pharmacists should be concerned about the general welfare of patients, and help patients get their basic health-care needs met, whether or not the need is dental, medical, or psychological.

The role of commissioned pharmacy officers or civil service pharmacists working in the PHS is specific to the agency for which they work. As of 2017, there were over 1200 PHS pharmacists.[2] Government pharmacy's greatest need is for clinical pharmacists to work with medically underserved populations. Most PHS pharmacists begin their careers in a clinical setting, advancing to senior clinical positions or moving to research or administration.

CENTERS FOR DISEASE CONTROL AND PREVENTION

The CDC started in Atlanta, Georgia, in 1946. The mission of the CDC is to promote health and quality of life by preventing and controlling disease, injury, and disability.[5] The CDC is the leading federal agency responsible for protecting the health of the American public by overseeing disease trends; studying disease outbreaks and health and injury risks; fostering safer, more healthful environments; and implementing illness and injury control and preventions.

The CDC employs approximately 14,000 people, in 70 occupations, working in 60 countries.[6] The CDC is headquartered in Atlanta and has offices in 10 additional locations in the United States. Field staff work in all 50 states and in more than 50 countries.

In 2017, about 10 commissioned pharmacy officers worked at the CDC in the drug service, the chronic disease service, vaccine safety and development, and sexually transmitted diseases. Pharmacists seeking a job at the CDC who are not commissioned officers in the PHS, increase their chances of employment by having a master of public health degree or an MS degree in biostatistics and epidemiology.

Food and Drug Administration

The FDA ensures the safety of foods and cosmetics and the safety and efficacy of pharmaceuticals, biological products, and medical devices. The FDA was established in 1906, but it was not a part of the PHS until 1968. The FDA was founded in Rockville, Maryland.

In 2017, of the 10,000 employees of the FDA, 307 (243 Commissioned Corps and 64 noncommissioned) were pharmacists.[7] Although pharmacists work in most of the centers of the FDA, a majority of the work is completed in the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). Locations range from FDA headquarters in Rockville, Maryland, to locations in 150 cities nationwide. The following is what the FDA listed on their website for pharmacists:

Pharmacists at the FDA perform duties that include[8]

- Compounding of prescriptions for physicians, dentists, and other licensed practitioners.
- Formulation, preparation, bulk compounding, selection, dispensing and preservation of drugs, medicines, and chemicals.
- Research and investigation in developing original techniques of compounding and new investigational drugs available for use.
- Advising on drug therapy and usage.
- Some positions involve the evaluation of drug proposals submitted by private industry and the surveillance of marketed drugs for safety and efficacy.
- Responsible for the proper interpretation of prescriptions and the dispensing of products as prescribed.
- Advising on significant new drugs and developments in the pharmaceutical, chemical, and medical fields.

Grade (Salary) Levels

The federal General Schedule (GS) grade levels at which these positions are most commonly filled are GS-9 through GS-13 at the headquarters level.

Note: For a list of GS-grade salaries, see the FDA Office of Human Resources website. https://www.fda.gov/AboutFDA/CentersOffices/OfficeofOperations/OfficeofHumanResources/default.htm.

Qualifications

For GS-9: Successful completion of a 5-year course of study leading to a bachelor's or higher degree in pharmacy from an approved pharmacy school, or 1 year of professional pharmacy experience equivalent to at least GS-7.

For GS-11: Successful completion of a 6-year course of study leading to a Doctor of Pharmacy (PharmD) degree; 1 year of professional pharmacy experience equivalent to at least GS-9; or, for research positions, completion of all of the requirements for a master's or equivalent degree in a related scientific field.

For GS-12/13: Specialized experience is required equivalent to the next lower grade level.

Indian Health Service

The IHS is the PHS agency responsible for providing health services to approximately 1.9 million American Indians and Alaska Natives who belong to more than 564 federally recognized tribes in 35 states.[2] The IHS and tribally managed programs operate in over 33 hospitals, 59 health centers, and 50 health stations. This task is complicated by the broad cultural, economic, and geographic diversity of the groups served. As a result, health programs must be individually designed to address the needs of each community.

The IHS was founded in 1924 and currently has about 15,000 employees, with about 500 pharmacy officers and civilian pharmacists: 75% of the practicing pharmacists are commissioned officers, 5% are civil servants, and 20% are direct hires by the tribes.

IHS pharmacists practice in a true pharmaceutical care environment in which they fully utilize their knowledge and skills.[9] The IHS has pioneered many progressive and innovative advances over the past 30 years. Pharmacists have access to the patient's entire health record, including laboratory results, immunization status, and past medical history, to assess the appropriateness of drug therapy.[10] Problems are resolved with providers prior to dispensing medications, and all patients are counseled on their medication therapy. In many locations, pharmacists are credentialed to provide primary care and use their prescriptive authority to evaluate and manage the care of certain patients.

The IHS has developed a rapid and reliable method of medication counseling for patients. The method uses a series of short questions and probes the patients for what they know about their medication (see Chapter 7).

An article that provides insight into IHS pharmacy practice is available.[11] Rewards of working for the HIS includes hands-on patient care, interdisciplinary teamwork, and a stimulating clinical experience not found elsewhere.

National Institutes of Health

The NIH, set up in 1887, is the world's premier medical research organization. The NIH supports over 38,000 research projects nationwide in diseases that include cancer, Alzheimer's, diabetes, arthritis, heart ailments, and AIDS. The NIH includes 27 separate health institutes and centers.[2] In 2017, the NIH employed approximately 18,000 people.[12]

The Clinical Center pharmacy has inpatient and outpatient services, a manufacturing facility, and a full analytical section to support investigators in their research. Clinical pharmacy specialists, supported by other pharmacists, provide a full range of services, including therapeutic drug monitoring and review, protocol adherence monitoring, and institutional review board membership. In 2017, there were 85 pharmacists working in the NIH center and hospital.[12]

Federal Bureau of Prisons

The Bureau of Prisons (BOP) was established in 1930 to provide more progressive and humane care for federal inmates, to professionalize the prison service, and to ensure consistent and centralized administration of the 11 federal prisons in operation at the time.

In 2017, the BOP consisted of more than 115 institutions, six regional offices, a central office (headquarters), two staff training centers, and 28 community corrections offices. The BOP is responsible for the custody and care of approximately 209,000 federal offenders. Approximately 82% of these inmates are confined in BOP-operated correctional facilities or detention centers.[13]

The BOP protects public safety by ensuring that federal offenders serve their sentences of imprisonment in facilities that are safe, humane, cost efficient, and appropriately secure. The BOP helps to reduce the potential for future criminal activity by encouraging inmates to participate in a range of programs that have been proven to reduce recidivism. The approximately 37,000 employees of the BOP ensure the security of federal prisons, provide inmates with needed programs and services, and model mainstream values. In 2017, there were about 130 commissioned pharmacy officers working for the BOP. Two articles on what it is like to work in a federal prison have been written.[14,15]

Environmental Protection Agency

The mission of the EPA is to protect human health and the environment. Since 1970, the EPA has been working for a cleaner, healthier environment for the American people.[2] In 2017, the EPA employed about 18,000 people across the country—at least one is a commissioned pharmacy officer. EPA staff are highly educated and technically trained.[16] EPA pharmacists work on various public health and sanitation programs ranging from watching viruses and bacteria in shellfish to developing detection methods for microorganisms in drinking water.

Agency for Toxic Substances and Disease Registry

The mission of the ATSDR is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related to toxic substances.[2]

The ATSDR began in 1980 in Atlanta, Georgia, is associated with the CDC and helps to prevent exposure to toxic substances from waste sites on the National Priority List of the EPA. In 2017, there are several commissioned pharmacy officers working in this agency.[17] Pharmacists with backgrounds in pharmacology and toxicology evaluate data and information on the release of hazardous substances into the environment, develop toxicological profiles, and set up research in toxicology and toxic effects.

Agency for Healthcare Research and Quality

The AHRQ, established in 1989, supports research on health-care systems, health-care quality and cost issues, access to healthcare, and effectiveness of medical treatments. The agency has about 300 employees.[2] In 2017, three pharmacists (two civilian and one commissioned officer) at AHRQ provided management for information development, helped develop grant announcements, and tracked the progress of research that the agency funds.[18]

Centers for Medicare and Medicaid Services

The CMS administers the Medicare and Medicaid programs, which provide healthcare to about one of every four Americans. Medicare provides health insurance for more than 42.1 million elderly and disabled Americans.[2] Medicaid, a joint federal-state program, provides health coverage for 44.7 million low-income persons, including 21.9 million children, and nursing home coverage for low-income elderly. The CMS also administers the State Children's Health Insurance Program, which covers more than 4.2 million children.

The CMS was established as the Health Care Financing Administration in 1977. In January 2006, the CMS started a Part D prescription benefit for Medicare beneficiaries. In early 2017, the CMS employed about 5000 people. Of these, 10 were commissioned pharmacy officers.

Substance Abuse and Mental Health Services Administration

The SAMHSA: (1) works to improve the quality and availability of substance abuse prevention, addiction treatment, and mental health services; (2) provides funding through block grants to states to support substance abuse and mental health services, including treatment for more than 650,000 Americans with serious substance abuse problems or mental health

problems; (3) helps improve substance abuse prevention and treatment services through the identification and dissemination of best practices; and (4) monitors prevalence and incidence of substance abuse. SAMHSA was established in 1982. In 2017, SAMHSA employed about 600 people, 3 of whom were pharmacists working in the pharmacologic alternative service.[20]

Other PHS Areas

In 2017, there were about 25 commissioned pharmacy officers who worked for the Department of Homeland Security (DHS), about 30 worked in the HRSA, and about 20 worked in the OS.[21]

National Pharmaceutical Stockpile

CDC's Strategic National Stockpile is the nation's largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. The stockpile ensures the right medicines and supplies are available when and where needed to save lives.[22]

When state, local, tribal, and territorial responders request federal assistance to support their response efforts, the stockpile ensures that medicine and supplies get to those who need them during an emergency. Organized for scalable response to a variety of public health threats, the repository contains enough supplies to respond to multiple large-scale emergencies, simultaneously.

The stockpile was created in 1999 to ensure the nation's readiness against potential agents of bioterrorism such as botulism, anthrax, smallpox, plague, viral hemorrhagic fevers, and tularemia. The mission was to assemble large quantities of essential medical supplies that could be delivered to states and communities during an emergency within 12 hours of the federal decision to use the stockpile. The September 11, 2001 terrorist attacks prompted federal legislation and directives to strengthen public health emergency readiness.[23]

Commissioned Corps

As one of the seven uniformed services of the United States, the U.S. PHS Commissioned Corps is a specialized career system designed to attract, retain, and develop health professionals who may be assigned to federal, state, or local agencies for international organizations to accomplish its mission. The Commissioned Corps of the PHS is led by the surgeon general and provides a wealth of opportunities for pharmacists.[24]

Most PHS pharmacists are members of the Commissioned Corps, with organization, structure, pay grades, and titles similar to the U.S. Navy.[25] Pharmacists who have a doctor of pharmacy degree and join the PHS are commissioned at a grade of 0–3, senior assistant pharmacist, which equals the rank of lieutenant in the Navy or captain in the Army and Air Force. PHS pharmacists who have a doctor of pharmacy and a specialty certification from the Board of Pharmacy Specialties (BPS) are eligible for extra pay.

The IHS, FDA, SAMHSA, and BOP offer extern rotations to senior pharmacy students. PHS programs have a total of 52 extern agreements with 50 schools of pharmacy. Students interested in externship assignments should contact their school externship and rotation coordinator. If the school does not have an agreement with the desired program, or with another location, have the rotation coordinator contact the appropriate program manager.

The PHS offers excellent opportunities for pharmacy students for paid employment for periods of 31–120 days throughout the academic year through the Junior Commissioned Officer Student Training and Extern Program (JRCOSTEP). JRCOSTEP participants work in the same exciting federal agencies and programs as full Commissioned Corps officers do. Typical assignments in locations throughout the country vary from 31 up to 120 days during official school breaks. Most JRCOSTEP participants are hired for the summer months (i.e., June, July, August), but other opportunities may be available throughout the year. They are not obligated to serve in the Commissioned Corps after graduation but may decide to serve an extended active duty assignment after they complete their professional education

Senior Commissioned Officer Student Training and Extern Program (SRCOSTEP) training and extern positions are available to individuals who are enrolled as full-time students in certain accredited programs with at least 8 months of educational training remaining in their final year. Applications should arrive no later than 12 months prior to graduation.

Pharmacy students should consider sending their applications 15 months before graduation to facilitate maximum sponsorship. In recent years, agencies have selected nurse, pharmacy, and physician assistant students. Applications are accepted from all Commissioned Corps eligible areas of study. In return for financial assistance, SRCOSTEP participants agree to work for the Commissioned Corps after graduation. The service obligation is equal to twice the time sponsored; that is, for 9 months of financial support, a SRCOSTEP participant commits to 18 months of employment with the division or organization that provided the support.

This program is very competitive. Applications for SRCOSTEP are due December 31 of the junior year.

DEPARTMENT OF DEFENSE

Over 1500 pharmacists work for the U.S. Army, Navy, and Air Force.

U.S. Army

The Army Medical Department (AMEDD) maintains the health of the men and women assigned to the fighting forces of the Army and provides healthcare to the family members of active duty personnel and military retirees and their families.[26] In 2017, the AMEDD had many commissioned pharmacy officers and civilian pharmacists working in the United States, Europe, Japan, Korea, Middle East, and Panama. These pharmacists are supported by enlisted pharmacy technicians and civilian technicians. AMEDD trains its own pharmacy technicians with an 18-week, structured course.

Army pharmacists are an integral part of the Army health-care team; they certainly do more than just handle prescriptions. Ambulatory care, inpatient drug distribution systems, nuclear pharmacy, oncology pharmacy, drug monitoring, and patient education services and nutrition support are just a few of the pharmacy practice activities for involvement. You could be assigned to a community hospital, an Army medical center, a troop medical clinic, or a field environment either in the United States or overseas.

Pharmacy services are provided at fixed military medical treatment facilities located on large Army installations and field hospitals. Army pharmacy is similar to civilian pharmacy except that Army hospitals often include high-volume outpatient pharmacies. Army pharmacists are being given direct patient care roles on interdisciplinary teams.

All Army pharmacists must join in field exercises to be prepared to provide services under combat. Being an Army pharmacist provides broad opportunities to gain further education and training.

One of the best opportunities for Army pharmacists is the ASHP training program that allows selected qualified candidates to basically do a customized residency. Completing such a program increases the chance to obtain more acceptable duty assignments and to advance in rank.[27]

Although rather dated, an article provides a glimpse of what it may be like to be a pharmacist in the Army.[28]

U.S. Navy

The mission of the Navy medical department is to provide prompt and effective healthcare to combat forces in times of conflict and to deliver cost-effective, high-quality services in peacetime. The Navy's health-care team delivers care to active duty personnel, retired military individuals, and family members at three naval medical centers, 26 naval hospitals, eight medical clinics, and 153 naval branch medical clinics worldwide.[29]

Complementing the Navy's land-based medical treatment facilities are deployable units: two 1000-bed hospital ships, six fleet hospitals, three medical battalions, and medical expansion assets to convert amphibious ships into casualty receiving and treatment ships.

In 2017, the Navy had many pharmacy officers on active duty along with civilian pharmacists. "Navy pharmacy is a leader on the Navy health-care team, and provides the professional expertise necessary for model pharmaceutical services for the fleet."[29]

Navy pharmacists are supported by over 1000 pharmacy technicians. The Navy has two technician training schools. The curriculum is 23 weeks long. Graduates receive the Navy enlisted classification (NEC) of Navy pharmacy technician.

All Navy hospitals have unit dose drug distribution systems or automated dispensing machines (ADMs), and complete intravenous admixture programs. Navy pharmacists use automation and a computer system that uses a universal pharmacy profile that is also used by the other military branches.

Navy pharmacists with proper education and training are encouraged to become involved in direct patient care and may be certified to perform specific direct inpatient and outpatient care. "Navy pharmacists have proven that their unique medical education provides valuable information and skills in all areas of military medicine."[29]

Although rather old, there are two articles about being a pharmacist in the Navy that may be helpful.[30,31]

U.S. Air Force

The Air Force medical service has 87 medical treatment facilities; 38 are small, 27 are medium size, and 22 are large, such as Wilford Hall Medical Center, a 500-bed facility at Lackland Air Force Base in San Antonio, Texas. The average number of beds is less than 30 at an Air Force medical treatment facility. However, the outpatient pharmacies in these facilities dispense 300 to 4000 prescriptions a day.

During combat, the Air Force typically deploys medical services through air-transportable clinics and hospitals, which are designed to be complete, efficient, and quickly mobile.

The Air Force pharmacy team consists of more than 1300 pharmacists and pharmacy technicians.[32] Most of the 257 Air Force pharmacists are commissioned officers. Air Force pharmacists are military officers first, and they continually voice the core values of the Air Force: integrity, service before self, and excellence.[33]

The Air Force pharmacy team provides timely and cost-effective healthcare to over eight million DOD beneficiaries, many of whom are elderly retirees suffering from chronic

illnesses. Pharmacists in the Air Force are focusing less on dispensing and distributive services and more on patient counseling and disease state management.

There are opportunities for pharmacists to advance through educational programs and the Air Force Institute of Technology program. Advancement in experience, education, and rank often means relocation from one facility to another. The reader may be interested in an article, "How One Hospital Pharmacist's Career Took Wing in the Air Force."[34]

Pharmacy technicians, both civilian and military, are taking on more responsibility in drug dispensing and distribution as pharmacists take on more clinical responsibility. Most Air Force pharmacy technicians are certified, and there is a 12-week course at the School of Healthcare Sciences at Sheppard Air Force Base, Wichita Falls, Texas.

Although rather old, there is a commentary on being an Air Force pharmacist is available.[35]

If you are interested in serving in the Armed Services as a pharmacist, a good place to start is at the career exploration site.[36]

Opportunities with the DOD

As you can see, the DOD, the largest U.S. employer, offers many rewarding and challenging jobs for pharmacists and technicians, as a service member or a civilian, throughout the United States and the world.[37]

DEPARTMENT OF VA

The primary objective of the Veterans Health Care Administration (VA) is to provide consistent, high-quality medical care to eligible veterans as prescribed by federal law. Other objectives include educating health-care professionals, performing basic and applied research, and offering emergency preparedness and backup to the nation in the event of a natural disaster or national emergency. There is a website for VA pharmacy careers that may be helpful.[38]

Today's VA health-care system is transforming itself from a medical center-based organization of 153 acute care centers (hospitals) and 135 nursing homes into 22 health-care networks (called VISINS) that stress primary and ambulatory care.[39]

With this has come improved roles for over 4000 pharmacists. The VA has targeted various pharmacy areas for implementation or improvement. These include staff development, prescribing authority for pharmacists, automation, design changes for the pharmacies, residency programs, and a pharmacy benefit management (PBM) product line. There is also interest in doing pharmacoepidemiological and pharmacoeconomic research in the geriatric population.

The VA pharmacy program is well known for two innovative, high-quality services: the Consolidated Mail Outpatient Pharmacy (CMOP) System and the ambulatory pharmaceutical care program, in which ambulatory care pharmacists have the ability to manage and prescribe medication for patients. Articles by Carmichael about the VA's ambulatory clinical pharmacy program may be of interest.[40,41]

CMOP System

In 1946, the VA became the first organization in the United States to provide medications for its patients using a mail delivery service through individual VA medical centers. In 1994, the CMOP at Leavenworth, Kansas, began the processing of high-volume mail prescription workloads using an integrated, automated dispensing system. Since that time the VA has expanded the program to include a total of seven CMOP facilities: (1) Leavenworth, Kansas, (2) Tucson, Arizona, (3) Chelmsford, Massachusetts, (4) Dallas, Texas, (5) Murfreesboro

(Nashville), Tennessee, (6) Hines (Chicago), Illinois, and (7) Charleston, South Carolina.[42] The VA says "In 2013 for the mail-order segment, VA was rated highest again with a score of 871 on a 1000 point scale, outpacing the mail-order pharmacy industry average of 797. This is the fourth consecutive year that VA Mail Order pharmacy has obtained the highest score on this U.S. Pharmacy Study customer satisfaction survey."[43]

The VA Mail Order Pharmacy processed 119 million outpatient prescriptions in fiscal year 2014. The Department of VA provides 80% of all outpatient prescriptions to Veterans via mail order utilizing the VA Mail Order Pharmacy, a system of seven highly automated pharmacies. The VA Mail Order Pharmacy processes 474,000 prescriptions daily and every work day over 328,000 Veterans receive a package of prescriptions in the mail. The VA utilization of VA Mail Order Pharmacy results in exceptional accuracy and lower processing costs than filling prescriptions at each VA Medical Center.[44]

Ambulatory Pharmaceutical Care

The practice of pharmaceutical care in the ambulatory care clinics of the VA may be the most advanced. As early as 1998, there were 242 clinical pharmacy specialists practicing in the 50 Veterans Administration Medical Centers (VAMCs).[45] Clinical pharmacists managed almost 30% of the clinics, most of which were therapeutic drug monitoring, anticoagulation, walk-in, or lipid management clinics. In 68% of the clinics, the pharmacists had prescribing privileges. About 77% of the clinical pharmacists had the doctor of pharmacy degree, and most were in the clinic 5 days a week.

A report in the *Journal of the American Pharmaceutical Association* provided a glimpse of the pharmaceutical care being provided by pharmacists in the ambulatory care clinics of four VAMCs[46]:

Reno, Nevada: At the Reno VAMC, the CMOP allows their pharmacists to do other things, such as practice pharmaceutical care. Pharmacists collaborate in the therapeutic management of patients in the oncology, AIDS, *Helicobacter pylori* (ulcer), lipid, and hypertension clinics. Driving the whole process is the electronic medical record allows pharmacists full access to laboratory results and records of all patient encounters.

Fort Myers, Florida: Some of the pharmacists practicing at this VAMC said things such as, "My whole focus is on making patients smarter and more informed"; "Most of the time I am pulling patients out of the jaws of therapeutic defeat"; or, "We use current [treatment] guidelines of the National Cholesterol Education Program religiously."[46]

Little Rock, Arkansas: A pharmacist at this VAMC follows about 300 psychiatric patients, most of whom have diagnoses of depression, bipolar affective disorder, schizophrenia, or posttraumatic stress disorder. The pharmacist meets with each patient for about 30 minutes and only refers the patient back to the primary care physician if the patient becomes unstable or needs assessment.

Oakland, California: In this VAMC, pharmacists are quantifying their clinical interventions in cost savings to the VA system. Software has been developed to track interventions, outcomes, and the cost impact. About 100 of the pharmacists' interventions were tracked for 3 months. Most of the interventions were for lack of a current indication and for drug therapy needed. The cost avoidance and savings projections amounted to $216,800.

Independent Prescribing Privileges

All the VA pharmacists working in the ambulatory care clinics work in ambulatory care teams. Each team is composed of a variety of providers that may include physicians, nurse practitioners, physician assistants, dieticians, and social workers. Patients are followed by their disease.

Most of the ambulatory care pharmacists in the VA have prescribing privileges, but they must use them under the protocol of the physician. This is called *collaborative practice*. However, a VAMC in West Palm Beach, Florida, may have been the first to allow its ambulatory care pharmacists to prescribe, change, or stop medications on their own authority. "Our notes are independent; our prescriptions are totally independent."[47]

The pharmacists with independent prescribing authority must have the doctor of pharmacy degree and have completed a residency in general or ambulatory care pharmacy practice. Other members of the primary care team refer patients to the pharmacist.

A Focus on Patient Outcomes

The Veterans Health Study (VHS) has as its focus the development, testing, and application of patient-centered assessments for monitoring patient outcomes in ambulatory care. One VA pharmacy service (Reno) has taken a lead in this area.[40] A publication concluded that "a system using pharmacists as independent practitioners to promote primary care has achieved high-quality and cost-effective patient care."[40]

Pharmacist Career Ladder Program

The VA department is also well known for working on career ladder programs for pharmacists. An example of such a program is at the Albuquerque VAMC, a 457-bed acute care teaching hospital with a 47-bed nursing home care unit.[48] The policy is to establish clinical privileges for all pharmacists with direct patient contact.

Some former barriers to this included inadequate instruction, not enough incentives, fragmentation of clinical services, and subjectivity of measuring competence. In response to this, a pharmacist credentialing committee created a career ladder with three levels of clinical privilege. The first level integrated basic clinical pharmacy knowledge with dispensing activities. The second level increased the number of clinical skills needed and allowed the pharmacist to act as a therapeutic consultant. The third level incorporated the skills necessary for specialty practice. Each level carries a modest pay increase over the preceding one.

Satisfaction

The satisfaction the pharmacists have with clinical privileges within the VA system can best be summarized by quotations from one of the pharmacists, Judy Siler, at the VAMC in Little Rock, Arkansas[46]:

> I wish every pharmacist could have a job like mine.
> This is the most fulfilling role for a pharmacist I've ever had.
> I see things differently now, not just appreciate the economic aspect, but the difference that medications can make in people's lives.
> I love it, the patient's love it, and the physicians and other clinicians are very supportive of my role.

FEDERAL HOSPITALS

One note before moving to other opportunities for pharmacists in the government is in order. It is about the basic pharmacy services—basic drug preparation and dispensing—within federal hospitals, which is outstanding. The American Society of Health-System Pharmacists conducted a national survey of pharmaceutical services in federal hospitals.[49] The results were impressive, with 85% of the responding hospitals offering complete unit dose services and 83% offering complete, comprehensive intravenous admixture services. Over 88% offered service to ambulatory care patients, had a computerized pharmacy system, provided drug therapy monitoring and patient education, and had a well-controlled formulary.

DRUG ENFORCEMENT ADMINISTRATION

The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substance laws and regulations of the United States. Its mission also is to bring to the criminal and civil justice systems of the United States anyone or any organization that grows, manufacturers, or distributes controlled substances through illicit traffic in the United States. It also recommends and supports unenforced programs aimed at reducing unlawful controlled substances on the domestic and international markets.

The DEA has two types of enforcement officers: special agents and diversion investigators.[50] Special agents carry weapons, work undercover, make arrests, and conduct physical surveillance. They focus on stopping the illegal import and production of controlled substances. Diversion investigators do none of these things. They focus on regulating legitimate handlers of controlled substances and investigate violations by these handlers.

The DEA employs about a dozen pharmacists with the following job titles: diversion program manager, diversion investigator, staff assistant, pharmacologist, and special agent.

WORKING FOR STATE GOVERNMENT

Pharmacists also work in various positions in state government, such as positions with boards of pharmacy; departments of public health; the Department of Social Welfare, which administers the Medicaid program; and state drug enforcement agencies.

REWARDS AND SATISFACTION

There is one common theme when discussing the rewards for pharmacists working for the government, and that is the satisfaction of helping people. Pharmacists working for the government often use terms such as *interesting*, *rewarding, satisfying*, and *making a difference*, when describing their jobs. The level and extent of pharmaceutical care in the federal government may be the highest anywhere in the country, and the leaders are the pharmacists working in the IHSs and the VAMCs. The other pharmacy services in the federal government, such as those at the NIH, are not far behind.

SUMMARY

Working for the government is frequently an overlooked career choice for new pharmacy graduates. This is probably because there has not been enough information presented to

pharmacy students. There are vast and interesting opportunities for pharmacists working for the government.

The U.S. PHS, the DOD, and the VA system in particular have been on the leading edge of pharmaceutical care and offer those with a doctor of pharmacy degree and residency opportunities that often exceed those in the private sector.

Although starting salaries for government pharmacists may not be as competitive as other opportunities, the job and retirement benefits may be superior and the job satisfaction high.

DISCUSSION QUESTIONS AND EXERCISES

1. What do you see as unique or special about working for the government as a pharmacist?
2. Some pharmacists with doctor of pharmacy degrees and advanced training (a residency, certification, or special coursework) may prescribe medication in collaboration with physicians. Does this interest you? Why or why not?
3. Based on what you have learned thus far, do you think pharmaceutical care (see Chapter 7) in government health-care facilities is more advanced, less advanced, or the same as in the private sector?
4. If you worked in a government facility as a pharmacist, would you prefer working in an acute care (inpatient) setting or ambulatory care (outpatient) setting? Why?
5. Arrange the following areas of government service in order of your interest. For example: VA > PHS > DOD > other.
   a. Department of Defense (DOD)
   b. Veterans Affairs (VA)
   c. Public Health Service (PHS)
   d. Other (DEA, federal hospitals, etc.)
6. Make an appointment to visit and interview a pharmacist who works for the government.
7. Based on what you know and what you have read thus far, what do you see as the pros and cons of being a government pharmacist?
8. Is working for the government as a pharmacist something you may want to do? Why or why not?
9. If you answered yes to question 8, would you like to work as a commissioned pharmacy officer or a civilian pharmacist?
10. If you answered "as a commissioned pharmacy officer," investigate the Commissioned Corps Website (http://www.usphs.gov).

CHALLENGES

1. Pharmacy practice in the U.S. government is progressive. After thoroughly reading this chapter, prepare a concise report for extra credit, if your professor agrees, about what you think is the best opportunity for you as a government pharmacist. Your research should go beyond what is provided in this chapter. Explain why you may pursue this opportunity by discussing the positives and negatives and end your report with the statement, "Therefore, I want to _____ because _____."
2. Pharmacy practice in the U.S. government is progressive, and pharmaceutical care may be advancing at a faster rate there than in the private sector. For extra credit,

and with the permission of your professor, explore this observation to see whether it is true and, if so, thoroughly explore and advance written arguments for why this is happening.

3. For extra credit and with permission of your professor, write a two- to three-page paper on the financial incentives for pharmacy graduates to pursue a career as a PHS or Armed Services pharmacist.

WEBSITES OF INTEREST

Agency for Healthcare Research and Quality: http://www.ahrq.gov/
Agency for Toxic Substances and Disease Registry: http://www.atsdr.cdc.gov/
Air force pharmacist: https://www.youtube.com/watch?v=Yi3Huq3sDvk
Centers for Disease Control and Prevention: http://www.cdc.gov
Department of Defense: http://www.defense.gov/
Department of Veterans Affairs: http://www.vacareers.va.gov/
Drug Enforcement Administration: http://www.dea.gov
Environmental Protection Agency: http://www.epa.gov
Federal Bureau of Prisons: http://www.bop.gov/
Food and Drug Administration: http://www.fda.gov
Indian Health Service: http://www.pharmacy.ihs.gov/
Military pharmacist: https://www.youtube.com/watch?v=9AwqFyGCVQU
Navy pharmacist: https://www.youtube.com/watch?v=kzSmydFlUJo
National Institutes of Health: http://www.nih.gov
NIH Clinical Center: http://clinicalcenter.nih.gov/
Substance Abuse and Mental Health Services Administration: http://www.samhsa.gov
U.S. Air Force: http://allpharmacyjobs.com/air_force_jobs.htm
U.S. Army: http://www.army.mil/
U.S. Navy: http://navy.com
U.S. Public Health Service Commissioned Corp: http://www.usphs.gov/
U.S. Public Health Service residency and student programs: http://www.usphs
VA pharmacist: https://www.youtube.com/watch?v=BvbqbhZIaUM
VA Patient centered care pharmacist: https://www.youtube.com/watch?v=QjNTVQfUJRU

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14 Drug Information and Poison Control

INTRODUCTION

Pharmacy emerged from its traditional dispensing and drug distribution roles in the early 1960s to a more clinical role. During this time, pharmacy also discovered it was a knowledge-based profession. Based on this discovery, pharmacy moved beyond its knowledge of the practice of pharmacy and its basic knowledge of drugs, to a greater need to help promote and achieve rational prescribing and use of drugs.

Studies revealed that drug prescribing was less than ideal. Some of the reasons for this were less emphasis on pharmacology and therapeutics in medical schools, rapid drug development, and many more published studies on drugs. Physicians had trouble keeping up with so many new drugs and with learning how these drugs fit into the overall drug therapy process. It became obvious to the profession that pharmacists could help improve therapeutics by providing unbiased, up-to-date drug information to physicians.

It was also during this time that hospital emergency rooms could no longer keep up-to-date on the ingredients in commercial products that could be harmful when ingested. The answer to this was the development of regional poison control centers. Because of the pharmacist's education and training, some pharmacists started working in these centers.

This chapter is about the provision of drug and poison information. It covers how drug information centers (DICs) and poison control centers function. Emphasis is on the process of receiving and answering questions and what it is like for a pharmacist to work in these centers.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Discuss the difference between a DIC and a drug information service (DIS).
- Identify the purpose and functions of a DIC.
- Discuss the value of a DIC.
- Compare and contrast working in a DIS in a drug company with working in a DIS in a hospital.
- Identify the purpose and functions of a poison control or information center.
- Explain some of the resources used in poison control centers to answer questions.
- Explain how a typical poison control or information center is staffed.
- Explain what it is like for a pharmacist to work in a poison control center.

DRUG INFORMATION

The term *drug information* has different meanings. Technically, drug information means "information about drugs that is printed in a reference or verbalized by an individual."[1]

Drug information can be about the drug itself or about the use of the drug. Drug information can also refer to a place (*DIC*) or to a person (*drug information specialist*).

Brief History

The first DIC was opened in the early 1960s at the University of Kentucky Medical Center.[2] The DIC was separated from the pharmacy service and was dedicated to providing drug information. The specific function was to provide comprehensive drug information to staff physicians, dentists, and nurses, and to evaluate and compare drugs. Another role of the DIC was to help educate students of the health-care professions about drugs.

Shortly after the University of Kentucky started its DIC, several DICs were started, mainly in academic health-care centers. One such center deserves mention. In the late 1960s, the DIC at the University of Michigan Medical Center received a large federal grant to study the provision of drug information and to provide a network of DICs in Michigan.[3–5]

The pharmacists working in these centers developed ways of classifying questions quickly, perform systematic searches, match resources with types of questions, and develop systems to track questions with answers. In addition, these pharmacists became knowledgeable about drugs and where to find information about drugs. Thus, in the eyes of many physicians and pharmacists, they became true *drug information specialists*. As time passed, DICs expanded services to include *drug usage evaluation* (DUE) for pharmacy and therapeutics committees and provision of continuing education about drugs through newsletters and conferences.

Drug Information Centers

During the 1970s and 1980s, DICs and DISs were started in many hospitals. A DIS is a distinct and promoted service of the pharmacy; however, the service does not have a separate area or a dedicated staff like a DIC. Most of the pharmacists take part in the DIS. In a DIC, drug information specialists provide the drug information.

DICs are found in academic health centers, community hospitals, government hospitals, managed care organizations, and schools of pharmacy and the pharmaceutical industry.[6–10] A survey in 2008 revealed there were 75 (down from 103 in 1999 and 89 in 2003) institutional DICs in the United States that met the criteria of an organized DIC.[11] The number of DICs today is strangely illusive.

Functions

The functions of most DICs are to answer drug information questions, to develop drug evaluations and comparisons for pharmacy and therapeutics committees, and to provide education about drugs. Some DICs have also evolved into drug policy development, disaster preparedness, and academic detailing.

The American Society of Health-System Pharmacists (ASHP) has guidelines on the pharmacist's role in providing drug information.[12]

Answering Drug Information Questions

The primary function of any DIC is to answer questions about drugs and drug therapy. These questions come from various people. Some DICs limit their service to health-care professionals only, whereas others also respond to questions from the public. Liability may differ for each choice.

Methods vary for receiving, researching, and providing answers to drug information questions. However, most DICs and pharmacists follow a basic pattern[13]:

1. *Receive and understand the question:* This seems easy, but it can be tricky. The basic steps in answering drug information questions are to
   a. *Identify the requester:* This is critical, especially in telephone inquiries, in case the call is disconnected. It is also important to know the caller's background: Is he or she a physician, pharmacist, nurse, or consumer?
   b. *Identify the question type:* The question type determines where to look for answers.
   c. *Get suitable background information:* Is there a patient involved? What is the diagnosis? What other drugs is the patient taking?
   d. *Reformulate the question:* It was learned early in the development of DICs that many drug information requestors do not ask what they really want to know. The adage "ask a silly question, get a silly answer" is applicable to answering drug information questions.[14] In addition, the background information uncovered may change the nature of the question.
2. *Search for data:* A search for answers to a question is based on the question type. Is it about the dose? Is it about an adverse effect? Is it about how one drug compares with another? Certain references are better than others for answering certain types of questions.[15,16] When searching for answers to questions, it is important to keep in mind these three general sources of information[17]:
   a. *Tertiary literature:* This includes textbooks and drug compendia, which should be consulted first, as they provide rapid access to information. They also familiarize the reader searching the biomedical literature by indexing and abstracting services such as Medline*, International Pharmaceutical Abstracts* (IPA), and the Iowa Drug Information System (IDIS). These services reference secondary review articles and primary literature.
   b. *Primary literature:* This contains the research articles published in professional journals. These provide specific, detailed information that is difficult to find without using the secondary literature sources.
   c. *The Internet:* This holds broad information, most of which is considered tertiary literature. However, unlike the other sources of information, the accuracy and completeness of the information cannot be guaranteed. Anyone can put anything on the Internet, whereas the other sources of health-care information must go through review by editors and peers. At best, the Internet should be considered a starting point for answering drug information questions. All information should be confirmed with a second source.
3. *Analyze data and develop a response:* Once the correct resources have been checked, the next step is to review the various sources found. The strengths and weaknesses of the various sources need to be considered. Reviewing the primary literature needs to be done carefully using *drug literature review* techniques taught in pharmacy school.
4. *Communicate the response:* Providing a response to a drug information question can be done orally (over the telephone or in person), in writing, or by a combination of the two. Talking with the person asking is always preferred, and doing it in person is better than talking over the telephone. If suitable, providing something in writing is also preferred.

5. *Follow-up:* DICs should periodically perform random checks on the quality of their DIS. The person asking the drug information question evaluates the quality of the response by judging the quality of the answer and the timeliness of the response.
6. *Documentation:* It is important for communication, quality assurance, and archival reasons to document information on the drug information question, requester, answer, and references used. Once a specific answer to the drug information question is developed, it should be documented with the references used.

The issue of quality assurance in answering drug information questions has been a long-standing interest of the profession. How accurate are the answers provided? Out of concern for the rapid growth of DICs and lack of DIC standards, a study evaluated the performance of DICs in answering a drug information question by anonymously calling each known DIC.[18,19] The quality and timeliness of responses varied widely. Similar studies were performed.[20,21] A quality assurance survey of 64 Internet pharmacies found that the percentage of correct answers to five drug information questions ranged from 7% to 96%.[22]

Another important issue in answering drug information questions is ethics. Many drug information questions, especially those from consumers, raise issues of confidentiality, truth telling, respect for the law, invasion of privacy, and social responsibility.[23] Pharmacists need to be sensitive to the ethical dilemmas often found in drug information questions.

A national survey of ethical issues presented to DICs was performed.[24] Six drug information questions, each posing an ethical dilemma, were presented to each DIC. Centers were asked if they would answer the questions, and if they would, how. The range on the willingness to answer the questions was 23%–96%. Answers to the questions varied, but overall, the pharmacists' responses suggested a high degree of moral and social responsibility.

Drug Evaluations

Another important function of many DICs, especially those in hospitals and managed care organizations, is to provide an evaluation on a drug requested for formulary status. This evaluation is in the form of comprehensive, unbiased, and comparative drug information. The basic content of a *drug evaluation* is: (1) some brief and basic information about the drug, (2) a review of clinical studies on the drug's efficacy and safety, (3) a comparison of the drug to the current formulary drug, (4) a pharmacoeconomic analysis, and (5) references.

Education

Most DICs are involved in educating health-care professionals, consumers, and pharmacy students about drugs and drug therapy. Some DICs publish drug information newsletters that include information about new drugs, highlight recently published studies, compare drugs, and print some recently received drug information questions with answers. Drug information pharmacists are often asked to present similar information at various professional meetings.

Key Resources

A fun game played among *drug information specialists* is to ask this question—If you were a drug information specialist on a remote island with 500 physicians and nurses and without electricity, what five sources of drug information would you want to have with you? Most would say

1.

2.

3.

There is an excellent guide that recommends which type of references to use based on the type of question.[25] For example, questions about

- Pharmacokinetics—(1) AHFS and (2) Facts and Comparisons
- Herbal medicines—(1) Natural Medicines and (2) Review of Natural Products
- Immunization schedules—(1) CDC website and (2) Gold Standard

Smart cellular phones are also useful devices for assessing drug information. Some smart phone applications include Lexipro, Eprocrates, and Drugdex.

Certainly, the Internet has changed everything, but is confounding. On one hand, it is a nice place to start, but in most cases, it should not be the primary source of information. It can be inaccurate, or is just opinion, rather than evidence-based.

Evidenced-Based Drug Information

A word about the quality of drug information. Secondary sources of information (such as summaries and reviews) are helpful, but when it comes to primary drug information concerning clinical studies, it is important to understand the hierarchy of evidence. The sources of information shown in the lower sections of Figure 14.1 are weak sources of evidence, while the higher the source on the pyramid, the higher the quality of evidence.

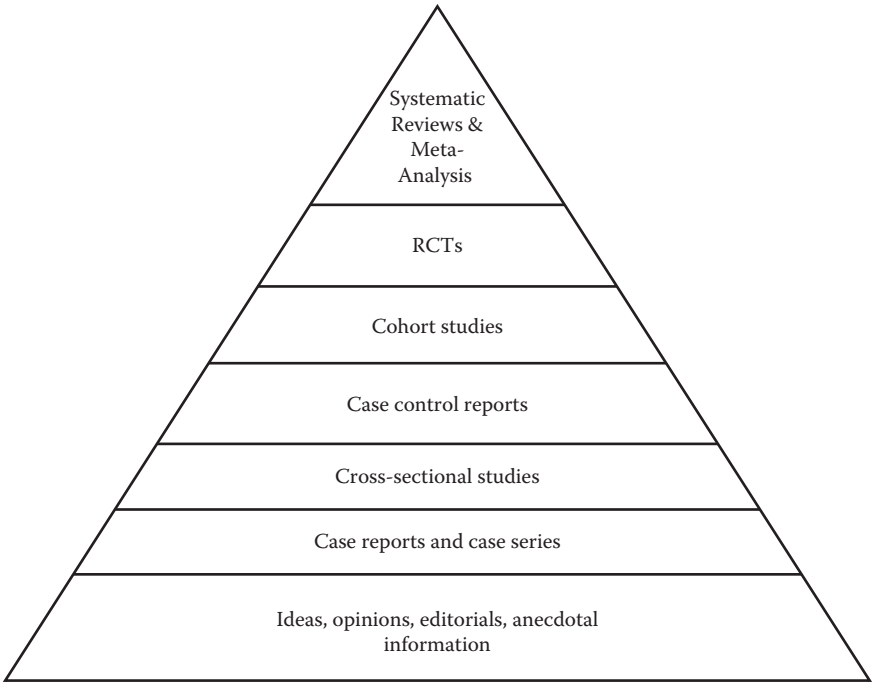

FIGURE 14.1 Hierarchy of clinical evidence.

Besides the level of the evidence, the quality of evidence must be considered. A system called GRADE is used for this purpose.[26] When the quality of evidence is as follows:

High: Further research is very unlikely to change our confidence in the estimate of effect.

- Several high quality studies with consistent results
- In special cases: one large, high quality, multicenter trial

Moderate: Further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate.

- One high quality study
- Several studies with severe limitations

Very Low: Any estimate of effect is very uncertain.

- Expert opinion
- No direct research evidence
- One or more studies with very severe limitations

Opinions should only be rendered, if asked, based on the quality and quantity of relevant evidence.

Drug Information in the Pharmaceutical Industry

The techniques used to answer drug information questions in a DIC within a pharmaceutical company are the same as used by DICs in other locations. What differs is the questions and who is asking.[27] DICs in the pharmaceutical industry handle more questions from the public, and most of their questions are about dosage and drug administration. They also receive requests for reprints of journal articles and for sample drugs. The most common requests handled by hospital-based DICs concern therapeutic use, drug efficacy, and adverse drug events.

Marketing

DICs continually need to market their services through newsletters, the development of a website, the use of phone stickers, and talking up the DIC.[28] Some exceptionally gifted DICs are located at the University of Toledo (http://www.utoledo.edu/pharmacy/druginforesources.html), and Washington State University (https://www.pharmacy.wsu.edu/facultyexperts/druginfocenter/index.html) pharmacy schools.

Some DICs have developed fee structures to provide DISs, chiefly answering questions, doing drug evaluations, or pharmacy and therapeutics committee support, to others outside their primary service area.[29,30] Some DICs have pooled their resources and have set up networks to provide service to a wide area. "By the way of a telecommunications platform and the Internet, the Drug Information Network aims to capture a greater share of the growing market for the information on drugs and health than the individual centers combined could."[31]

Value

DICs provide value by supplying up-to-date, unbiased, and timely drug information about drugs and drug therapy. The value is in the quality of the information and the time saved. One study determined the workload and impact of one DIC by measuring the number of practitioner hours saved (PHS) and the associated monetary value.[32] In a 3-month period, 308 responses were recorded, which represented 266 PHS. The economic impact, extrapolated over a 1-year period, was $43,950.

Drug information pharmacists provide added value when they effectively answer drug information questions involving judgment. This is because of the quality of the information provided. There are two basic types of drug information questions. The first is the library-type question. Library-type questions ask for a fact—a question is asked and an answer is delivered. For example, "What is the normal dose of oral furosemide in adults?" The answer is 40 mg. A drug information question involving judgment is different. For example, "I have a patient with Lyme disease. Do you think the new drug panaceamycin would be the best drug to use in this patient?" The answer is not simple and involves clinical expertise and judgment on the part of the pharmacist.

Drug Information Pharmacists

Drug information pharmacists have varied educational and training backgrounds, but most have a doctor of pharmacy degree and have completed a specialized residency in drug information. There are several drug information residencies in hospitals, schools of pharmacy, and the pharmaceutical industry. There are also drug information residencies that combine experience in industry and academia.

Although drug information residencies are considered specialized, and drug information pharmacists work in a specific area, the practice of drug information is not a pharmacy specialty. Drug information pharmacists are considered clinical pharmacists and have a strong knowledge base about drugs and drug therapy. However, they are generalists, that is, they know some information about a lot of drugs rather than knowing a lot of information about a specific pharmacotherapeutic area. An excellent commentary on drug information specialists is available.[33]

The *Drug Information Association* (DIA) is an important support system for drug information specialists. The web address for the DIA is located at the end of this chapter.

Newer Roles for Drug Information Specialists

Several new roles have emerged for drug information specialists during the last few years:

- *Disaster Preparation:* Some drug information specialists located in organized healthcare settings such as hospitals have been given the responsibility to be prepared for environmental or terrorist threats. Two excellent articles have been published on this.[34,35]
- *Drug Policy Development:* Some traditional DICs are including more of the drug policy development needed to optimize and standardize medication management efforts across the care continuum, and across multiple sites as organizations continue to grow into larger integrated delivery networks. In the near future, healthcare will be more consolidated and more centralized to maximize economies of scale. For best practices in medication management to occur, the DI center can play a leading role to create more continuity of care around medication, particularly as patients transition from inpatient to outpatient care, and also horizontally across entities in a system.
- *Academic Detailing:* Because the biased detailing about medications has become so strong, particularly in hospitals by drug manufacturers, some drug information

specialists are academically detailing physicians on the hospital staff, sometimes based on excellent data from internal *drug use evaluations*.[36]

Rewards and Satisfaction

Those who answered a survey of pharmacists who had completed postgraduate training in drug information expressed a high level of satisfaction with their career choice.[37] Most were satisfied with the geographical location, opportunities for creativity and innovation, respect from the supervisor, interactions with other professionals, autonomy, benefit-to-society, compatibility with family commitments, opportunities for advancement, and competitive salary.

Future of Drug Information

The practice of providing drug information has been changing. Drug information pharmacists are being trained better. The activities of drug information pharmacists in hospitals have broadened to include performing drug-use evaluations in health-care institutions, pharmacoeconomics, drug policy development, academic detailing, and health outcomes. In addition, drug information pharmacists have embraced information technology. These changes show how drug information pharmacists and centers are adapting to the changing health-care environment. Thus, the future is bright for this interesting area of pharmacy practice.

POISON INFORMATION

Every 13 seconds in the United States, a poison control center receives a call about an unintentional poisoning.[38] Readers may not realize some pharmacists work in these centers. Although this is an important and narrowly defined area of practice, poison control practice is yet to be recognized by the pharmacy profession as a specialty area. Thus, pharmacists who are poison information specialists are not yet eligible for board certification by the Board of Pharmacy Specialties (BPS). However, they can become a certified poison information specialist by meeting criteria of the American Association of Poison Control Centers (AAPCC).

Brief History

Before 1950, there was no formal system in the United States for poison prevention or treatment. These important works were left to hospital emergency rooms. Information about the potential poisons in various commercial products was lacking, and physicians had to treat most victims of poisoning based on patient history and symptoms.

In the 1930s, pharmacist Louis Gdalman set up a poison information service at St. Luke's Hospital in Chicago, Illinois.[39] "In 1950, our poison control center was described as nothing more than a desk, chair, and telephone located in the inpatient pharmacy." In 1953, based on recommendations of the American Academy of Pediatrics, the poison center at Presbyterian–St. Luke's Hospital was formally recognized.

The number poison centers based in emergency rooms rose to a high of 600 during the 1960s and 1970s.[40] The AAPCC was founded in 1958 with a goal of improving the treatment and outcomes of patients who are poisoned. In 1978, the AAPCC developed criteria for certification of regional poison centers. In 1983, the AAPCC took over (from the federal government) and improved the collection and analysis of poison data. Budget cuts during the 1980s and 1990s decreased the number of poison control centers in the United States.

Poison Control Centers Today

The Poison Control Program in the United States is mandated by the federal government to[41]

- Fund poison centers serving all states and territories
- Establish and maintain a single, national toll-free number (1-800-222-1222) to ensure universal access to poison control services
- Implement a nationwide media campaign to educate the public and health-care providers about poison prevention, poison center services, and the 1-800 number

In 2015, there were 55 poison control centers serving 323 million people, nationwide.[42] Most (95%) of these were AAPCC certified. The certification standards for poison control centers are extensive and rigorous.[43] Some of the requirements for certification include the provision of free service 24 hours a day, 7 days a week; questions answered by certified poison specialists; and supervision by a board-certified medical toxicologist and clinical toxicologists. There must also be public education provided.

Poison centers provide various services: telephone management advice about poison exposure of patients, telephone follow-up, poison prevention information, professional education about the recognition and management of poisoning, data collection and analysis, and community resource functions.

Statistics

In 2015, poison centers handled 2.8 million cases, about 2.2 million of which were about people coming in contact with dangerous or potentially dangerous substances.[42] Medication was implicated in 57% of the exposures. A majority (70%) of poison exposures were in children under the age of 6. In 2017, unintentional poisoning was the second-leading cause of injury in the United States, outstripping deaths by firearms for the second year in a row.

Most (87%) of the poison exposures were unintentional, and most (74%) were by ingestion. During 2017, there were more than 136,053 unintentional drug-poisoning deaths in the United States.[44] The most frequent causes of poison deaths are analgesics (11.6%), sedatives/hypnotics/antipsychotics (10.3%), and antidepressants (6.9%).[42]

Resources

Poison control center resources include computerized information systems such as *Poisindex* (Micromedex), which provides identification of poisons, ingredients, dosage, symptoms, and treatment information on exposure to drugs, chemicals, and plant and animal toxins. Other resources include textbooks on pharmacology, toxicology, industrial chemicals, plants, snakes, mushrooms, and ocular and dermal toxicology.

Cost Effectiveness

Poison control centers have been under great pressure to keep services and remain financially viable. Funding has always been a battle. Most funding comes from state budgets and host institutions. The federal government provides less than 5% of the funding needed to run poison control centers.

The AAPCC keeps good track of funding, and the poison control centers try to be cost effective. A study revealed that poison control centers are consistently cost effective.[45,46] According to the Institute of Medicine (IOM), every dollar spent on poison center services saves $7 in medical spending.[47]

Answering Poison Questions

Each poison control center has written policies and procedures on how questions are to be answered. The most important procedure is to record the telephone number of the person calling in case contact is lost. Each call is documented into an automated data collection system. Information recorded includes a history of the poisoning event, including information about the substance, amount, route of administration, time of exposure, and patient age, weight, prior medical conditions, and current symptoms.

While this is being done, information on the poison is gathered from a computerized information system. Treatment information and advice are then provided. If needed, the poison control center will call 911 for an ambulance and then the emergency department will let the staff of the hospital know to expect a patient poisoned from a certain substance.

Staffing

Individuals with specialized skills and training work in poison control centers. Staffing is likely to include[43]

- *Medical director*, who may be trained in pediatrics or emergency medicine and is usually a board-certified medical toxicologist.
- *Managing director*, who may be a board-certified clinical toxicologist. This individual usually is a pharmacist, nurse, or toxicologist.
- *Specialists in poison information*, who are the nurses, pharmacists, and physicians who answer the poison information questions. Qualifications for certification as a specialist in poison information (CSPI) have been published.[42]
- *Educators* who are individuals who may or may not have a health-care background. Educators provide poison prevention education in the community.
- *Consultants* in the community, such as mycologists (mushroom experts), entomologists (insect experts), herpetologists (snake experts), and experts in hazardous materials, water quality, and other areas are usually available to help poison control centers when they are needed.

Disaster Planning and Terrorism

If an organized health-care setting does not have a DIC that is handling disaster preparedness, this effort will usually fall on the poison center if there is one, or the pharmacy or emergency room if there is no poison center.

A 15-year follow-up study on how well poison control centers are prepared for disaster showed that most centers have a written disaster plan, are backed up by another center, regular disaster drills, and are comfortable in their ability to operate in a disaster.[48]

The Poison Information Pharmacist

The AAPCC regulations state the person who answers the poison center must be a nurse or pharmacist who is a CPIS. Although this is a career option for pharmacists, most pharmacists,

especially new graduates, do not consider it. Pharmacy schools need to do a better job of making pharmacy students aware of this option. In one study, there were 179 pharmacists working in 63 poison control centers. Of these, 108 had a Bachelor of Science degree, 7 had a Master of Arts degree, and 64 had a Doctor of Pharmacy or Philosophy degree.[40]

Rewards and Satisfaction

There are several articles about poison control work as a career for pharmacists.[49–52] These provide testimonials to the high level of satisfaction pharmacists have in working in this area. One pharmacist stated "This has been, without a doubt, the most rewarding pharmacy employment experience I have had."[53] The highlights for this pharmacist were working with other credentialed health professionals and being an integral part of a lifesaving emergency service.

Although not written by a pharmacist, a reference is provided about the experiences of a new poison information specialist.[53] The article provides an inside look at what takes place inside a regional poison control center and why poison information specialists enjoy their jobs so much.

Future of Poison Information

Although poison control centers are an essential public resource and have been shown to be cost effective, funding support will continue to be a problem. The IOM has recommended that the basic funding for poison control centers be federal.[47] It is hoped that the federal government will address the needs of poison control centers soon.

SUMMARY

Drug and poison information centers provide a useful, value-added service to health professionals and the public. Pharmacists play an important part in delivering these services. Pharmacists who work in DICs and in poison control centers provide specialized knowledge and have a high level of job satisfaction.

DISCUSSION QUESTIONS AND EXERCISES

1. What is the importance of drug information? What need does it provide?
2. Why is it important for every pharmacist to take on the role of drug information provider?
3. Select five secondary sources of drug information. Go to the library and review these resources. What are the strengths of each reference?
4. Select three electronic databases for drug information. What are the strengths of each database? Go online and learn how to use at least one of these databases.
5. While in the library, select one primary literature reference in medicine (e.g., *Journal of the American Medical Association, Lancet*, or *Annals of Internal Medicine*) and one primary literature reference in pharmacy (e.g., *American Journal of Health-System Pharmacists, Pharmacotherapy*, or *Journal of the American Pharmacy Association*). What is your opinion of these sources of drug information?
6. Make an appointment to interview a pharmacist or pharmacy resident working in a DIC.
7. What do you feel are the pros and cons of being a drug information pharmacist?

8. Based on what you know and have read thus far about being a drug information pharmacist, is this something you may want to do? Why or why not?
9. Make an appointment to interview (by telephone or in person) a poison information pharmacist.
10. What do you feel are the pros and cons of being a poison information pharmacist? Is this something you may want to do? Why or why not?

CHALLENGES

1. The number of DICs has dwindled, but the quality of the drug information personnel has improved. For extra credit, and with the permission of your professor, research and write a concise report on the number of pharmacist-operated DICs since their beginning and track volume, note various trends, and provide theories on why the number of DICs is dropping. Is this a good thing or a bad thing for pharmacy?
2. The IOM has recommended that poison control centers be funded with federal dollars. For extra credit, and with the permission of your professor, make an argument (in writing), based on facts, for the federal funding of poison control centers based on preventing deaths from unintentional poisoning.

WEBSITES OF INTEREST

American Association of Poison Centers: http://www.aapcc.org/
Drug Information Association: http://www.diahome.org/

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15 Pharmacy Academia

INTRODUCTION

At the core of pharmacy is knowledge. Various study commissions in pharmacy have confirmed this by stating that pharmacy is a "knowledge-based" profession. The knowledge starts with study, and study starts in pharmacy school. It continues, if one wishes, into graduate studies, or a residency or fellowship training. Being a pharmacist also includes a commitment to *lifelong learning*. This means pharmacists must continually keep up with the latest developments in drug therapy, changes in pharmacy laws, and changes in the profession.

The part of pharmacy responsible for much of this training is academia, which consists of 140 colleges and schools of pharmacy in the United States. Academia is also a place of scholarship and the discovery of new knowledge. It is where new ideas in the sciences and practice of pharmacy are generated and tested. In a sense, academia is the brain trust of the profession.

This chapter is about schools and colleges of pharmacy, the role of faculty in teaching and research, and the service provided by the academic pharmacy community. This chapter discusses how schools of pharmacy are structured and accredited and how curriculums are developed and assessed, and also discusses what it takes and what it is like to be a pharmacy faculty member. The broad role of faculty is given and provides an appreciation for pharmacy faculty being more than just teachers. This chapter concludes with some information on the rewards and satisfaction of pharmacy faculty members.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Provide a brief history on academic pharmacy.
- State how pharmacy schools differ.
- Discuss the issue of supply and demand for pharmacists.
- Explain how pharmacy faculty differ.
- Explain the main responsibilities of pharmacy faculty.
- Explain the scholarship of teaching.
- Define the term *lifelong learning*.
- Explain the scholarship of research.
- Explain how pharmacy faculties are evaluated.
- Discuss how satisfied faculties are working in academia.

A BRIEF HISTORY

Formal pharmacy education in the United States made slow progress before the Civil War (1861–1864). Much of the training of a pharmacist was from apprenticeship, that is, practical training directly provided by a pharmacist to a pharmacist apprentice. There was no formal pharmacy training.

There is some controversy and dispute about which college or university was the first to provide formal pharmacy coursework on a collegiate level.[1] Coursework in pharmacy may have taken place during Civil War times at what is now known as the Philadelphia College

FIGURE 15.1 A revolution in pharmaceutical education. (From Bender, GA and Thom, RA. *Great Moments in Pharmacy: The Stories and Paintings in the Series, a History of Pharmacy in Pictures, by Parke Davis & Company*. Detroit, MI: Northwood Institute Press, 1965. Courtesy of Pfizer Inc.)

of Pharmacy. In 1860, the University of Michigan (UM) (Ann Arbor) offered a laboratory course in pharmacy for medical students. In 1865, Baldwin University (Berea, OH) became the first to offer pharmacy instruction as part of a general college program. The Medical College of South Carolina (Charleston) graduated a few men in pharmacy in 1867.

In 1876, a course in pharmacy was launched at the UM in 1868 and became a separate school of pharmacy.[1] The UM was noted for its pioneering and controversial approaches to pharmacy education. Dr. Albert B. Prescott, a medical doctor, abandoned the traditional requirement of pregraduation apprenticeship and developed laboratory courses in the science of pharmacy (see Figure 15.1). The pharmacy coursework at the UM was based on a curriculum that included basic sciences that demanded students' full-time attention.[1]

SCHOOLS AND COLLEGES OF PHARMACY

Universities name their individual subunits either colleges or schools. In pharmacy, there are both. Traditionally, a college of pharmacy is part of a university, whereas a school of pharmacy is part of a college. However, today, there is basically no difference between a college of pharmacy and a school of pharmacy.

Statistics

The following statistics about schools and colleges of pharmacy have been supplied by the American Association of Colleges of Pharmacy (AACP). As of February 2017, there were[2]:

- One hundred and forty accredited colleges and schools of pharmacy (up from 82 in 2000).
- Seventy two were private institutions (up from 27 in 2000).

- One hundred and forty colleges and schools offered the doctor of pharmacy (PharmD) degree as a first professional degree. Eight colleges and schools offered the PharmD degree as a post-bachelor of science (BS) degree in 2016.
- Seventy-eight colleges and schools offered graduate programs in the pharmaceutical sciences at the master of science (MS) and/or doctor of philosophy (PhD) level.

Accreditation

The American Council on Pharmaceutical Education (ACPE) accredits schools and colleges of pharmacy. A survey team from the ACPE visits each school and college of pharmacy usually every 6 years. The ACPE makes sure the colleges and schools of pharmacy are living up to the minimum standards for higher education in pharmacy.

Structure

Few schools and colleges of pharmacy are structured exactly the same; however, there is a typical model. Every college or school of pharmacy has a dean and the chief academic officer for the school. In this capacity, the dean is accountable for all actions of the school.

Under the dean may be associate or assistant deans. They have responsibility for specific program areas. For example, there may be an associate dean for academics, one for administration, one for enrollment, and one for student affairs (sometimes called the dean of students). These assistant and associate deans may perform full-time administrative work or may also have some teaching responsibilities.

Many schools and colleges of pharmacy divide faculty into various departments, such as the department of pharmaceutical science, the department of pharmacy administration, and the department of pharmacy practice. Sometimes, the department of pharmacy administration is part of one of the other two departments. A department chairperson oversees managing the department, and there may be a vice chairperson if the department is large.

Sometimes, large departments are subdivided into various specialty areas. For example, the department of pharmaceutical science may be divided into divisions such as medicinal chemistry, pharmacology, and pharmaceutics. The department of pharmacy practice may be divided into various clinical areas, such as medicine, ambulatory care, and community pharmacy.

Other positions in academia include the director of continuing education and the director of professional affairs, both of whom may be in faculty or staff positions. Other staff positions include secretaries, work-study students, and other support staff.

PHARMACY STUDENTS

The following statistics about pharmacy students have been supplied by the AACP. In July 2016[2]:

- Professional degree enrollment was 63,460. The number of students already holding a BS degree in pharmacy and enrolled in PharmD degree programs was 936 (down from 1,931 in 2009).
- In 2015, of the total number of students enrolled in first professional degree programs, 61.4% were women and 13.6% were underrepresented minority students.

- The attrition rates (those dropping out) averaged 10.8% per year during 2010–2015.
- Total fall 2015 full-time graduate student enrollment was 4421 (3294 in PhD degree programs and 1127 in MS degree programs). Just over 51% were females, and U.S.-educated pharmacists made up 9.8% of the total PhD degree enrollment. Women accounted for 49.8% and U.S.-educated pharmacists made up 10.3% of the total full-time PhD enrollment.
- In 2014–2015, there were 13,994 first professional degrees in pharmacy, 561 PhD degrees, and 720 MS degrees awarded.

SUPPLY OF PHARMACISTS

Until recently, pharmacy academia did an excellent job of supplying the correct number of pharmacists for the profession—not too many, and not too few. However, in 2001, a group known as the Pharmacy Workforce Center predicted a shortage of 157,000 pharmacists nationally within two decades, based on the aging population and increasing responsibilities, while the number of pharmacists stood still.[3] Following this announcement, the market kicked in. There were just 72 pharmacy schools in 1987, and today there are 140. Many of the new ones are "for profit."

The National Center for Health Workforce Analysis has said that between "2012 and 2025: the pharmacist supply is projected to grow by 35 percent, while the demand for pharmacists is projected to grow by only 16 percent."[4]

Foreign Graduates—U.S. citizens who have completed their pharmacy education outside the United States are considered to be "foreign pharmacy graduates," while foreign nationals who graduated from schools in the United States are not.

For foreign pharmacy graduates to practice in the United States, the person must (a) complete an application and pass the Foreign Pharmacy Graduate Equivalency Examination (FPGEE), (b) apply for and pass the Test of English as a Foreign Language (TOEFL), and (c) apply for and pass the Test of Spoken English (TSE) before they may apply and sit for a state board exam, the North American Pharmacy Licensure Examination (NAPLEX).[5]

PHARMACY FACULTY

In the fall of 2016, there were 6346 (versus 5349 in 2009) full-time and 279 (versus 553 in 2009) part-time pharmacy faculty members at 135 (versus 114 in 2009) colleges and schools of pharmacy.[2]

Rank

Every faculty member holds a certain academic rank and is a member of an academic department. *Faculty rank* is determined objectively and is based on academic productivity: the quality and quantity of scholarly activity as documented in scientific or clinical publications, research grants and contracts, peer and recognition, and publications and recognition for teaching.

The ranks (starting with the lowest) are instructor, assistant professor, associate professor, and (full) professor. To achieve the rank of professor, the candidate usually must have achieved national or international recognition. Moving from one rank to the next rank typically takes 7 years or more.

Achieving promotion based on teaching, practice, service, and research is not an easy task. In most cases, proving productivity in the research/scholarly activity is the hardest

hurdle for junior faculty (those at the entry-level, assistant professor level). Many junior level pharmacy practice faculty on the tenure track (eligible for tenure) do not have the background in research training to do the work that is necessary to be promoted to associate professor. For example, a survey of 349 faculty members discovered that most felt they could meet the promotion requirements for teaching, service, and practice. However, fewer than half believed they were able to meet the research expectations due to lack of training in research skills.[6]

This problem is endemic and has resulted in some colleges of pharmacy putting in place junior pharmacy faculty "learning academies" to foster professional growth and long-term retention.[7]

Tenure

Tenure is the right to be in one's position permanently and is the highest achievement in academia. Higher education grants tenure to individuals proven to be academically productive and suitable for permanent status at the university where they teach and perform their research. Unlike rank, tenure is more of a "family" decision of the existing tenured faculty at a school.

Once tenure is granted, the faculty member has a job for life as long as the tenured person does not violate any major rules of the university. Three things should be noted about tenure. First, under the original idea of tenure, most academics are required to develop new knowledge. In doing this, academics explore the yet-to-be discovered, and some of their ideas can be considered unusual or strange by some, especially if the ideas contradict public or current scientific opinion. However, it is important for society that these critical minds explore new knowledge; thus, tenure is available to protect these individuals' *academic freedom*.

The second feature of tenure is that it is not available to all faculty. In most schools of pharmacy, you must hold a certain rank (associate or professor) to apply, and you must be in a *tenure track position*. The department of pharmacy practice, sometimes called the department of clinical pharmacy, may have two tracks, tenure, and nontenure. The tenure track positions in the department of pharmacy practice are for the researcher–teachers, whereas the nontenure track positions are for the teacher–practitioners.

Teacher–researchers are full-time pharmacy practice faculty at a school of pharmacy, have the PharmD degree, and probably have completed a specialty residency or a research fellowship in a specific area (e.g., cardiology, infectious disease, or psychiatry). These tenure track pharmacy practice faculty members conduct significant pharmacy research, provide a significant amount of didactic instruction, provide service to the university, and may or may not see patients or provide experiential training for students.

Teacher–practitioners are full-time or cofunded (salary partially paid by a practice site) pharmacy practice faculty who have the PharmD degree, probably have completed a general or specialty residency program, and see patients routinely. These nontenure track faculty members do a modest amount of research, do some teaching in the classroom, and provide some service to the university, but mostly provide experiential training to students at clinical sites where they routinely see patients. Teacher–practitioner faculties do not qualify for tenure.

The third feature of tenure is that if you are eligible, you must apply within a certain time frame (which varies from school to school), and if you apply and do not get it, you are provided with a 1-year terminal contract and must leave the school at the end of that year.

Faculty members in the departments, other than those in pharmacy practice, are researcher–teachers. Most have the PhD degree, and some have completed postdoctoral research fellowships. Researcher–teachers do a significant amount of research and didactic teaching and provide service to the university. All are on the tenure track.

Several other people who help teach pharmacy students are

Graduate students: Students working toward a MS or PhD degree in pharmacy sometimes teach pharmacy students in the classroom and laboratory.

Guest lecturers: An important source of teaching is the use of outside guest lecturers. These guests are able to bring the real world into the classroom. An example is inviting a practicing pharmacist–attorney into the pharmacy law and ethics course to discuss professional risk.

Residents and fellows: Pharmacists doing postgraduate residency training in pharmacy and pharmacy research fellows can provide "cutting edge" knowledge for students as well.

Adjunct pharmacy practice faculty: Practicing community, hospital, clinical, and consultant pharmacists are the backbone of the experiential program of any school or college of pharmacy. Adjunct faculty, many of whom volunteer, feel it is their duty and honor to help train pharmacy students.

Some of the newer colleges and schools of pharmacy do not have tenure.

Faculty Responsibilities

Academics have three primary responsibilities: teaching, research, and service. Some colleges include practice as a four category or include in the "service" component. How much time a faculty member devotes to each area depends on two things: the appointment (tenure track or nontenure track) and negotiation between the faculty member and the chairperson of the department.

The time of a seasoned, tenure track faculty member who is conducting a lot of research might be divided as follows: 50% research, 35% teaching, and 15% service. A new, tenure track faculty member who is just starting his or her research might have his or her time divided as follows: 30% research, 50% teaching, and 20% service. Most of the service will be active involvement in various committees of the school and active in the life of the school.

Nontenure track pharmacy practice faculty who are paid entirely by the college or school of pharmacy might have their time divided as follows: 20% research, 60% teaching, and 20% service. Most of the teaching for nontenure track faculty will be for experiential (clinical rotation) teaching. For cofunded (partially paid by a practice site and partially paid by the school of pharmacy) nontenure track pharmacy practice faculty, the faculty member's time allocation from the school might be 5% research, 40% teaching, and 55% service. Most of the service part will be maintaining an active practice site and seeing patients there.

Scholarship of Teaching

Teaching, whether it is in the classroom (didactic teaching) or providing practical training (experiential teaching), is an important function of every pharmacy faculty member. Most pharmacy faculty members take their teaching seriously. Even if they do not teach much,

pharmacy faculty members seek to improve the content and delivery of the material they are teaching. There is also a priority on being innovative and trying new things.

Each time pharmacy faculty members teach something, they learn and plan what they will do differently next time to be better. Thus, the scholarship of teaching is a continuous quality improvement process. Some authors have offered advice on how to improve and be excellent in teaching pharmacy. The 10 important features of teaching are[8]:

1. *Creativity:* In course design and delivery and motivating students
2. *Knowledge of the discipline:* More than the presentation of material involved in teaching
3. *Course design skills:* Ability to design something worthwhile
4. *Classroom skills:* Promotion of active, versus passive, learning
5. *Student evaluation skills:* Ability to write good test questions
6. *Empathy for students:* Sensitivity, supportiveness, and firmness when needed
7. *Interface with the curriculum:* Teach what every graduate needs to know
8. *Knowledge of the profession:* Up to date about the profession
9. *Effective self-management:* Ability to balance all responsibilities
10. *Sense of the future:* Having students think about the future

Another approach to improving and being an excellent teacher is to concentrate on six qualitative standards[9]:

1. *Having clear goals:* Are the basic purposes of the course stated? Are the learning objectives practical and achievable? Are important questions asked and discussed?
2. *Being adequately prepared:* Preparedness is an absolute must to be successful.
3. *Using appropriate methods:* Do the methods demonstrate the goals? Are the methods applied effectively? If something is not working, will there be a change?
4. *Achieving significant results:* How much of an impact will this course have on students?
5. *Providing an effective presentation:* Is the style suitable? Is the delivery organized?
6. *Having reflective critique:* Does the teaching scholar evaluate his or her own work?

Undergraduate Teaching

The focus of this chapter is on the PharmD degree. The pharmacy profession is changing so rapidly that the curriculum for the PharmD degree must be dynamic and innovative. Pharmacy schools should not teaching students for practice today, but for practice 10 years from now. To do this, academia needs to keep current with the direction of the profession. How is this done?

One of the strong points about pharmacy academia is its connection to pharmacy practice, to the profession's leadership, to all professional pharmacy organizations, to the government, to the pharmaceutical industry, and to other health professions. The organization that helps pharmacy schools keep up with new developments is the AACP.

The AACP is not only a listener to new topics but also a cosponsor of programs such as "Pharmacy in the 21st Century," a symposium on what pharmacy may be like in the future. Besides a council of deans (all deans of pharmacy schools) and a council of faculty (faculty representatives from each school), the AACP has various academic sections and special interest groups for faculty to come together to discuss various topics of interest and the direction of the profession.

The AACP has provided leadership and support to schools in moving toward the entry-level and nontraditional PharmD and in moving toward ambulatory and pharmaceutical care. The schools are also putting more emphasis on teaching about managed care and improving clinical practice in community pharmacies.

The starting point for any undergraduate curriculum is to develop terminal outcome objectives—what every graduate is expected to know. There are two types of curriculum outcomes: (1) professional outcomes and (2) competencies and practice outcomes and competencies.

Each of the competencies may have three advancement levels, with level 1 the easiest, but it must be mastered before going to level 2 competencies. The level 2 competencies must be mastered before moving to mastering the level 3 competencies. Figure 15.2 provides an example of a pharmacy practice learning outcome and the competencies needed to demonstrate achievement of the outcome.

Once pharmacy faculty agrees on curricular outcomes, the next step in building the curriculum is to develop a topic outline on how to teach the various competencies represented in the document for the curricular outcome. Once the faculty agrees on the topic outline, the topics can be arranged into various courses. Thus, all learning flows from what every graduate needs to know: the curricular outcomes.

Outcome: The graduate will be able to collect and evaluate patient data to properly assess patients and to determine appropriate courses of action such as prescription drug therapy, nonprescription drug therapy, non-drug therapy, or referral to another healthcare professional.

Level 1 Competencies:

a. Collect and organize patient data into a format that facilitates making decisions to meet the patient's healthcare needs.
b. Use appropriate interviewing and patient assessment skills to assess the patient's health status.
c. Recommend appropriate non-pharmacological treatment to meet the self-care needs of the patient.

Level 2 Competencies:

a. Select information from the patient record or profile that the pharmacist may need to make decisions on determining a patient's healthcare needs.
b. Obtain necessary additional information from a healthcare professional to address a patient's healthcare needs.
c. Assess pertinent patient data to determine a patient's healthcare needs related to the presenting problem.
d. Record information related to identification, resolution, or prevention of medication-related problems in individual patients.
e. Develop and conduct health screening, promotion, and prevention programs.

Level 3 Competencies:

a. Devise a plan for meeting healthcare needs related to the patient's presenting problem.
b. Devise a methodology for documenting recommendations based on professional and practical considerations.
c. Determine when other health professionals are most appropriate for managing the patient's healthcare needs.

FIGURE 15.2 An example of one pharmacy practice outcome and the competencies needed to demonstrate its achievement.

The curriculum of each school and college of pharmacy is unique. It is unlikely that the curriculum of any school is exactly like that of another. The curriculum will be different if one school of pharmacy has a 0-to-6 program (all 6 years of pharmacy in one place) and another has a 2-to-4 program (2 years of prepharmacy and then 4 years of pharmacy school). An example of the four professional years of one pharmacy school is shown in Figure 15.3.

A current curricular strategy in some schools and colleges of pharmacy is to integrate some of the coursework. This means that rather than learning individual topics such as physiology, pathology, pharmaceutical chemistry, pharmacology, pharmacokinetics, and therapeutics, the coursework is divided into various diseases, and the student learns all of these topics by disease. This means the courses will be team taught by faculty members from several disciplines and several departments.

For example, when studying cardiovascular disorders, one topic will be angina. Someone from pharmacy administration will discuss the occurrence (epidemiology) of angina. Next, instructors from the department of pharmaceutical science will discuss the anatomy and physiology of the coronary arteries, the pathology of angina, and the chemistry and pharmacology of the drugs used to treat the various forms of angina. Next, members of the department of pharmacy practice will discuss the pharmacokinetics and the therapeutics in treating angina. Last, a faculty member from the department of pharmacy administration will discuss the health outcomes associated with treating angina.

Another new curricular idea is to teach one course at a time rather than have the student be responsible for four to five courses throughout one semester. The idea of one course at a time allows the student to be devoted to one learning subject and lessens the problem of students only studying when there is a test. The Mercer University School of Pharmacy in Atlanta has mastered this type of scheduling and most students love it.

Accelerated Pharmacy Education

Some colleges of pharmacy have experimented with a year-around approach that can lead to commencement in 3 years. Here is a partial list of colleges that offer these programs:

- Albany College of Pharmacy—Albany, NY
- Duquesne University—Pittsburgh, PA
- Ferris State University—Big Rapids, MI
- Lake Erie College of Osteopathic Medicine—Erie, PA
- Massachusetts—Worchester, MA
- Midwestern—Glendale, AZ
- Pacific University—Hillsboro, OR
- South University—Savannah, GA
- University of Appalachia—Oakwood, VA
- University of the Pacific—Stockton, CA
- University of South Nevada—Henderson, NV

The jury is still out on whether these accelerated programs are a good or a bad idea.

External PharmD Degree

As schools and colleges of pharmacy have made a decision to provide the PharmD degree as the only entry-level degree in pharmacy, there has been a need to provide ways for practicing

First Professional Year	Semester Hours	
Course	**Fall**	**Spring**
Introduction to Pharmacy	2	
Research Design and Literature Evaluation	2	
Communication Skills for Pharmacists	3	
Pharmacy Law and Ethics	2	
Principles of Pharmaceutical Sciences	3	
Medical Immunology	3	
Introduction of Pharmacy Practice Experience I	1	
Practice of Pharmacy I	2	
	18	
Health Care Delivery		2
Leadership and Advocacy in Pharmacy		2
Pharmacy Management		3
General Principles of Pharmacotherapy		2
Pharmaceutics		4
Principles of Pharmacokinetics		2
Introductory Pharmacy Practice Experience II		1
Practice of Pharmacy II		2
		18

Second Professional Year	Semester Hours	
	Fall	**Spring**
Nervous System Disorders I	5	
Nervous System Disorders II	4	
Integument and Special Senses	3	
Pharmaceutics Laboratory	1	
Elective I	2	
Introductory Pharmacy Practice Experience III	1	
Practice of Pharmacy III	2	
	18	
Cardiovascular/Renal Disorders I		5
Cardiovascular/Renal Disorders II		5
Cardiovascular/Renal Disorders III		4
Elective II		2
Introductory Pharmacy Practice Experience IV		1
Practice of Pharmacy IV		2
		18

Third Professional Year	Semester Hours	
	Fall	**Spring**
Musculoskeletal Disorder and Pain	5	
Endocrine Disorders	5	
Gastrointestinal Disorders	3	
Elective III	2	
Introductory Pharmacy Practice Experience V	1	
Practice of Pharmacy V	2	
	18	
Pulmonary Disorders		3
Infectious Disease I		4
Infectious Disease II		3
Hematology/Oncology		3
Elective IV		2
Introductory Pharmacy Practice Experience VI		1
Practice of Pharmacy VI		2
		18

Fourth Professional Year	Semester Hours
Advanced Pharmacy Practice Experiences	
Community Pharmacy Practice	5
Institutional Pharmacy Practice	5
Acute Care Pharmacy Practice	5
Acute Care Pharmacy Practice	5
Ambulatory Care Pharmacy Practice	5
Elective I	5
Elective II	5
Elective III	5
Pharmacotherapy Case Conference	1
	41

FIGURE 15.3 A typical curriculum for four professional years in pharmacy school.

pharmacists with BS degrees to earn a PharmD degree.[10] As it is difficult for practicing pharmacists to take 4 years to attend a full-time, on-campus PharmD program, some schools and colleges of pharmacy have developed nontraditional PharmD degree programs for practicing pharmacists. The term *nontraditional* means the learner is an adult, and the delivery of the program is nontraditional.

A nontraditional PharmD degree program is a structured, flexible educational program for practicing pharmacists to earn a PharmD degree. The curricular outcomes of a nontraditional PharmD degree program and an on-campus PharmD degree program are the same: to graduate, the learner or student needs to demonstrate all the competencies in order to demonstrate the outcomes. As most nontraditional PharmD degree students are practicing pharmacists, many already have some of the needed competencies for the PharmD degree but need to demonstrate these before they are allowed credit toward the degree. Thus, in some of the nontraditional PharmD degree programs, the course of study is individualized and specific to those competencies needed.[11]

Graduate Education

Besides providing the entry-level PharmD degree, colleges and schools of pharmacy provide graduate education in various pharmacy disciplines. A majority of the colleges and schools of pharmacy in the United States offer the MS and the PhD degrees, usually in pharmacy administration or pharmaceutical science.

In pharmaceutical science, the main areas of concentration are pharmacology, toxicology, pharmaceutics, medicinal chemistry, and pharmacokinetics, but there are other areas as well (Figure 15.4). In pharmacy administration, there can be a concentration on pharmacoeconomics and health outcomes research.

Besides coursework, there is usually a *thesis* requirement (a formal, lengthy research paper) for the MS degree, whereas a *dissertation* (a formal, lengthy report exploring original research) is required to earn a PhD degree.

People earning a MS or PhD degree in pharmaceutical science work in academia (pharmacy schools), as research scientists in the pharmaceutical industry, or in the government (U.S. Food and Drug Administration [FDA], Centers for Disease Control and Prevention [CDC], National Institutes of Health [NIH]). A position in academia provides more variety (teaching, research, and service), whereas the other positions are mostly predominately research.

People suited for graduate degrees in pharmaceutical science like science classes and want to pursue a science-based career. These individuals like the laboratory, and they would like to contribute to the health and well-being of society through developing medicines and therapies. An example of a curriculum for a PhD degree in pharmaceutical science is provided in Figure 15.4. To qualify, a person must have earned a previous degree, such as a BS degree. The previous degree requirement varies from school to school.

A person holding a MS or PhD degree in pharmacy administration usually works in academia (pharmacy schools) or for a pharmaceutical company or private company doing pharmacoepidemiology, pharmacoeconomics, or health outcomes research.

Further information on careers in the pharmaceutical sciences is available.[12]

Delivery Strategies for Pharmacy Education

Early studies have shown that lecturing may be the worst way to teach.[10] The teacher provides words of wisdom, and the student records what she or he thinks is important (most students

Core Curriculum	Semester Hours
Introduction to Pharmaceutical Sciences	3
Isotope Techniques	3
Research Techniques I	3
Research Techniques II	3
Quantitative Aspects of Drug Action I	3
Quantitative Aspects of Drug Action II	3
Pharmaceutical Biotechnology	3
Seminar	3
Subtotal	21
Elective Coursework	14
Dissertation	35
Total	70

FIGURE 15.4 An example of curriculum for a PhD in pharmaceutical science.

think every word is important). Then, most students try to memorize their notes before an examination. Once the exam is over, there is a "brain dump," and the student moves on to studying in the same manner for the next examination. This is no way to learn and to remember what is important.

There is a strong feeling, based on good studies, that active learning and self-learning are the best ways to learn. To do this, the professor should be more of a "guide from the side" than a "sage from the stage."

Active learning means the learning is student focused, rather than faculty focused, which means getting students involved in their learning rather than letting them be passive learners.[10] Pharmacy students should be able to learn by doing, thinking critically, and problem solving. To do this, students will need to learn most of the course content by reading and by reviewing selected cases before coming to class. In this manner, the professor can take the course and the class to the next level—discussion and application of the course content.

Self-learning can be carried out by reading required texts and journal articles or by learning material a professor places on a CD-ROM or on the Internet. A review of case studies and preparation to discuss the cases in class are also effective learning strategies.

Besides reviewing cases, various techniques can be used to promote active learning in the classroom. Application exercises can be designed for students to work in small groups. The application exercise is used to see if the students have the ability to apply what they have learned from their reading and self-learning.

Another active learning strategy is the use of *problem-based learning* (PBL), which employs a problem as the vehicle for learning. The problem is relevant to future tasks that will be performed as a clinician and serves to guide the student in self-directed learning. Learning results from the process of working toward understanding a clinical problem. This stimulates the student to use reasoning skills and to search for information and possible ways to solve the problem.

The goals of these strategies are to make the learning "student focused"; to encourage students to think critically; to solve problems, to learn on their own; and to promote *lifelong learning*.

For the experiential part of the pharmacy curriculum, it is now recommended by the *Accreditation Council for Pharmacy Education* (ACPE) that there be experiential training in all four professional years of the PharmD degree curriculum. In some schools of pharmacy, students in their first professional year (P1s) gain *introductory pharmacy practice experience* while shadowing students in their fourth professional year (P4s), who spend their entire year on various *advanced pharmacy practice experiences*. However, shadowing is only a descriptive term, as all pharmacy students need to learn by doing during experiential clerkships rather than just observing.

Students in their second professional year (P2s) may gain introductory experience in community pharmacy practice, whereas students in their third professional year (P3s) might gain introductory experience in hospital pharmacy practice. This varies from school to school.

Assessment and Evaluation

Teaching and learning are not complete without adequate assessment and evaluation of the teaching and learning. The assessment of student learning is accomplished by testing. This is the most objective method of assessment, and if the testing instrument is constructed properly, the assessment is valid. Experiential training, especially during the fourth professional year, can be assessed by evaluating professional and clinical competencies, as stated in the *curricular outcomes* outlined in the curricular outcomes document of the school.

Evaluation of teaching takes two forms: evaluation by the students of the course and evaluation of the faculty teaching the course. Most students underestimate the power of their input and the value schools of pharmacy place on these evaluations. The outcomes of the course evaluation can result in major changes in course design.

Student and peer (other faculty member) evaluations of individual faculty are used by the faculty member's department chairperson to evaluate the faculty member for teaching effectiveness and to address changes the faculty member may need to make to be a more effective teacher. Evaluating a faculty member's teaching is part of the overall annual evaluation of the faculty member by the chairperson, and the evaluation directly affects the faculty member's merit increase for the coming year.

The Scholarship of Research

Most pharmacy students think of pharmacy professors only as teachers. Many students assume that when they are off from school (spring break and summer vacation), so are their professors. The truth is that most pharmacy faculty members have full-time, year-round appointments. That is because most professors spend less than half of their time teaching. They must also perform research and provide service. Most tenure track faculty spends as much time in research as they do in teaching.

The *research* performed by a pharmacy faculty member is dependent on the credentials of the faculty member, the position he or she holds (tenure track or nontenure track), and the extent of external funding he or she has for research. It also depends on how much support (school, graduate students, or fellows) the faculty member has to do the research and his or her agreement with the department chairperson. The time spent on research, teaching, and service is renegotiated each year based on the needs of the school and the goals of the faculty member.

Pharmacy students need to understand a few things about the research their professors are conducting. First, tuition money is not used to support pharmacy research. The money for research comes from pharmaceutical companies, government agencies, and private foundations.

It is the job of the pharmacy faculty to find funding for their research, and this is not an easy task. Faculty must write grant proposals to be funded, and the competition is stiff.

Second, the quality of the research undertaken by faculty members and their graduate students and fellows in the schools and colleges of pharmacy in the United States is high quality, every bit as good as those working in the pharmaceutical industry and the government.

Third, students benefit a great deal from the research ideas pursued by their professors. Many times, continuing aspects of research performed by professors are shared with students. In these situations, the students receive the latest information about a topic. This is because professors must be well read and versed on what everyone else is doing in their area of interest.

The outcomes of research are publishing the results in a reputable journal and presenting the results at professional meetings. To do this, the research is carefully reviewed by a group of peers to ensure that the work was done according to well-accepted research techniques.

Service

Pharmacy faculty members are also obligated to provide service. Service has several components:

Service to the university: To run effectively, a university needs continual input from its faculty. It gets this by having various university committees, many of which are composed of faculty members. Examples of a few university committees are the faculty (House of Delegates), the university benefits committee, and the institutional review board (IRB).

Service to the school of pharmacy: Like the university, a school of pharmacy also has various committees composed of faculty. Some important committees are the curriculum committee, the promotion and tenure committee, and the faculty advisory committee.

Service to the faculty member's department. A faculty member's department may also have several standing committees and ad hoc task forces to which faculty members are appointed or volunteer their services.

Service to the profession: Pharmacy faculty members are often part of various international, national, state, and local professional pharmacy organizations, serving as officers, chairpersons, or members of a committee. Faculty members also make presentations at meetings of these organizations. Some faculty members serve as reviewers of manuscripts submitted to professional publications, including scientific and clinical journals and books.

Service to practice: Some pharmacy practice faculty will have some of their time assigned to mentoring students on introductory or advanced practice experiences. Faculty members who are pharmacists should practice pharmacy to keep their skills up to date and to be able to introduce practical examples when teaching.

Service to the community: Unlike service to the profession, faculty members are not required to provide service to the community. However, universities are a part of a larger community. Therefore, if faculty members perform service to the community, they receive credit as it brings honor to the university.

FACULTY EVALUATION

Department chairpersons evaluate their faculty members in most schools and colleges of pharmacy on a routine basis. However, the process varies widely from school to school.

The criteria for the review involve how well the faculty member performed his or her teaching, research, and service. The evaluation document may be a faculty member's plan for the year, as agreed to by the faculty member's chairperson. For example, there may have been agreement on the extent and quality of teaching performed, the amount of research, the number of publications and grants submitted and approved, and the extent of service. This assessment has bearing on annual increases in salary and provides feedback to the faculty member on the possibility of promotion and tenure.

JOB SATISFACTION

There has been concern about job turnover among pharmacy faculty for some time. One study determined that a pharmacy faculty member's decision to remain or leave an institution is dependent on developing a sense of commitment toward the institution.[11] This commitment is facilitated by the amount of support from the institution and department chair, and satisfaction with the teaching environment.

In 2015, a survey answered by 811 of 4787 (16.9% response) pharmacy faculty members in the United States, found high levels of job satisfaction among responders, but lower levels of satisfaction with work-life balance and comparable levels of stress to the general population.[13]

Another survey concerning job satisfaction sent to 1000 pharmacy faculty, and answered by 266, revealed moderate levels of job satisfaction.[14] Global and salary satisfaction improved with higher salary levels. Low-to-moderate levels of satisfaction were found among female faculty members versus males for having time for family and personal needs. Pharmacy practice faculties were significantly more satisfied with working in an intellectually challenging environment compared with nonpractice-related faculty.

PREPARATION FOR AN ACADEMIC CAREER

Being successful in academia means more than just having the educational and training requirements to be a member of the academy. Successful academics are outstanding teachers, scholars, and service providers. Successful academics like to pursue new knowledge and possess superb library, writing, and presentation skills. They like dealing with data. They are also lifelong learners, not only in pharmacy and science but also in the arts.

To be the most successful in academia, it is recommended that pharmacist considering a tenure track position have a (1) PharmD, (2) a general practice residency (PGY1), and (3) a 2-year research fellowship. For those applying for a nontenure track faculty position, completing steps 1 and 2 above are recommended.

SUMMARY

A career in academia can be challenging and rewarding. Although academia does not offer the financial rewards that come with positions in practice and in industry, it has other satisfying rewards. Academia offers diversity and flexibility. It also offers the satisfaction of seeing students learn and grow and discover the joy of being part of a health-care team.

Professors are widely respected individuals, who are usually interesting people, in that they are often well read and traveled, and academia is a wonderful place for intellectual pursuit, exchange, and stimulation.

DISCUSSION QUESTIONS AND EXERCISES

1. Designate your level of interest (1 = low, 10 = high) for the following academic functions:
   a. Didactic, classroom teaching
   b. Research (basic science, clinical, or pharmacy practice)
   c. Experiential teaching (teaching students on pharmacy practice rotations)
   d. Academic administration or service or practice (working with patients)
   e. Practice (working with patients)
2. In regard to teaching, do you like to
   a. Help people learn new things?
   b. Help people problem solve?
   c. Help people think critically?
   d. Help people apply new knowledge?
3. In regard to research, do you like
   a. Solving puzzles?
   b. Designing experiments?
   c. Collecting data?
   d. Analyzing data?
   e. Writing?
   f. Making presentations?
4. What proportion (percentage) of time, if any, would you like to spend working with patients?
5. If you were a pharmacy faculty member, how would you prefer to spend your time? For the following five areas, assign percentages of time to each. The total must add to 100%. Didactic teaching (____%), experiential teaching (____%), research (____%), service (____%), and practice (____%).
6. Faculty members of a school of pharmacy are supposed to be *academics*, and academics are supposed to be *scholars*. What do these terms mean?
7. Make an appointment to interview at least two of the following:
   a. A tenure track basic science faculty member
   b. A tenure track faculty member in pharmacy administration
   c. A tenure track faculty member in pharmacy practice
   d. A non-tenure track faculty member in pharmacy practice
8. What do you see as the pros and cons of academic pharmacy?
9. What do you think is the greatest reward of being a pharmacy professor?
10. Based on what you know and have read thus far, does academic pharmacy interest you? Why? Why not?

CHALLENGES

1. Pharmacy needs more students in graduate programs (pharmaceutical science and pharmacy administration). For extra credit, and with the permission of your professor, look into the graduate courses at your college of pharmacy and write a concise paper on how schools of pharmacy can attract more undergraduate students into their graduate programs.
2. You will never really know what it is like to be a professor of pharmacy unless you take a didactic elective or senior rotation in academic pharmacy. If your school of

pharmacy does not have either of these experiences available, for extra credit, and with the permission of your professor, find an interested pharmacy professor you can shadow for at least 8 hours and write a concise report of your experience.

WEBSITES OF INTEREST

Accreditation Council for Pharmacy Education: http://www.acpe-accredit.org/
American Association of Colleges of Pharmacy: http://www.aacp.org
American Foundation for Pharmaceutical Education: http://www.afpepharm.org

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16 Pharmacy Organizations

INTRODUCTION

From its beginning, the pharmacy profession formed groups of pharmacists that shared common interests and concerns. At first these groups (mostly in Europe) were called guilds. Guilds eventually became associations. Now, these groups are called *professional organizations*. Pharmacy organizations are important to current and future practitioners as they help define, defend, and promote the profession.

This chapter provides brief histories about pharmacy organizations, explains what they do, and discusses the kinds of organizations and why they are important. The importance of pharmacists joining pharmacy organizations is also discussed, and several pharmacy organizations are highlighted.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Define a professional pharmacy organization.
- Discuss some brief history of pharmacy organizations.
- Provide two roles for pharmacy organizations.
- Name at least three types of pharmacy organizations.
- State the importance of joining pharmacy organizations.

A BRIEF HISTORY

Before the colonization of America, various European trade professions banded together into *guilds*. Pharmacy guilds provided a way for apothecaries and chemists to gather to discuss items of common interest, share medicinal recipes, settle on how young apprentices should be trained, and keep the profession together. Pharmacy guilds often received royal or city sanctions.[1] Associations formed from guilds and were organized for economic, social, professional, and scientific purposes. Thus, it was natural for the first chemists and apothecaries in the United States to form associations when they came here from Europe and elsewhere.

Few chemists and apothecaries existed during colonial times in the United States. Physicians dispensed most of the medicine. In early 1821, John Redman Coxe, a prominent professor at the University of Pennsylvania, was concerned about the varying skills among chemists, apothecaries, and druggists in Philadelphia.[2] He made a suggestion "to which 16 prominent Philadelphia druggists affixed their signatures, proposing that an honorary degree be granted to such apothecaries 'as they have taken every measure to become perfect masters of their profession'."[2] This action by the University of Pennsylvania roused the indignation of those druggists not granted the honorary degree.

A committee was appointed by the university to look further into this matter. One of the recommendations of the committee was to set up a College of Apothecaries. This college was founded on March 13, 1821, as the first recognized professional pharmacy organization in the

FIGURE 16.1 The American Pharmaceutical Association, 1852. (From Bender, GA and Thom, RA, *Great Moments in Pharmacy. The Stories and Paintings in the Series, a History of Pharmacy in Pictures, by Parke Davis & Company*, Detroit, Northwood Institute Press, 1965. Courtesy of Pfizer Inc.)

United States. About a year later (March 20, 1822), the name was changed to the Philadelphia College of Pharmacy.

Soon, cities such as Boston (1823) and New York (1829) formed their own local pharmacy associations.[3] In 1852, the American Pharmaceutical Association (APhA) became the first national pharmaceutical organization in the United States (Figure 16.1).[4] Under the APhA (now the American Pharmacist Association), statewide pharmacy organizations started to grow; the first one was in Maine in 1867.

National pharmacy organizations that followed the APhA included the National Wholesale Druggists Association (NWDA) in 1882, the National Retail Druggists Association (NRDA) in 1883, and the National Association of Retail Druggists (NARD) in 1898. The National Association of Boards of Pharmacy was formed in 1904, the National Chain Store Association (NCSA) in 1933, the American College of Apothecaries in 1940, and the American Society of Hospital Pharmacists in 1942. Relatively new national pharmacy organizations include the American Society of Consultant Pharmacists (formed in 1969), the American College of Clinical Pharmacy (formed in 1979), and the Academy of Managed Care Pharmacy (formed in 1988).[3,5]

THE ROLE OF PHARMACY ORGANIZATIONS

Most pharmacists do not have the time nor the financial resources to attend to the current conflicts or opportunities facing the profession. Pharmacy organizations can help in this area. “Organized associations are to pharmacists what government is to its citizens. They represent, protect, and propagate the profession of pharmacy.”[6]

Each pharmacy organization has a constitution, bylaws, a statement of beliefs, a mission statement, and sometimes a vision statement to govern the organization. Most pharmacy organizations are member driven and have elected officers and full-time staff members.

William A. Zellmer has set forth the argument that national pharmacy organizations play a role in transforming the profession, and he uses pharmaceutical care to state his case.[6] Zellmer's view is that national pharmacy organizations have played a critical role in diffusing the idea of pharmaceutical care deeply into the profession, and time will show that pharmacy organizations are effective change agents for pharmaceutical care.

THE IMPORTANCE OF MEMBERSHIP

It is important for pharmacists to belong to pharmacy organizations. "After investing time and money in pharmacy school, pharmacists should ensure their place on the health-care team by joining a professional association," said Patricia Poole, who was a pharmacy student at the time she wrote that statement.[6]

As reported in *American Pharmacy*, and based on information from a report by Schering Laboratories, "Inside Pharmacy: The Anatomy of a Profession," pharmacists belonging to a national pharmacy association said they were very satisfied with work in general (52%) compared to nonmembers (31%).[7] Members of pharmacy organizations were also satisfied in dealing with patients and had status and pride as pharmacists. When asked about their reasons for joining a national pharmacy organization, pharmacists cited education and training, financial benefits, social benefits, and influence on legislation.[8]

PHARMACY ORGANIZATIONS

Pharmacy organizations can be divided into five types: (1) practitioner organizations, (2) educational organizations, (3) special interest organizations, (4) trade organizations, (5) pharmacy technician organizations, and (6) other organizations. The following is a comprehensive, but not exclusive, descriptive summary of various national pharmacy organizations.

Pharmacy Practitioner Organizations

The following are organizations in which the active members are primarily pharmacists:

American College of Apothecaries (ACA)

2830 Summer Oaks Drive
Bartlett, TN 38134
http://acainfo.org/
(901) 383-8119
(901) 473-8187 (fax)

The mission of the ACA is dedicated to advancing the entrepreneurial spirit of member pharmacists through education, innovation, mentoring, fellowship, and training.

American College of Clinical Pharmacy (ACCP)

13000 West 87th Street Parkway
Lenexa, KS 66215-4530
http://www.accp.com
(913) 492-3311
(913) 492-0088 (fax)

The ACCP is a professional and scientific society that provides leadership, education, advocacy, and resources enabling clinical pharmacists to achieve excellence in practice and research.

Academy of Managed Care Pharmacy (AMCP)

675 North Washington Street, Suite 220
Alexandria, VA 22314
http://www.amcp.org
(703) 684-2600
(703) 684-2651 (fax)

The AMCP is a national professional society dedicated to the idea and practice of pharmaceutical care in managed care environments. AMCP represents over 9000 pharmacy professionals, including students, serving the unique medication needs of the senior population.

American Pharmacists Association (APhA)

2215 Constitution Avenue, NW
Washington, DC 20037-2985
http://www.pharmacist.com
(202) 628-4410
(800) 237-2742
(202) 783-2351 (fax)

The APhA is a national professional society for pharmacists. The APhA is dedicated to improving public health by helping its members and strengthening the profession of pharmacy. Currently, the APhA has more than 63,000 members.

American Society of Consultant Pharmacists (ASCP)

1321 Duke Street
Alexandria, VA 22314-3563
http://www.ascp.com
(800) 355-2727 or (703) 739-1300
(703) 739-1321 (fax)

The ASCP is an international professional association that provides leadership, education, advocacy, and resources to advance the practice of senior care pharmacy. Currently, the ASCP has more than 9000 pharmacist members.

American Society of Health-System Pharmacists (ASHP)

7272 Wisconsin Avenue
Bethesda, MD 20814
http://www.ashp.org
(866) 279-0681
(301) 657-1251 (fax)

The ASHP represents pharmacists who practice in hospitals and other parts of health-care systems. The history of the organization has been documented.[9] The ASHP currently has more than 43,000 members.

International Academy of Compounding Pharmacists (IACP)

4638 Riverstone Boulevard
Missouri City, TX 77459
http://www.iacprx.org
(281) 933-8400
(281) 495-0602 (fax)

Since 1991, the IACP has fought to protect, promote, and advance the art and skill of the compounding pharmacy profession. IACP represents more than 4000 pharmacists, physicians, technicians, and patients who are committed to practicing quality pharmacy compounding.

National Community Pharmacists Association (NCPA)

100 Daingerfield Road
Alexandria, VA 22314
http://www.ncpanet.org
(703) 683-8200
(800) 544-7447
(703) 683-3619 (fax)

The NCPA represents the pharmacist owners, managers, and employees of nearly 22,000 independent community pharmacies across the United States.

National Pharmaceutical Association (NPhA)

107 Kilmayne Drive, Suite C
Cary, NC 27511
http://npha.net
(877) 215-2091
(919) 469-5858 (fax)

The NPhA is dedicated to representing the views and ideas of minority pharmacists on critical issues affecting healthcare and pharmacy. The NPhA seeks to serve as a role model, through its members, for minority youth and vigorously supports their recruitment into the profession.

Joint Commission of Pharmacy Practitioners (JCPP)

2215 Constitution Avenue, NW
Washington, DC 20037
https://jcpp.net/
(202) 429-7549

The JCPP is a federation of national pharmacy practitioner organizations: AMCP, ACA, ACCP, APhA, ASCP, ASHP, and NCPA. Nonpractitioner organizations, including AACP, NABP, and NCSPAE, are liaison members. The JCPP meets quarterly to examine current issues facing the profession and explores whether they wish to collaborate on any issues.

National Alliance of State Pharmacy Associations (NASPA)

2530 Professional Road
Richmond, VA 23235
http://www.ncspae.org/
(804) 285-4431
(804) 285-4227 (fax)

The mission of the NASPA is to enhance the professional management of state pharmacy associations and to facilitate communication and activities related to issues of common concern among our state association members.

Educational Organizations

The following organizations are exclusively involved with education or the accreditation of education for students in pharmacy schools or pharmacists:

Accreditation Council for Pharmaceutical Education (ACPE)

135 S. LaSalle Street, Suite 4100
Chicago, IL 60603-4810
http://www.acpe-accredit.org
(312) 664-3575
(312) 664-4652 (fax)

The ACPE is a national agency for the accreditation of professional degree programs in pharmacy and providers of continuing education (CE). The ACPE is an autonomous and independent agency whose board of directors is drawn from AACP, APhA, NABP, and the American Council on Education (ACE).

American Association of Colleges of Pharmacy (AACP)

1727 King Street
Alexandria, VA 22314
http://www.aacp.org
(703) 739-2330
(703) 836-8982 (fax)

The AACP is a national organization representing the interests of pharmaceutical education and educators. It is composed of 135 U.S. pharmacy colleges and schools, including more than 6000 full-time faculty, and 279 part-time faculty.

American Foundation for Pharmaceutical Education (AFPE)

6076 Franconia Rd., Suite C
Alexandria, VA 22310-1758
http://www.afpenet.org
(855) 624-9526 (toll free)
(703) 875-3095
(703) 875-3098 (fax)

The AFPE is the only U.S. organization whose sole purpose is funding undergraduate research projects, graduate education, and faculty research at schools and colleges of pharmacy.

Special Interest Organizations

The following organizations are for pharmacists interested in a certain aspect or specialty practice in pharmacy:

American Association of Homeopathic Pharmacists (AAHP)

4332 S. E. Logus Road
Milwaukie, OR 97222
http://www.aahp.info/
(513) 402-8847 (answering service)

The AAHP is a not-for-profit corporation representing the interests of homeopathic manufacturers, distributors, and individual pharmacists in cooperative efforts with regulatory agencies and other organizations nationally.

American Association of Pharmaceutical Scientists (AAPS)

2107 Wilson Boulevard, Suite 700
Arlington, VA 22201-3042
http://www.aaps.org
(703) 243-2800
(703) 243-9650 (fax)

The AAPS represents members employed in academia, industry, government, and other research institutes worldwide.

American College of Veterinary Pharmacists (ACVP)

2830 Summer Oaks Drive
Bartlett, TN 38134-3811
http://www.vetmeds.org
(877) 838-6337
(901) 383-8865 (fax)

The ACVP, a subsidiary organization of the ACA, supports the efforts of independent pharmacists who provide services for animals and veterinarians.

American Institute of the History of Pharmacy (AIHP)

777 Highland Avenue
Madison, WI 53705-2222
http://www.aihp.org
(608) 262-5378

The AIHP is a nonprofit national organization devoted to advancing knowledge and understanding of the place of pharmacy in history. It is composed of pharmacists and pharmacy historians.

American Society for Automation in Pharmacy (ASAP)

492 Norristown Road, Suite 160
Blue Bell, PA 19422-2359
http://www.asapnet.org
(610) 825-7783
(610) 825-7641 (fax)

The ASAP helps its members in advancing the application of computer technology in the pharmacist's role as caregiver and in the efficient operation and management of a pharmacy.

American Society of Pharmacognosy (ASP)

2720 Dundee Road, # 260
Northbrook, IL 60062
http://www.pharmacognosy.us/
(773) 995-3748

The ASP is an international group that brings together men and women dedicated to the promotion, growth, and development not only of *pharmacognosy* but also of all aspects of those sciences related to and dealing in natural products.

American Society for Clinical Pharmacology and Therapeutics (ASCPT)

528 North Washington Street
Alexandria, VA 22314
http://www.ascpt.org/
(703) 836-6981

The mission of the ASCPT is to advance the science and practice of clinical *pharmacology* and translational medicine for the therapeutic benefit of patients and society.

American Society for Parenteral and Enteral Nutrition (ASPEN)

8630 Fenton Street, Suite 412
Silver Spring, MD 20910-3805
http://www.clinnutr.org
(301) 587-6315
(301) 587-2365 (fax)

The ASPEN represents members who are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. Physicians, pharmacists, nurses, dieticians, and other health professionals belong to the ASPEN.

American Society for Pharmacy Law (ASPL)

3085 Stevenson Drive, Suite 200
Springfield, IL 62703
http://www.aspl.org
(217) 529-6948
(217) 529-9120 (fax)

The ASPL is an organization of pharmacist–lawyers; its members are pharmacists who are interested in the law as it applies to pharmacy, lawyers who are interested in the subject of pharmacy law, and students of these disciplines.

Association of Clinical Research Professionals (ACRP)

99 Canal Center Plaza, Suite 200
Alexandria, VA 22314
http://www.acrpnet.org/
(703) 254-8100
(703) 254-8101 (fax)

The ACRP's mission is to promote excellence in clinical research. It is a nonprofit organization with more than 13,000 members and is setting standards for clinical research competence and workforce development.

Christian Pharmacists Fellowship International (CPFI)

P.O. Box 1154
Bristol, TN 37621
http://www.cpfi.org/
(423) 844-1043

The CPFI is a worldwide ministry of individuals working in all areas of pharmaceutical service and practice. Their mission is to serve Christ and the world through pharmacy.

College of Psychiatric and Neurologic Pharmacists (CPNP)

8055 O Street
Suite S113
Lincoln, NE 68510
(402) 476-1677
(888) 551-7617 (fax)
https://cpnp.org/

The mission of CPNP is to promote excellence in pharmacy practice, education, and research to optimize treatment outcomes of individuals affected by psychiatric and neurologic disorders. Also, the CPNP is working toward a world where every individual with a psychiatric or neurologic disorder has a care team that includes a psychiatric and neurologic pharmacist accountable for optimal medication therapy.

Food and Drug Law Institute (FDLI)

1155 15th Street NW, Suite 910
Washington, DC 20005
http://www.fdli.org
(202) 371-1420
(800) 956-6293
(202) 371-0649 (fax)

The FDLI is a nonprofit institute dedicated to advancing public health by providing a neutral forum for critical examination of the laws, regulations, and policies related to drugs, medical devices, other health-care technologies, and foods.

Hematology/Oncology Pharmacy Association (HOPA)

8735 W. Higgins Road
Suite 300
Chicago IL 60631
http://central.hoparx.org/home
(877) 467-2791

The HOPA is a professional organization dedicated to supporting hematology/oncology pharmacy practitioners in optimizing cancer patient care.

International Society for Pharmaceutical Engineering (ISPE)

Worldwide Headquarters
7200 Wisconsin Ave., Suite 305
Bethesda, MD 20814
(301) 364-9201
(240) 204-6024 (fax)

The ISPE connects 18,000 members in 90 countries worldwide from all areas of the pharmaceutical manufacturing industry. Their purpose is to deliver technical and operational solutions to support members across the global pharmaceutical and biopharmaceutical industry in the manufacture of quality medicines for patients.

International Society for Pharmacoepidemiology (ISPE)

5272 River Road, Suite 630
Bethesda, MD 20816
http://www.pharmacoepi.org
(301) 718-6500
(301) 656-0989 (fax)

The ISPE is a nonprofit international professional membership organization dedicated to promoting pharmacoepidemiology, the science that applies epidemiological approaches to studying the use, effectiveness, value, and safety of pharmaceuticals.

International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

505 Lawrence Square Blvd. S
Lawrenceville, NJ 08648
http://www.ispor.org
(800) 992-0643
(609) 586-4982 (fax)

The ISPOR is an international organization promoting the science of pharmacoeconomics and health outcomes research.

International Society of Oncology Pharmacy Practitioners (ISOPP)

Suite 206, 201 Bewicke Avenue
North Vancouver, BC, Canada V7M 3M7
http://www.isopp.org/
1-778-338-4142
1-604-984-6434 (fax)

The ISOPP connects and informs oncology pharmacy experts.

Parenteral Drug Association (PDA)

Bethesda Towers
4350 East Highway, Suite 600
Bethesda, MD 20814
http://www.pda.org
(301) 656-5900
(301) 986-0296 (fax)

The PDA is a nonprofit, international association of scientists involved in the development, manufacture, quality control, and regulation of pharmaceuticals and related products.

Pediatric Pharmacy Advocacy Group (PPAG)

5865 Ridgeway Center Parkway
Suite 300
Memphis, TN 38133
http://www.ppag.org/
(901) 820-4434
(901) 767-0704 (fax)

The PPAG is an international, nonprofit, professional association representing the interests of pediatric pharmacists and their patients.

Society of Infectious Diseases Pharmacists (SIDP)

823 Congress Avenue
Suite 230
Austin, Texas 78701
http://sidp.org/
(512) 328-8632

The SIDP is an association of health professionals dedicated to promoting the appropriate use of antimicrobials. The organization provides education, advocacy, and leadership in all aspects of the treatment of infectious diseases. Members are pharmacists and other health-care professionals, who are involved in patient care, research, teaching, drug development, and governmental regulation and are concerned with all facets of antimicrobial use.

Society of Palliative Care Pharmacists (SPCP)

1400 N. Roosevelt Blvd.
Suite 245
Schaumburg, IL 60007
http://www.palliativepharmacist.org/

The SPCP promotes exceptional patient care by advancing pain and palliative pharmacists through education, development, and research in collaboration with the transdisciplinary team.

Society of Veterinary Hospital Pharmacists (SVHP)

Wil Gwin, R.Ph., DICVP
Purdue Veterinary Teaching Hospital
Purdue University
625 Harrison St,
West Lafayette, IN 47907
http://svhp.org/
(765) 494-9178
(765) 4906-2569 (fax)

The purpose of the SVHP is to further the interests and CE for veterinary hospital pharmacists.

Pharmacy Technician Organizations

The following organizations are for pharmacy technicians, educators of pharmacy technicians, or accreditation of pharmacy technician programs:

American Association of Pharmacy Technicians (AAPT)

P.O. Box 68139
Omaha, NE 68139
http://www.pharmacytechnician.com
(336) 333-9356
(877) 368-4771
(336) 333-9068 (fax)

The AAPT provides leadership and represents the interests of its members to the public as well as health-care organizations.

National Pharmacy Technician Association (NPTA)

P.O. Box 683148
Houston, TX 77268
http://www.pharmacytechnician.org/
(888) 247-8700
(888) 247-8706 (fax)

The NPTA is the leading provider of technician-specific CE in the United States. You can access CE online with immediate grading and certificate issuance.

Pharmacy Technician Certification Board (PTCB)

2215 Constitution Avenue NW, Suite 101
Washington, DC 20037-2985
http://www.ptcb.org
(800) 363-8012
(202) 429-7596 (fax)

The PTCB is the organization that oversees the process of pharmacy technician certification.

Pharmacy Technician Educators Council (PTEC)

1426 Prince Street
Alexandria, VA 22314-2841
http://www.pharmacy.org/pharmtech.html
(703) 683-9493

The PTEC is an organization for educators of pharmacy technicians.

Pharmacy Trade Organizations

The following organizations represent the interests of owners of corporately owned drug companies, wholesalers, and pharmacies, rather than pharmacists:

Chain Drug Marketing Association (CDMA)

43157 West Nine Mile Road
Novi, MI 48376-0995
http://www.chaindrug.com
(248) 449-9300
(248) 449-9396 (fax)

The sole purpose of the CDMA is to support chain drug owners' marketing and merchandising efforts.

Food Marketing Institute (FMI)

2345 Crystal Drive, Suite 800
Arlington, VA 22202
http://www.fmi.org
(202) 452-8444
(202) 429-4519 (fax)

The FMI is a trade association that serves as the voice of food retail. The organization assists food retailers in their noble role of feeding families and enriching lives.

Generic Pharmaceutical Association (GPhA)

777 Sixth Street Northwest, Suite 510
Washington, D.C. 22201
http://www.gphaonline.org
(202) 249-7100
(202) 249-7105 (fax)

The GPhA represents the generic drug manufacturers and shares a commitment to improving consumer access to high-quality, affordable medicine.

Healthcare Distribution Management Association (HDMA)

901 North Glebe Road Suite 1000
Arlington, VA 22203
http://www.healthcaredistribution.org
(703) 787-0000
(703) 812-5282 (fax)

The HDMA is the only trade association representing pharmaceutical and related health-care product distributors (e.g., drug wholesalers) in the Americas.

National Association of Specialty Pharmacy (NASP)

1800 Diagonal Road
Suite 600
Alexandria, VA 22314
info@naspnet.org
http://www.naspnet.org
(703) 842.0122

The NASP is a 501(c)(6) trade association representing all stakeholders in the specialty pharmacy industry. Its members include the nation's leading specialty pharmacies, pharmaceutical and biotechnology manufacturers, GPOs, distributors, and more. With over 100 corporate members and 1200 individuals, the NASP is the unified voice of specialty pharmacy in the United States.

National Pharmaceutical Council (NPC)

1717 Pennsylvania Ave. NW, Suite 700
Washington, D.C. 20006
http://www.npcnow.org
(202) 827-2100

The NPC is a health policy research organization dedicated to the advancement of good evidence and science, and to fostering an environment in the United States that supports medical innovation.

National Association of Chain Drug Stores (NACDS)

1776 Wilson Blvd., Suite 200
Alexandria, VA 22209
http://www.nacds.org
(703) 549-3001
(703) 836-4869 (fax)

The NACDS represents chain drugstore owners, including supermarket chains, traditional chain drugstores, and mass merchandisers.

Pharmaceutical Care Management Association (PCMA)

325 7th St., NW
Washington, DC 20004
http://www.pcmanet.org
(202) 756-5700

The PCMA represents managed care pharmacy and its health-care partners in pharmaceutical care: managed care organizations, pharmacy benefits managers (PBMs), health maintenance organizations (HMOs), preferred provider organizations (PPOs), third-party administrators, health-care insurance companies, drug wholesalers, pharmaceutical manufacturers, and community pharmacy networks.

Pharmaceutical Research and Manufacturers of America (PhRMA)

950 F Street Northwest, Suite 300
Washington, DC 20004
http://www.phrma.org
(202) 835-3400
(202) 835-3414 (fax)

The PhRMA represents the leading U.S. research-based pharmaceutical and biotechnology companies that are devoted to developing medicines that allow patients to live longer, healthier, happier, and more productive lives.

Other Organizations

Board of Pharmacy Specialties (BPS)

2215 Constitution Avenue Northwest
Washington, DC 20037-2985
http://www.bpsweb.org
(202) 429-7591
(202) 429-6304 (fax)

The BPS improves the public health through recognition and promotion of specialized training, knowledge, and skills in pharmacy and certification of pharmacist specialists.

Commission for Certification in Geriatric Pharmacy (CCGP)

1321 Duke Street, Suite 400
Alexandria, VA 22314-3513
http://www.ccgp.org
(703) 535-3016

The CCGP tests and certifies pharmacists in geriatric pharmacy.

International Pharmaceutical Federation (FIP)

2517 JP The Hague
The Netherlands
https://www.fip.org/
(31) (70) 302-1970
(31) (70) 302-1999 (fax)

The FIP is a worldwide federation of national (professional and scientific) associations; it has a mission to represent and serve pharmacy and pharmaceutical sciences around the globe.

National Association of Boards of Pharmacy (NABP)

1600 Feehanville Drive
Mount Prospect, IL 60056
http://www.nabp.net
(847) 391-4406
(847) 375-1114 (fax)

The NABP is the only professional association that represents the state boards of pharmacy in all 50 states, the Virgin Islands, New Zealand, nine Canadian provinces, and the four Australian states.

United States Pharmacopeial Convention (USP)

12601 Twinbrook Parkway
Rockville, MD 20852-1790
http://www.usp.org
(301) 881-0666
(800) 227-8772

The USP sets standards to ensure the quality of medicine for human and veterinary use. The USP also develops authoritative information about the correct use of medicines. National health-care practitioner reporting programs support U.S. public health standards and information programs.

SHOULD PHARMACY ORGANIZATIONS CHANGE?

An article, "Restructuring America's Pharmacy Associations," asked whether pharmacy organizations adequately represent and address the concerns of the profession.[10] The main thrust of this editorial was that many pharmacy organizations are in decline because of the restructuring of healthcare, which has caused reduced memberships, especially at the state level. Another thought is that enormous energy is being used to fight undesirable changes in healthcare that take place anyway. The author calls for a strategic assessment of the organizational structure of American pharmacy.

Another question is whether there are too many pharmacy organizations. Currently, no one organization can speak for the practice of pharmacy. Donald E. Francke, during his A. K. Whitney Award lecture, wrote:

> It is my firm conviction that American pharmacy will not come into its own until we have a majority of our pharmacists actively supporting their national professional organization. Someone has defined an organization as a medium for the efficient movement of groups of men towards goals to which they aspire. How can we move American pharmacists towards professional goals until we enroll them in our association? Only when this is done will the Association, its ideals, its ethics, its concepts of professional service be ingrained in all who practice our profession.[9]

The JCPP represents the seven pharmacy organizations that represent practicing pharmacists. This is a good start; however, this group only works by consensus, is not known by many pharmacists, and does not have trumping power over the minority opinions of its member organizations. At this point, one voice for pharmacy seems far off, but it remains a dream of many pharmacists.

The question is—what will it take to unite pharmacy into one voice that speaks and advocates on behalf of the profession and who will lead the effort?

SUMMARY

There are over 30 professional organizations in pharmacy. They are divided into practitioner, educational, special interest, technician, trade, and other types of organizations. Pharmacy organizations play a critical role in representing their members, and they are important change agents in moving pharmacy forward. Therefore, it is important for every pharmacist to be a member of at least one pharmacy organization. Joining one national, one state, and one local pharmacy organization is ideal.

DISCUSSION QUESTIONS AND EXERCISES

1. Why are professional pharmacy organizations important? Of all of these reasons, which reason is most important to you? Why?
2. I recommended that all pharmacists belong to at least one national, one state, and one local professional pharmacy organization. Why?

3. Using the listing of professional organizations in this chapter, select one organization that interests you from each of the following types of organizations.
   a. Practitioner organizations
   b. Educational organizations
   c. Special interest organizations
   d. Pharmacy technicians' organizations
   e. Trade organizations
   f. Other organizations
4. Using your answers to question 3, visit the websites of these organizations (as listed in this chapter). Which organizations impress you the most? Why?
5. Investigate when and where local pharmacy organizations meet in your area. Attend two different meetings.
6. Before you graduate from pharmacy school, attend one state and one national pharmacy meeting.
7. In your opinion, what is the most important thing a professional pharmacy organization can do for its members?
8. Make an appointment to interview a pharmacist working for a professional pharmacy organization.
9. Based on what you know and have read, what are the pros and cons of working for a professional pharmacy organization?
10. Is working for a professional pharmacy organization something you think you may want to do? Why or why not?

CHALLENGES

1. Some believe the pharmacy profession has too many pharmacy organizations speaking for it and that the messages sent to the public and Congress are diluted and sometimes conflicting. For extra credit, and with the permission of your professor, prepare a concise report on this issue. Are there too many pharmacy organizations speaking for pharmacy? What can be done about it? Are there other models available to follow?
2. For extra credit, and with the permission of your professor, write a concise report debating the pros and cons of belonging to a national, state, and local pharmacy organization. Discuss how your dues money should be apportioned and why.

WEBSITES OF INTEREST

The website for each pharmacy organization is in the text for each organization listed.

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17 How Drugs Are Discovered, Tested, and Approved

INTRODUCTION

It is exciting to read about a scientific "breakthrough" in developing a new drug, especially if you or a loved one has a debilitating or terminal disease. However, on further reading, you discover the product is still several years away from availability for use. Your exhilaration turns to frustration. Frank E. Young, former commissioner of the U.S. Food and Drug Administration (FDA), believes this happens because of the way the media reports the news, and the public's unclear understanding of drug development, testing, and approval.[1]

Pharmacy is about patients, drugs, caring about the patient, and the patient receiving the best drug. Therefore, it is important to understand how drugs are discovered, developed, tested, and approved for use.

This chapter focuses on new drug development in the United States. It begins with a brief history of drug discovery and then moves on to how drugs are discovered. Next, information on drug design, drug testing, drug standards, and the critical step of drug approval is presented. All of this takes time. This process is discussed along with the associated developmental costs. This chapter concludes with information on the postmarketing surveillance of drugs, generic drugs, over-the-counter (OTC) drugs, and the future of drug discovery and development.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Discuss how drugs are discovered.
- Discuss how drugs are tested.
- Outline the drug approval process in the United States.
- Explain the terms *Investigational New Drug (IND) application*, *New Drug Application* (NDA), and *investigational review board* (IRB).
- Provide, from a pharmaceutical company viewpoint, why drugs cost so much.
- Discuss drug standards and the U.S. Pharmacopeia (USP).
- Define the term *current good manufacturing practice* (CGMP).
- Discuss generic, biosimilars, and OTC drugs.
- Define the importance of postmarketing surveillance.

A BRIEF HISTORY OF DRUG DISCOVERY AND DEVELOPMENT

Although many small steps took place in discovering and developing modern drugs, the first breakthrough was by Swedish pharmacist Carl Wilhelm Scheele, who in the early 1800s isolated organic plant acids. In 1816, a young German apothecary, Friedrich Serturner, gave the world its first class of organic substances—the *alkaloids*—by isolating morphine

from opium. Soon to follow (1817–1820) was the discovery of emetine from *ipecacuanha*, strychnine from *nux vomica*, and quinine from cinchona bark by two French pharmacists, Pierre-Joseph Pelletier and Joseph-Bienaime Caventou.[2]

These drug discoveries stimulated interest in standardizing drug formulas. In 1820, the *U.S. Pharmacopeia* (USP) was started to develop drug standards. Following this was a surge in discovering new medicinal plants from various parts of the world, including jungles, forests, and mountainous areas. These excursions to find new drugs continued at a brisk pace until 1940 and then declined.

In the late 1800s and early 1900s, scientists discovered *biological products* such as diphtheria antitoxin. Horses were inoculated with diphtheria toxin. After the horse developed diphtheria antibodies, the serum was collected from the horse and purified to make diphtheria antitoxin. Soon to follow were other biological products of animal origin.

Ernest Fourneau (1872–1949), a French pharmacist at the Pasteur Institute, identified that bismuth and arsenic compounds could be used to treat syphilis. He also developed sulfa drugs and discovered the properties of antihistamines. These discoveries signaled the arrival of modern chemotherapy. In 1883, German scientists *synthesized* (made in a test tube) antipyrine. This dramatically changed drug discovery, design, and development from this point forward.

Research in pharmacy rapidly evolved between 1925 and 1945. The biggest step forward took place in 1929 when Alexander Fleming discovered penicillin. However, it was the pharmaceutical manufacturers—under the pressure of World War II—that developed mass production and purification methods for penicillin and made it affordable and widely available to physicians.

The last breakthrough discussed in this chapter is considered one of the greatest discoveries in medical science. In 1952, James Watson and Francis Crick, working at the Cavendish Laboratory in Cambridge, United Kingdom, solved the puzzling structure of deoxyribonucleic acid (DNA).[3] This achievement was preceded by the work of Erwin Chargaff and Rosalind Franklin.[4] This event, and the discovery of what makes up the human genome in 2000, will have a major impact on treating disease for the next generation.

HOW NEW DRUGS ARE DISCOVERED

Developing a new drug is complex and time consuming. Some feel it is like finding a needle in a haystack or a diamond in the rough. Drug discovery and development start with a human need and are based on *good science*. Good science uses proven scientific methods and avoids shortcuts in designing and developing new drugs.

The object of *drug discovery* is to find new active ingredients or to modify the chemical structures of existing active ingredients of drugs to form the basis of a new drug. The object of *drug development* is to provide superior dosage forms and ways of delivering effective drugs into the body.

The discovery of a new drug (the active ingredient of a drug product) and development of one or more dosage forms are so complex and technical that no one individual is qualified to carry out the operation from beginning to end. Thus, drug discovery, development, and approval take the services of many trained workers skilled in applying their knowledge to the problems of pharmacy.[5]

Pharmaceutical development is mostly done by scientists—usually those with a doctoral (PhD) degree—working for pharmaceutical companies in which extensive research laboratories, sophisticated equipment, and resources are available to do the research. However,

pharmaceutical research is also conducted in most of the 140 colleges of pharmacy. Most bench (laboratory) research on drugs is performed by basic science faculty members. Pharmaceutical companies often contract with a college of pharmacy or an independent research institute to conduct some of their drug research.

DRUG DISCOVERY

The active ingredients of drugs are extracted from plants, mammalian hormones, microorganisms, and various semisynthetic and synthetic compounds. Today, some of the synthetic compounds are genetically engineered.

Plant Poisons

Before it was discovered that drugs could be synthesized, plants were the main source of physiologically active substances that could be tested for therapeutic properties. Some examples of drugs found from plants are morphine (from the opium poppy), quinine (from cinchona bark), digitalis (from foxglove), and belladonna (from deadly nightshade). These alkaloids are not present in these plants to supply humans with medicines but probably are present to discourage predators. The problem of using alkaloids from plants as drugs is a matter of purity and the ability to produce enough quantity. Not all plants of the same species are grown under the same conditions. Thus, the alkaloid within each plant will vary in potency.

Inorganic Chemicals

The fluids and tissues of the body contain various inorganic substances—chemicals such as potassium, sodium, chloride, and calcium—to help maintain homeostasis. Disease can cause the body to have either too much or too little of these substances. Fortunately, these chemicals are plentiful in nature and can be purified and made into sterile medicinal preparations for use by physicians.

Drugs from Animal Sources (Biologics)

Administering substances found in animals dates back to ancient Egypt. Apothecaries of old used substances from crayfish, earthworms, frogs, lizards, scorpions, snails, swallows, toads, vipers, and wood lice to compound powders, oils, and syrups.[6] Products drawn from animal sources such as thyroid, insulin, estrogen hormones, epinephrine, and diphtheria antitoxin are still used today.

Drugs from the Seas

Natural product researchers have recently discovered interesting raw plant material as a source of new drugs in the tropical rain forests. However, a frontier for finding new sources of drugs is in the tropical seas.[7] Researchers at the natural products branch at the National Cancer Institute (NCI) and at about 15 other laboratories throughout the country are screening such organisms as algae, invertebrates, and sponges. They are hoping to discover compounds that will lead to new drugs with antitumor, anti-inflammatory, antibacterial, and antiviral potential.

As of this writing, four substances from marine life are in clinical trials as anticancer drugs, and four others are in preclinical trials—two as anticancer agents and two as anti-inflammatory agents.

Screening for New Natural Drug Products

Screening is the discovery of new drugs that might be of use later in clinical medicine.[8] Various approaches are used for screening compounds for pharmacological activity. All pharmacological screening is dependent on test methods that have a significant bearing on the disease they are to match in the laboratory.[9] Discovering compounds and then testing them in various diseases is not considered to be a practical or fruitful approach to drug discovery.

The initial testing of drugs is always carried out in laboratory glassware (an *in vitro* experiment) rather than in an animal model (an *in vivo* experiment). A screening test must be selected that a skilled technician can perform easily and that will alert the technician to any potential the compound may have for the targeted disease selected. An example is a potential drug substance inhibiting an enzyme associated with the disease. Once the experiments are set up, hundreds of potential compounds can be screened using these methods. Today, some screening of potential drug compounds is automated.

Synthetic Substitutes

Because of the variances in the potency of medicinal substances found in plants, it was necessary to see whether these substances could be made in a test tube. The first drug for which synthetic substitutes were sought was quinine. Next came morphine and cocaine.[6] Once the structural formula is discovered for a new drug, an attempt is made to synthesize it, as this is the fastest and most inexpensive way to make a drug. This is how most drugs are produced today. However, sometimes the basis of a drug comes from a natural product and then is altered in the laboratory to become a *semisynthetic drug*.

Biotechnology

The latest approach to developing new drugs is *biotechnology*. The science of biotechnology is defined as the process of *in vitro* (in a test tube) change of genetic material for the purpose of creating new gene combinations or changes.[8] It relies on living systems to produce biological materials. Sometimes, this process is called *molecular biology* or *genetic engineering*. The biotechnological approach to new drugs has been limited to proteins. Recombinant hepatitis B vaccine and recombinant insulin were two of the first biotechnological drugs.

NEW METHODS OF DRUG DESIGN

Until recently, most new drugs were discovered through random screening or through molecular change. However, new and exciting methods of drug discovery are starting to be employed. Rational drug design, using powerful computers, computational chemistry, x-ray crystallography, nuclear magnetic resonance spectroscopy, and three-dimensional structure activity relationship analysis, is creating specific, biologically active molecules by virtual reality modeling.

Computer modeling is a recent technique to develop new drugs. One method is to simulate what would happen to people with certain biological profiles when they take the drug.[9]

Computer modeling would predict which patients would benefit and which patients may not. Another feature of computer modeling is developing drug-delivery *nanocarriers*.[10]

THE DRUG RESEARCHER

It takes a team of scientists to develop a new drug. These scientists come from several disciplines, mainly pharmaceutical chemistry, clinical pharmacology, clinical pharmacokinetics, clinical toxicology, and pharmaceutics.

Pharmaceutical Chemistry

If the active ingredient is a natural product, pharmaceutical chemists will try to synthesize the parent compound. Once this is completed, these scientists may alter the parent compound by molecular change to decide if any of the analogues of the compound are more active. After animal testing, they will discover whether any are less toxic.

Clinical Pharmacology

The next step in the development of a drug is to see how the potential drug works in animals—preferably one with the disease for which the drug is intended, but this is rare.

Biopharmaceutics and Clinical Pharmacokinetics

Before a drug dosage form can be tested in animals, it must be determined how long it takes to dissolve and be available to the body. This involves testing the *bioavailability of the drug*. The results vary based on the chemical makeup and pH (acidity and alkalinity) of the drug and on other nondrug components of the *dosage form* (e.g., capsule, tablet, liquid) of the drug. During testing in animals, the absorption, distribution, metabolism, and excretion (ADME) of the drug are carefully measured using serum drug levels—or other body fluid levels—and mathematical models to see how the drug is being handled, pharmacokinetically, in the body.

Clinical Toxicology

When testing in animals, an initial dose, then a usual dose, then a maximum dose is established for the substance. These form the basis for a starting dose for human testing.

Pharmaceutics

The active ingredient must be delivered in the proper dosage form to arrive at the intended site of action. This process will involve selecting the best routes of administration and designing the delivery method for the drug so it dissolves and is absorbed into the patient's circulation at the correct time. The drug may be in any one of the many dosage forms available: capsules, compressed tablets, liquid oral dosage formulations, a *parenteral* (injectable) product, a controlled-release product, an ointment or cream, or a *transdermal* medication. Unlike ointments (oil-soluble semisolids) and creams (water-soluble semisolids), for which the drug in the cream or ointment base is passively absorbed into or through the skin, transdermal medication is actively transported through the skin with the help of a *catalyst*.

DRUG TESTING

A potential new drug must pass many tests before it will be considered for licensure by the FDA and marketed in the United States. These tests begin in the laboratory. If the potential drug shows promise, it will move into animal testing. If it continues to show promise, it will move into limited and then expanded human testing.

Animal Testing

During the animal testing phase of a potential new drug, researchers try to use as few animals as possible, and they always handle the animals with care. Two or more species are typically tested, and the testing is mainly to assess the drug for toxicity.

Other goals of animal testing are to see how and how much of the drug is absorbed (biopharmaceutics), how it is handled (pharmacokinetics), how it is broken down in the body (metabolized), and how it is eliminated (excreted). Scientists may add other chemicals to the active ingredients in the dosage form (the drug) to heighten its dissolution, absorption, or distribution in the body.

In the process of animal testing, many drugs stop showing any promise and are eliminated from further consideration. A former pharmaceutical company representative has estimated that for every 2000 chemical substances studied, only 200 (10%) show any potential in early tests.[11] Of these, only 20 may be tested in humans, and only 1 may be found to be safe and effective enough to be approved by the FDA. Other estimates are gloomier. Success is about 1 in 10,000.

Testing in Humans

Once the preclinical testing (laboratory and animal studies) is complete and a drug continues to show promise, it is tested in humans. Although drug testing is performed by the drug company sponsoring the drug rather than the FDA, the FDA has developed different phases of testing in humans (Table 17.1).[12,13] These are called phases 1, 2, 3, and 4. Each phase uses progressively more humans for testing. Drug companies arrange with physicians, hospitals, and clinical pharmacy faculty to conduct these clinical trials.

However, before a pharmaceutical company can start testing an *investigational drug*—a drug only approved for investigation by the FDA—in humans, it must provide the FDA with the results of laboratory and animal research. It also must file a detailed plan of how the clinical trials will be performed: how many people, how they will be selected, where the studies will be done, how the safety and effectiveness of the drug will be evaluated, and what findings would cause the study to be changed or halted.[11] All of this goes to the FDA in the form of an IND.

Phase 1 Clinical Trials

Testing of a potential new drug in humans starts with a low dose in a small number (20–80) of healthy volunteers. The volunteers are tested in a secure environment and carefully checked. Doses are slowly raised until there is a *dose response*—when the intended effect can be measured. The main objective of phase 1 testing is to find the initial dose in humans and to see whether a human can tolerate the drug. The patients take the drug for approximately a month. Other important things to learn during phase 1 are how the drug is absorbed, distributed, metabolized, and excreted (pharmacokinetics); which organs are affected by the drug (pharmacology); how the drug is tolerated (toxicology); and whether there are any side effects.

TABLE 17.1
How Experimental Drugs Are Tested in Humans

Phase	No. Tested	Length	Purpose	% of Drugs Successfully Completed[a]
1	20–80	Several months	Mainly safety	70
2	Several hundred	Several months to 2 years	Some short-term safety, but mainly effectiveness	33
3	Several thousand	1–4 years	Safety, effectiveness, and dosage	25–30

Source: U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *From Test Tube to Patient: Improving Health Through Human Drugs*, Department of Health and Human Services, Rockville, 1999.

[a]For example, of 100 drugs for which investigational new drug applications are submitted to the FDA, about 70% will successfully complete phase 1 trials and go on to phase 2; about 33% will complete phase 2 and go to phase 3; 25–30 will clear phase 3 (and, on average, about 20 of the original 100 will ultimately be approved for marketing).

Phase 2 Clinical Trials

If the drug continues to show promise—there is a definite dose response in humans and the drug appears to be safe—the drug enters phase 2 testing. In this phase, the drug is tested in patients—a few hundred—who have the disease or condition for which the drug is intended. During this phase, extensive pharmacologic, toxicological, pharmacokinetic, and clinical monitoring takes place. The initial dosing and usual dosing are determined during this phase. Phase 2 is the critical phase in the clinical testing process. Many potential drugs do not make it past this point.

Phase 3 Clinical Testing

If the drug makes it out of phase 2 testing, it will be tested in phase 3 to discover the drug's efficacy: how good it is in treating the disease or condition for which the drug is intended. This phase will also reveal short-term side effects and risks in people whose health is impaired.

The investigational drug will be used in several randomized, controlled studies in various clinical research facilities—usually Veterans Affairs centers and university teaching hospitals—throughout the United States. In recent years, the use of outside contractors for clinical drug development has been expanding. Sponsors are outsourcing more clinical studies to *contract research organizations* (CROs). These fee-for-service, independent *clinical research organizations* have emerged because of the need to speed the development process and get drugs approved sooner. Academic health centers, which traditionally have performed most of the phase 3 work for the drug companies, produce high-quality work but are not known for their speed.

CROs work as partners with the pharmaceutical companies, from submitting the IND application to submitting the NDA, but even they are subject to competition. The newest players in this business are *site management organizations* (SMOs). SMOs work to bring

investigators to a sponsor during site selection and work as a conduit for central contracting and quick patient uptake. Some SMOs are led by pharmacists.

During phase 3 testing, several thousand patients receive the investigational drug during a randomized, controlled study. A *randomized, controlled study* is a scientifically designed study with two patient groups that are randomly assigned: one group receives the drug, and the other receives a placebo. A *placebo* is a drug that looks exactly like the real drug but does not contain the active ingredient of the drug. The nurse, patient, and physician are *blinded*—they do not know whether the patient received the real drug or the placebo. However, the pharmacist in the research facility does know and therefore is usually in charge of randomizing patients.

WHO OVERSEES RESEARCH ON INVESTIGATIONAL DRUGS?

Research on investigational drugs is controlled by the FDA and by local, independent, IRBs. Federal rules and regulations govern IRBs. For example, the IRB can be part of an organization, such as a hospital or university, but must act independently of that organization. The composition of the IRB is also dictated by federal regulation. For example, IRBs must be composed of at least five people with varying backgrounds who are knowledgeable in the research areas to be covered. Racial, ethnic, and other interests must be represented. There also must be a nonscientific person on the board. Most IRBs are composed of a combination of medical investigators, medical practitioners, a layperson, a member of clergy, an attorney, a pharmacist, and a nurse, and some have an ethicist. The chairperson of the IRB is usually a medical practitioner but can be a pharmacist. The secretaries of many IRBs are pharmacists.

The FDA works closely with the drug companies and makes sure the sponsor (pharmaceutical company) is fulfilling the requirements of the agency. The sponsor is responsible for

- Fulfilling all FDA requirements
- Selecting investigators and study monitors
- Informing investigators
- Reviewing ongoing investigations
- Keeping and retaining records
- Inspecting the records and reports of the sponsors
- Disposing of any unused supply of investigational drugs

The following are the responsibilities and accountabilities of the clinical investigators:

- Fulfilling all IRB requirements
- Controlling the investigational drug
- Receiving IRB approval to perform the investigation
- Receiving IRB approval for a patient consent form
- Obtaining patient consent
- Following the study protocol—the research plan
- Keeping and retaining records
- Inspecting the investigator's records and reports
- Filing necessary reports with the IRB and sponsor

The overall responsibility of the IRB is to ensure that risks to study subjects are minimized. The specific responsibilities of the IRB are to

- Review and approve the qualifications of the investigators
- Review and approve the study protocol
- Make sure the selection of study patients is fair and equitable
- Review and approve the patient consent form
- Review and approve the procedure to obtain patient consent
- Routinely review the progress of the study
- Review and make substantial changes to the study protocol
- Routinely review patient outcomes

DRUG STANDARDS

It is important that drugs be manufactured according to high standards. As it turns out, these standards are not established by the FDA, but by the USP. The USP was started in 1820 over concern about drug purity and consistency.[14] The USP helps to ensure that consumers receive medicines of the highest possible quality by setting the standards manufacturers must meet to sell their products in the United States. The standards set by the USP concern purity and the amount of active ingredients, when and how quickly oral dosage forms of a drug are bioavailable (dissolve and are absorbed) to the body, and the labeling and safe use of the drug.

The USP is an independent, not-for-profit organization but works closely with the FDA and drug companies. It makes *reference standards*—pure, accurately measured samples of the drug—available for drug companies to calibrate their analytical equipment and, in turn, to measure samples of the drugs they produce to ensure accuracy. Being able to put "USP" on the label of a drug shows the drug meets all USP requirements.

HOW DRUGS ARE APPROVED FOR USE

The FDA only approves drugs it feels are safe and effective. However, the drug may not be absolutely safe. There is always some risk with every drug. In addition, every individual's physical makeup is different. Thus, the drug may not be handled by the body the same way in all people. The Center for Drug Evaluation and Research (CDER) of the FDA carefully evaluates drugs for efficacy and risk, while the Center for Biologics Evaluation and Research (CBER) evaluates vaccines and biologics.[12] However, when the FDA's advisory committees, composed of various outside experts, and the FDA feel that the benefits of the drug outweigh its risks, the drug is approved.

The FDA has 180 days to approve a new drug once it receives an NDA. However, this time is extended if the FDA needs more information from the sponsor, which is normally the case. Thus, it may take as long as 1–2 years to approve the drug. This will vary by how the FDA classifies the new drug.

Classification of New Drugs by the FDA

The FDA classifies NDAs to assign review priority based on the chemical type and potential benefit of the drug.[15]

Chemical Type

The chemical types are as follows:

New molecular entity: An active ingredient that has never been marketed before
New derivative: A chemical derived from an active ingredient already marketed
New formulation: A new dosage form or new formulation of an active ingredient already on the market
New combination: A drug that contains two or more compounds, the combination of which has not been marketed
Already-marketed drug product: A product that duplicates the already-marketed drug product of another firm

Potential Benefit

Types of potential benefits are as follows:

Important gain: May effectively treat or diagnose a disease not adequately treated or diagnosed by any marketed drug.
Modest gain: Offers a modest, but real, advantage over other marketed drugs.
Little or no gain: Essentially the same medical importance and use as a marketed drug.
Orphan drug candidate: A product that treats a rare disease affecting fewer than 200,000 Americans. There are an estimated 2,000 rare diseases.

Thus, a new drug that is a new molecular entity represents an important therapeutic gain (classified 1A) receives the highest priority review. An overview of the regulatory approval process is available.[16]

TIME AND COST OF DRUG DEVELOPMENT

It takes time to do good research, and it takes time to develop a new drug. Developing a new pharmaceutical agent may take more than a decade, but usually it takes an average of 12 years.[17] Some high-priority drugs, such as those for the human immunodeficiency virus (HIV), have been approved much faster. Most of the time spent is in clinical trials (2–10 years). Figure 17.1 shows the typical timeline for the new drug development process.[18]

In 2015, America's pharmaceutical research and biotechnology companies invested a record $58.8 billion in the research and development of new life-changing medicines and vaccines.[19] Yet, the total expenditures for drug research and development is a matter of some controversy since the pharmaceutical industry claims have not been subject to independent validation.

The average cost to develop a new pharmaceutical in 2014 was $2.5 billion.[20] Part of the reason for this high cost is to help pay for the drugs investigated that did not make it to market (about 87.2%).[21]

The biggest single item driving up research and development costs is contract studies, mainly in the clinical area and the preclinical area, such as toxicology studies or analytical sample costs. One vice president and chairperson of research at a major drug company was quoted as saying, "We'd take a lot of cost out if we could develop drugs with two or three clinical trials and a few thousand people, instead of 20 trials and 20,000 patients."[22] The total per patient cost to a pharmaceutical company for a good recruiting site (for patients), including monitoring and data-processing fees, approaches $6000 ($3000 for the investigator or site and $3000 for the patients).

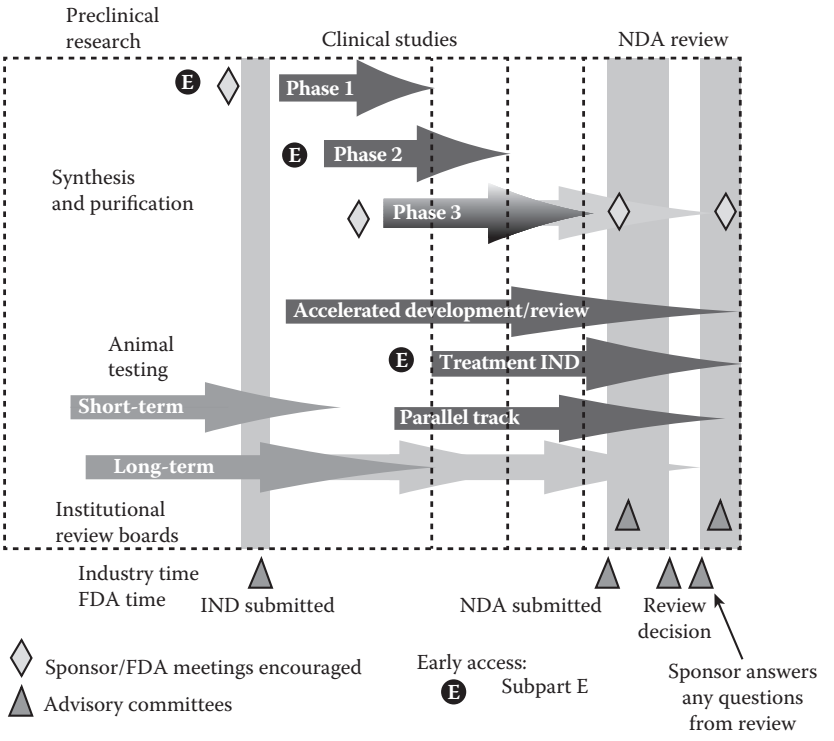

FIGURE 17.1 Timeline for the development of a new drug in the United States. (From U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Report to the Nation 2004.)

These costs are putting a premium on innovation and spurring a profound shift in research strategies. Drug companies that do not have the means to develop successful new drugs may find themselves forced into mergers or takeovers to carry growth or even to survive.

DRUG MANUFACTURING

Once a drug company has its NDA approved by the FDA, it can start marketing and producing the drug. The production process for a drug is beyond the scope of this text. However, it is important to know that the drug manufacturer must follow CGMPs.[23] If they do not, the FDA can claim the drug is *adulterated* and can stop the manufacturer from making further quantities of the drug until CGMP is restored.

GENERIC DRUGS

A generic drug is a drug product that is an identical copy of active ingredients, formulation, and strength that is marketed by a company other than the company that did the original research on the drug product (the innovator).[24] These drugs are sometimes called "me too" drugs. The innovator firm would have completed many years of research and spent much money before getting approval from the FDA to market the drug. Innovator firms are allowed to patent and provide a trade name for their newly approved drug. The patent gives the innovator about 20 years to market the drug without competition.

At the end of the patent period, other drug companies may develop a generic version of the product developed by the innovator and may do so without extensive clinical testing by applying for an *Abbreviated New Drug Application* (ANDA) with the FDA. If approved, the company marketing the generic version of the product of the innovator must use the generic—common—name of the drug rather than a trade name.

Because competition enters the picture when a patent expires, generic drugs usually sell for 20%–75% less than the brand-name product. But are generic drugs safe? Are they as effective as the brand-name products? The answers to these two questions are yes and yes. Drug companies—both brand-name and generic firms—making generic drugs must test the bioavailability of the drug. This *bioavailability* is dependent on the dissolution, disintegration, and absorption of the drug into the body. With only a few exceptions, generic drugs are as bioavailable and as safe as their trade-name counterparts.

BIOSIMILARS

Biosimilar drugs are less costly versions of biologics that are built from chemical compounds. "They are different from generics because the active ingredients in brand and generic drugs must match."[25] A biosimilar drug is similar to an already approved biologic drug, and thus can "piggyback" on the branded drug to get approved. However, there is still a lot of controversy as to whether a biosimilar is indeed, as good as the branded product. Pharmacists will be key in evaluating these agents when they come up for review and approval at Pharmacy and Therapeutic (P&T) Committee meetings.[26]

It is estimated that biosimilars "will deliver total savings of as much as $110 billion to health systems across Europe and the U.S. through the next four years (2017–2020)."[27]

DRUG EFFICACY STUDY IMPLEMENTATION DRUGS

Drug Efficacy Study Implementation Drugs (DESI) are drugs that were approved solely based on their safety prior to 1962. Thereafter, Congress required drugs to be shown to be effective as well. The FDA initiated a DESI to evaluate the effectiveness of those drugs that had been previously approved on safety grounds alone. These drugs, and those identical, related, and similar to them, may continue to be marketed until the administrative proceedings evaluating their effectiveness have been concluded, at which point continued marketing is only permitted if an NDA is approved for such drugs.[25]

HOMEOPATHIC DRUGS

Homeopathy is a system of medicine based on the observation that high doses of pharmacologically active substances cause symptoms when administered to adults. These same substances, when prepared in very dilute form, may relieve similar symptoms in conditions resulting from different etiologies.[28]

Homeopathic drugs, unlike dietary supplements, are subject to the Food, Drug, and Cosmetic Act and regulations issued by the FDA. However, instead of the new drug approval process, premarket approval for homeopathic drugs is by way of monograph approval of the Homeopathic Pharmacopeia Convention of the United States.

NONPRESCRIPTION DRUGS

The FDA has always applied the same standards to *nonprescription drugs* as it does to prescription ones when the proposed OTC drug meets the criteria for a new drug. The problem with OTC drugs has not been safety but effectiveness. Do all of them work? Since 1990, the FDA has systematically evaluated all OTC products for the safety and effectiveness of their active ingredients.[15] Some OTC drugs are similar to prescription-only (Rx) drugs but have smaller amounts of the active ingredients as the prescription version.

Sometimes, an approved prescription drug is considered safe enough for self-use and is switched to OTC status.[29] For a switch to occur, the drug must be safe at the dose recommended on the label. In addition, the answer to the following four questions must be yes: (1) Can the consumers read the label? (2) Can they understand the label? (3) Do they follow the label? (4) Do they achieve the desired outcome?

A manufacturer wanting to switch a prescription-only product must provide substantial evidence to the FDA that the switch is reasonably safe and is in the public's best interest.

POSTMARKETING SURVEILLANCE OF NEW DRUGS

All drugs have some degree of risk, and this risk is not evenly distributed throughout the population. These risks are described as side effects or adverse drug reactions (ADRs).

Side effects are minor, predictable, unwanted effects of the drug. These effects stem from the pharmacology of the drug. Therefore, they are experienced by most people taking the drug—some more than others. These effects go away when the drug is discontinued. An example would be drowsiness associated with some antihistamines used for hay fever.

Adverse drug events (ADEs) are moderate-to-severe, sometimes life threatening, unwanted, usually unpredictable, effects of the drug. Predictable ADEs are based on the pharmacology of the drug and are dose related. An example would be respiratory depression associated with narcotic analgesics. Unpredictable ADEs are the most troubling and can be the most severe. These reactions are considered to be bizarre, as they are not based on the pharmacology of the drug and are not dose related. An example would be thrombocytopenia (decreased platelets) associated with the use of heparin—an anticoagulant.

Even the most extensive premarket testing of a new drug can never uncover all of the potential side effects, ADRs, or *drug interactions* (one drug affecting the action of another drug). Testing 3000 people over a period of months or even a few years will not always detect a rare reaction. The effect may occur in just one person in 10,000 people.[12] However, once the drug is approved, literally thousands of all types of patients receive the drug in a short period of time. This is when new effects of the drug may be discovered.

To help monitor the serious adverse effects of drugs, the FDA has a reporting system called *MedWatch*. Serious ADRs are fatal, are life threatening, cause hospitalization, prolong hospitalization, or result in disability. ADRs are reported to the FDA by health-care personnel or patients through *MedWatch*. The FDA quickly puts all reports into a computer system and then searches for any significant patterns. There is a similar program for the reporting of serious ADRs for vaccines. This program is cosponsored by the FDA and the Centers for Disease Control and Prevention (CDC) and is called the *Vaccine Adverse Event Reporting System* (VAERS).

Should an important, new adverse event emerge and be confirmed, the FDA and the drug manufacturer have several options. One is to change the directions for the product to reduce the dose or warn certain vulnerable groups of people. In urgent and unusual circumstances, products can and have been withdrawn from the market by the manufacturer either voluntarily or after pressure from the FDA.

CURRENT ISSUES IN DRUG DEVELOPMENT

Drug companies have complained that the drug approval process takes too long and have lobbied the U.S. Congress to do something about it. This has resulted in legislation requiring the FDA to speed up the approval process. The FDA, although concerned about this, has done a remarkable job in speeding up the process. In fact, there is recent evidence that the FDA is now approving new drugs too quickly, as many drugs have had to be removed from the market because of safety issues.

Increasing numbers of new drugs are being removed from the market. Under pressure, the FDA adopted a faster approach that sometimes disregarded the warnings of its own experts. Further concern is that the agency is moving too quickly on switching prescription-only drugs to OTC status. Drug companies like to switch their drugs to OTC status as it is more profitable.

Another new development is that drug companies are starting to test their drugs overseas, where there is less delay and less scrutiny. Companies looking for lucrative drugs are turning to poorly paid foreign physicians and looking for a faster turnaround on drug testing. The FDA is only capable of inspecting a small number of foreign test sites; thus, there is concern. There is also concern that drug testing and investments overseas robs the U.S. government of tax dollars.

The FDA under Fire

The FDA is always under public scrutiny, especially what happened after rofecoxib (Vioxx) was removed from the market (2004) because of a heightened risk of myocardial infarction. The FDA has been accused of making drug safety a much lower priority than approving drugs. The FDA's drug safety section resides under the office of new drug approval and has a much smaller staff and budget.

The FDA is also under fire for having advisory panels with experts who have conflicts of interest because they receive grants or receive financial honorariums for speaking on behalf of drug companies. Many drugs were approved by the FDA with the understanding that the manufacturer of the drug would study the drug (primarily for safety) after approval, but rarely did this happen, and the FDA rarely checked to see that the studies were done.

FUTURE OF DRUG DISCOVERY

In 2000, a major scientific event took place. The human genome was mapped. The human genome is the basis for understanding the blueprint that directs our external appearance and behavior, as well as the quality of our internal organs. The human genome project is changing, dramatically, how drugs are discovered and developed. We are now on the verge of possessing genetic information on various diseases and the custom designing of drugs for patients with a certain genetic makeup. Although this is exciting, it is also complex. How all of this will affect the approval process for new drugs and the practice of pharmacy is unknown.

One of the most exciting areas of biotechnology research is *stem cells*. Stem cells are of wide interest because they have the potential, under suitable conditions, to develop into almost all different types of cells. The most concern is with the use of embryonic stem cells. It is also the most controversial as an embryo must be destroyed to harvest the stem cells. However, a development in the use of adult stem cells shows that these cells have wider potential than originally thought, and they can be harvested without controversy.[30]

There is also excitement about using *surrogate markers*—a kind of clinical trial "crystal ball." Surrogate markers are tests or patient milestones that researchers can use as stand-ins to predict longer term results, such as survival.[21] Also at this time, drug researchers are optimistic about *metabolomics*—studying the changes in concentrations of metabolites within the cells of the body to find unique patterns or profiles and a screening tool for disease.[32]

SUMMARY

Consumers and patients in the United States can be confident and proud of the drug discovery, development, and approval process for new drugs. They are less confident that once drugs and vaccines are approved, the medications are continually monitored for safety. Unfortunately, not all patients respond the same to all medication, and some medication harms some people, but not all people. Medications are approved for use by the FDA when the evidence says the benefits of the drugs outweigh the drug's safety.

Many pharmacists work in the drug discovery, development, and approval process for drugs and vaccines in the United States. Some work for pharmaceutical companies, some perform drug research in colleges of pharmacy and in hospitals, whereas others work for the FDA and CDC and help with the drug approval process or help perform postmarketing surveillance.

DISCUSSION QUESTIONS AND EXERCISES

1. What intrigues you the most about the following?
   a. The drug discovery process
   b. The drug investigation and testing process
   c. The drug approval process
2. Put the following in order of your interest: drug discovery, drug investigation and testing, and drug approval.
3. Which do you think is better: a drug designed to take once a day or one to be taken three times a day? Why?
4. A patient comes to you (the pharmacist) and is concerned that animals are being used to test drugs. How would you handle this?
5. How do you feel about giving people with an active disease a placebo (no active drug) because they were selected for the control group in a study?
6. How do pharmacists discover the results of new studies on drugs?
7. The FDA approves drugs as generally safe and effective. However, five drugs approved during the past 3 years have been removed from the market. Why do you think this has happened?
8. What would you do if a patient told you (the pharmacist) he or she was taking drugs ordered over the Internet that are not approved for use by the FDA?
9. What do you think the advantages and disadvantages are in doing drug research for a drug company versus doing drug research in a school of pharmacy?
10. Interview someone who does drug research. Ask what he or she likes and does not like about the job.

CHALLENGES

1. There are still some highly prevalent diseases throughout the world that have no drugs or vaccines to prevent them. For extra credit, and with the permission of your professor, investigate and prepare a concise report about two or three major diseases in this category. Make predictions about what would happen if vaccines or drugs were available to prevent these diseases throughout the world. Also, explore why these vaccines or drugs are not available and what can be done about this problem.
2. The number of students pursuing graduate degrees (master-of-science or doctor-of-philosophy) in pharmacy that would allow them to do drug research has declined. For extra credit, and with the permission of your professor, explore and write a concise report about this problem. Why does the problem exist? How bad is it? Advance at least five plausible arguments on how this problem can be solved for society.

WEBSITES OF INTEREST

Association for Accessible Medicines (formerly Generic Pharmaceutical Association): http://www.gphaonline.org
Food and Drug Administration: http://www.fda.gov
Homeopathic Pharmacopeia: http://www.hpus.com/
Pharmaceutical Research and Manufacturers of the United States: http://www.phrma.org/
U.S. Pharmacopeia: http://www.usp.org

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18 The Pharmaceutical and Biotechnology Industry

INTRODUCTION

Not that long ago, the usual choices for new pharmacy graduates were in community or hospital practice. Since 1980, the opportunities for pharmacists have exploded. One of these opportunities is working in the pharmaceutical and biotechnology industry.

There have always been pharmacists in the pharmaceutical industry. Indeed, several pharmaceutical companies were founded by pharmacists. However, in the past, most pharmacists working in the pharmaceutical industry were used as salespeople to convince physicians to prescribe their company's products. Today, pharmacists work in a wide variety of positions within pharmaceutical companies.

This chapter discusses how pharmaceutical companies are organized and highlights those areas within a pharmaceutical company where pharmacists work. Information is presented on the various titles pharmacists hold within the pharmaceutical industry, the transition from practice, career development, and the pros and cons of working for a pharmaceutical company.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Discuss how pharmaceutical companies are organized.
- Identify the departments in the pharmaceutical and biotechnology industry in which pharmacists work.
- Name three job titles held by pharmacists in the pharmaceutical and biotechnology industry.
- Discuss some of the issues associated with going from practice to the pharmaceutical and biotechnology industry.
- Explain how pharmacists can grow within the pharmaceutical and biotechnology industry.
- Contrast the pros and cons of working as a pharmacist in the pharmaceutical and biotechnology industry.

PHARMACEUTICAL COMPANIES

The pharmaceutical industry is large, diverse, and important. It produces chemicals, over-the-counter and prescription drugs, and other health products. Over 100 pharmaceutical companies are involved in the research of new drugs in the United States. Research-based pharmaceutical and biotechnology companies are devoted to discovering medicines to allow patients to live longer, be healthier, be happier, and lead more productive lives.

TABLE 18.1
Top Five Pharmaceutical Companies by 2016 Revenue

Rank	Pharma Company	Revenue (Billion)
1	Johnson & Johnson	$70
2	Bayer	$51
3	Novartis	$49
4	Pfizer	$49
5	Roche	$48

These companies invest billions of dollars to develop new medicines, even more on marketing and advertising than on research and development.[1] Most of the high cost for research and development is because only 1 of every 10,000 potential medicines makes it through the research-and-development (R&D) pipeline and is approved for use by the Food and Drug Administration (FDA).

Table 18.1 shows the top five pharmaceutical companies ranked by 2016 revenue. The top biotechnology companies for 2016 were Amgen, Novo Nordisk, Gilead Sciences, Allergan, and Celgene.[2] Because of mergers occurring, it is important to keep in mind the top five listings are dynamic.

All pharmaceutical companies employ pharmacists—some more than others. Pharmacists enjoy working in various positions within pharmaceutical companies. Some have become presidents or chief executive officers (CEOs) of these large corporations.

The emerging importance of biotechnology drugs is compelling. Many of the world's biggest-selling drugs are now biotechnology products, underlining the importance of the sector for the global pharmaceutical industry.

Organizational

Although individual pharmaceutical companies are organized differently, most have some of the same features. The most common areas in pharmaceutical companies where pharmacists work are R&D, government or regulatory affairs, medical affairs, pharmacovigilance, sales and marketing, trade and professional relations, and management and administration.[3]

Research and Development

The R&D division is responsible for the discovery and development of new drug products, dosages, and dosage forms.

Basic research is where breakthrough products are first imagined. Basic research involves studies of diseases and the synthesis of new drugs to treat these diseases. If a promising new drug is identified, it must go through rigorous acute and chronic toxicity studies in animals before it can be tested in humans (see Chapter 17, "How Drugs Are Discovered, Tested, and Approved").

Basic research is also where improvements are made to existing drugs. Pharmaceutical companies are always looking for ways to improve the effectiveness of and reduce any side effects of their approved drug.

Pharmaceutical development is closely related to research. It involves testing the chemistry, stability, and compatibility of a new compound. Development also is the area in which formulation of the dosage form, *pharmaceutic*s, takes place. "In a nutshell, pharmaceutical development bridges the gap between research and production. The product is taken from a research level to an intermediate level before going into full scale manufacturing."

Clinical research follows new products from the beginning through the four phases of clinical studies (see Chapter 17, "How Drugs Are Discovered, Tested, and Approved"). Clinical research involves planning, implementing, monitoring, and reporting clinical trials in humans.

Regulatory Affairs

The regulatory affairs department is responsible for representing data for drug products to the U.S. FDA. People working in government affairs monitor legislation and regulations. They also testify before state and federal legislators, and present to professional groups the views of the company on a piece of legislation or a regulation.[4]

Government affairs must keep executive management up to date on key developments in legislation and healthcare and represent the company in public and professional meetings. Personnel working in regulatory affairs must also recommend actions the company should take on particular issues.

Manufacturing, Production, and Quality Control

Manufacturing, production, and quality control are closely related, but in most companies, these are separate departments.

Manufacturing includes the buying of raw materials and the transformation of these materials into the finished product. At all levels, the goal is to ensure the production of a quality product.

To do this, pharmaceutical companies must comply with regulations called *good manufacturing practices* (GMPs).[3] Manufacturing is influenced by new technologies that are often changing.

Production involves producing the right amount of product at the right time. Work in production includes heading production units, supervising production employees, planning schedules, preparing budgets, and working to modernize equipment and procedures.

Quality control involves conducting tests to ensure that the product meets precise quality standards. People working in quality control are committed to meeting high manufacturing standards and quality assurance.

Medical Services/Affairs

Sometimes a part of medical services or operations, *medical affairs* supports many parts of the company through drug information, medical writing, and communication with various health-care professionals, including pharmacists. In most cases, this department focuses on adding value to existing products or funding new publications. Medical services may include all or some of the following disciplines: clinical applications, clinical development, disease state research, epidemiology, postmarketing surveillance, trade and professional relations, and medical affairs.

Sales and Marketing

Major pharmaceutical companies employ large numbers of people in their sales and marketing divisions. *Sales* is one of the largest areas of most pharmaceutical companies. Sales representatives are employed to discuss the features and benefits of the drug products of the company with physicians, pharmacists, and other health-care professionals. Anyone who may increase the use (and therefore sales) of these drugs is a potential client.

Marketing involves positioning the drugs of a company to maximize sales. The marketing department matches the benefits of the drug with the needs of patients and physicians and

develops marketing information for the sales representatives of the company. This information is also used in advertising the drug in medical journals, subject to approval by the FDA.

Trade and Professional Relations

The area of trade and professional relations within a pharmaceutical company provides services to the various health professions, chiefly medicine, pharmacy, and nursing. This department works to develop close relationships with the leadership and key opinion leaders of the health professions. Examples are the provision of continuing education, help in sponsoring speakers or support for national and state meetings of various health professional groups, and attendance at these meetings, when possible.

Management and Administration

"Managers and administrators make sure that their department works smoothly and is in line with the rest of the company. Hard work, dedication, and consistent success in each position of higher responsibility marks the company executive."[5]

PHARMACISTS IN THE PHARMACEUTICAL INDUSTRY

Pharmacists have been associated with the pharmaceutical industry since its beginning. Most companies recognize that the pharmacist's education and training provide an excellent background for work within the industry. Most pharmacists working in the pharmaceutical industry work for sales and marketing, and some work in management and administration, R&D, production and quality control, medical information, and drug safety.

Working in Sales

Pharmaceutical companies need knowledgeable sales representatives to promote the use of their products. Some companies, most notably Eli Lilly and Merck & Co, use many pharmacists as sales representatives, although individuals with business, science, or other backgrounds are also employed. Although some companies use college graduates with business or other backgrounds as sales representatives, the advantage of using pharmacists is their education and ability to communicate with other health-care practitioners. Pharmacists also understand the health-care delivery system and what is important to patients.

All sales representatives receive intensive training in the life sciences (if they are not pharmacists), communication, sales techniques, and the strategic goals of the company before they start work. Once oriented, sales representatives usually start their jobs working with "seasoned" sales representatives, and learning continues as long as the person holds the job.

The position as a local sales or field representative is considered entry level, but it is one that is important if the pharmacist wants to advance to a marketing or managerial position with increased responsibility in the company. Each sales representative has a territory to cover. The territory can be a large metropolitan area, part of a state, or several states. Thus, travel varies from company to company.

The major responsibility of a sales representative is to call on physicians to discuss the features and benefits of the products of the company. Thus, sales representatives must have a clear understanding of the indications, contraindications, dosing guidelines, side effects, and drug interactions of the products they detail. Sales representatives can only discuss information in the package insert that is approved by the FDA. This is referred to as "on-label" information.

There are also hospital sales representatives who call on physicians, nurses, pharmacy managers, and clinical pharmacists working in hospitals. Hospital sales representatives usually work as local sales representatives before they become hospital representatives.

Each sales representative reports to a district sales manager, who supervises a group of sales representatives. District sales representatives work for regional sales managers, who in turn usually report to a vice president of sales or product manager.

Managed care has dramatically changed how pharmaceutical companies conduct business. Today, account mangers interact with managed care accounts to maximize access to the products of a company. One goal is to get the product of the company on the managed care formulary with as few limitations as possible. Account managers report to regional account managers, who are responsible for all managed care plans within a larger area. Regional account managers report to a national account director, who is responsible for a single national account, such as Aetna, United Health Care, or Kaiser Permanente.

For those interested, some testimonials have been written by pharmacists who are pharmaceutical sales representatives.[5,6] There is also an excellent article, "How Do Pharmaceutical Companies Choose Sales Representatives?"[7] A sample job description is also available.[8]

Working in Marketing

A successful track record in sales can lead to opportunities for increased responsibility in marketing. Marketing is composed of product, price, promotion, and place. The perspective a previous sales representative can bring to the marketing area is important. The marketing department conducts research, planning, development of distribution channels, pricing, advertising, and support for sales representatives. Pharmacists dispense these roles well, especially if they also have a master of business administration or master of science degree in pharmacy.

Within the marketing division are product managers, who are responsible for the overall marketing strategy of a single product. They make decisions such as whether money should be spent in direct-to-consumer advertising or on sales ads in professional journals. Product managers report to the director of marketing, who has overall responsibility for multiple products.

An excellent reference, written by a pharmacist who has worked in the marketing area for a pharmaceutical company, is available for those seeking more information on this field.[6]

Working in Advertising

The pharmaceutical industry has been criticized for its aggressive promotion of its products to physicians, pharmacists, and the public.[9,10] The *direct-to-consumer advertising* of the industry is accused of spending an inordinate amount of time and a great deal of expense pointing out the benefits of its drugs and little time talking about the risks of its drugs.[11–13] Some pharmaceutical companies have overstepped their bounds in promoting the products of their company to physicians. This has resulted in tighter federal guidelines for the relationship of the pharmaceutical industry with doctors.[14]

Working in Management and Administration

Management positions exist in sales in the field (district sales managers) or in the administration of the company. Managers make sure their department works smoothly and is in line with the strategic plan of the company.

The move into management takes excellent people with organizational skills. "The RPh on your business card is very important when you start out in sales, but not that important later on. You are looked at for what you are and the knowledge you have, not for the title of pharmacist."[15]

Some pharmacists have advanced through the ranks of pharmaceutical companies to become high-level executives. A reference providing more insight on this is provided.[14]

Working in Research and Development

Pharmacists working in the basic research areas of a pharmaceutical company usually need a graduate degree (master of science or doctor of philosophy) in the physical–chemical areas. These areas include working at the research bench in pharmaceutics, pharmacokinetics, pharmaceutical chemistry, and toxicology. These pharmacists conduct and lead the early research on new drugs.

Pharmacists working in clinical research have a chance to develop and oversee clinical trials testing the safety and efficacy of new drugs. Pharmacists working in this area usually need a doctor of philosophy or doctor of pharmacy degree and sometimes a research-based clinical fellowship in a specific area of drug therapy.

Two references on pharmacists working in the basic and clinical research areas of pharmaceutical companies are provided for those interested in learning more about this interesting work.[15,16]

Working in Medical Affairs

Medical affairs, sometimes called the medical department, medical services, or medical operations, usually provides various functions.

Working as a Medical Science Liaison

Pharmaceutical companies have found a need to have knowledgeable *medical science liaisons* (MSLs) who are trained technical experts on the products of the company and related disease states. MSLs provide the latest information to opinion leaders in medicine and pharmacy, often well before a drug is approved by the FDA. Their goals are to support product utilization and formulary adoption. In addition to this, MSLs function to coordinate investigator-initiated studies. These are independent research projects funded by the company, submitted by key opinion leaders, and may provide postmarketing scientific information surrounding a product of a particular company.

Scientific liaisons differ from salespeople in that they can discuss information outside the package insert, referred to as "off label." Scientific liaisons cannot be involved in commercial or promotional activities. Pharmaceutical companies maintain strict adherence in separating the activities of sales and medical affairs.

These positions require a doctor of pharmacy, medicine, or philosophy degree along with extensive clinical experience (usually 5 years), typically in a specialty area of drug therapy (e.g., infectious disease, cardiology, respiratory diseases).

Working in Drug Information

There is a need within a pharmaceutical company to provide accurate and up-to-date drug information in response to inquiries from health-care professionals, consumers, and other departments within the company. This job requires skills in drug information retrieval, drug

literature evaluation skills, communication, and knowledge of the products of the company. Most companies hire pharmacists with doctor of pharmacy degrees, and most prefer someone who has also completed a residency in drug information. Pharmaceutical companies may have several medical information pharmacists, and these can be aligned to each product therapeutic area.

Working in Medical Writing

Medical departments of pharmaceutical companies write product monographs (written summaries on the technical details of a drug) and sales training manuals to support the sales and marketing division. They also prepare scientific manuscripts for publication in medical and pharmacy journals and write technical documents for submission to the FDA. Pharmacists have the scientific and clinical background to do this job well; however, candidates for these positions also need good writing skills.

Working in Outcomes Research

Medical practice has advanced to measuring the success of drugs by the health outcomes they produce rather than their theoretical value based on the pharmacology of the drug. Health outcomes include clinical outcomes, humanistic outcomes, and economic outcomes (see Chapter 10, "Managed Care Pharmacy"). Pharmaceutical companies understand they now have to perform outcome studies to prove to practitioners (physicians and pharmacists) that their drug produces positive outcomes.

Outcome researchers develop and conduct outcome studies to support their products. Pharmaceutical companies are now beginning to incorporate outcomes research during the phase trials. Some will work with customers (mostly managed care organizations and some large hospitals) to develop the means to answer some research questions customers want answered. Most pharmaceutical companies hire those with doctor of pharmacy degrees who have completed a pharmacoeconomics fellowship or pharmacists with graduate degrees (master of science or doctor of philosophy) in health outcomes or pharmacoeconomics to do their health outcomes work.

Outcomes research sections of pharmaceuticals need to do a better job of aligning their efforts for what is needed out in the field, and what's best for patients and their providers, rather than what is solely best for the company. Any company that does this will reap great benefits. What may be needed is improved incentives by big payers (like Center for Medicare & Medicaid Services [CMS]—Medicare) and more pharmacists with training in outcomes research. Additionally, contracts with payers that contain terms based on outcomes can highlight a drug's value.[17,18]

The pharmaceutical industry has a long-standing aversion to a requirement to compare their drugs to competitor products, rather than what is required by the FDA for approval, which is comparison to a placebo. Comparing the effectiveness of products is called *clinical effectiveness research* (CER).[19] CER is a dirty word to the pharmaceutical industry. Shivers went down their spines when a very old diuretic (hydrochlorothiazide) was shown to be as effective as newer, more expensive drugs as a first step in treating essential hypertension.[20] The pharmaceutical industry has fought "tooth-and-nail" to prevent CER from being incorporated into new health-care legislation.[21]

Working in Drug Safety

The drug safety field is responsible for maintaining a database of postmarketing adverse drug events and reporting serious events to the FDA. These reports may come to the attention

of the company via consumers, health-care professionals, or the MSLs or sales representatives of the company. All employees are required to report product adverse events within 24 hours. *Pharmacovigilance* is the term applied to the science of the detection, assessment, understanding, and prevention of adverse events. Most pharmaceutical companies have a department of pharmacovigilance.

Another role of the pharmacovigilance department is to conduct additional clinical studies following the approval of a drug by the FDA (phase 4 studies). These postmarketing studies may be performed to answer additional questions about a drug or its place in therapy or may be required by the FDA as a condition of approval of a drug. Formal postmarketing surveillance can be performed by pharmacists if they have added training in pharmacoepidemiology. Such training can be gained by earning a master of science degree in biostatistics and epidemiology or by completing a fellowship in pharmacoepidemiology.

One reference is provided on careers for pharmacists in the medical affairs department of pharmaceutical companies.[22]

Working in Manufacturing, Production, and Quality Control

The manufacturing and production of pharmaceuticals provide an ideal job for pharmacists interested in using their technical knowledge and getting involved in the rapidly changing world of technology. The pharmacist in the manufacturing and production area must be task oriented, have a sound understanding of people, and have strong managerial skills. "Because pharmaceutical operations are specialized, high-level careers in this area almost always need an advanced degree."[23]

Working in Trade and Professional Affairs

Pharmacists are ideally suited to work in the trade and professional affairs sections of pharmaceutical companies. After all, they understand the profession, and they know the needs and concerns of hospital, clinical, community, managed care, and consultant pharmacists. Pharmacists working in the trade and professional affairs departments are well-known and well-liked individuals because it is their job to help pharmacists, and pharmaceutical companies are generous with resources to the profession.

Working in Regulatory Affairs

Pharmacists working in the regulatory affairs divisions of pharmaceutical companies help prepare *Investigational New Drug* (IND) applications and *New Drug Applications* (NDAs) for submission to the FDA. Before writing these, they must analyze data from animal, laboratory, and clinical studies. This division must also monitor all health-care legislation and regulations. Thus, an interest in legal affairs is a plus.

Regulatory affairs is a sophisticated and complex process; thus, there are master of science programs at two colleges of pharmacy, and certification by examination is available.[20] An excellent reference is provided for readers interested in this field.[22]

Moving from Practice to the Industry

There is usually some concern when a pharmacist is faced with a decision to give up practice to go to work for a pharmaceutical company. Some of this concern is about losing touch

with patients, and some is about losing some autonomy. One pharmacist has documented his concerns, thought process, and the pros and cons of making the transition to the pharmaceutical industry.[24]

Female Pharmacists in the Pharmaceutical Industry

Women, particularly female pharmacists, have made great strides in the pharmaceutical industry. A survey showed that women like the personal growth and interesting responsibilities.[25] Despite these findings, the industry recently sponsored a brainstorming meeting designed to help raise awareness of the need to have more women in top positions and to increase the understanding of the challenges women face.[26]

SATISFACTION AND CAREER ADVANCEMENT

Pharmacists working in the pharmaceutical industry are satisfied with the work and enjoy knowing that what they do helps people improve their quality of life by using the drugs of their company. Working for a pharmaceutical company can be exciting as new drugs work themselves through the discovery, development, and clinical trial process and then are approved for use and launched.

Pharmacists working for pharmaceutical companies find the salaries, benefits, and incentives attractive. The downside for some pharmacists is missing direct patient care, and working long hours add to the stress and pressures that can come with working for a major corporation.

At the same time, career advancement can be rapid. The following would be a typical career path to becoming vice president of marketing[27]:

1. Professional sales representative
2. District sales manager
3. Product manager
4. Director of marketing and sales
5. Vice president of marketing

The following is an example of how someone in a pharmaceutical company could advance to be the president of the company[28]:

1. Professional sales representative
2. Coordinator of sales training
3. District sales manager
4. Product manager
5. Regional sales manager
6. Vice president of sales
7. Vice president of marketing
8. President

"Hard work, dedication, and consistent success in each position of higher authority marks the company executive."[28] Pharmacists, with their backgrounds and training, are contributing much to the success of the pharmaceutical industry, and they have the ability to rise to high levels within the corporate structure of these companies.

CASE STUDIES

There are two interesting case studies of pharmacists: one pharmacist who has spent his entire career in the pharmaceutical industry, and another pharmacist who started out in practice and then switched to a career in the pharmaceutical industry, and then went back to practice.[29,30] These case studies provide more insight into what it is like to work for a large pharmaceutical company. Description of a day in the life of a pharmaceutical sales representative is also available.[31]

CRITICISMS OF THE INDUSTRY

The pharmaceutical industry provides many new and wonderful drugs. However, to provide a balanced view of the pharmaceutical industry, one must provide some current criticisms. Here are just a few from a previous editor of the *New England Journal of Medicine* and a well-known academic physician at the Harvard Medical School.[32,33]

- The pharmaceutical industry claims to be a high-risk industry, but every year has higher profits than any other industry.
- The pharmaceutical companies are not that innovative—most drugs are "me too" drugs.
- Many of the most innovative drugs are researched by academic medical centers, financed by the federal government (National Institutes of Health), and then acquired by pharmaceutical companies.
- Drug companies promote diseases to match their drugs.
- The drug companies have too much influence over medical education and practice.
- Big drug companies spend far more on sales and marketing than on research.

Other criticisms include having influence over many members of the drug advisory panels of the FDA by funding many of these members' research or paying honorariums for speaking on behalf of the pharmaceutical companies or being on their advisory boards and having unbalanced direct-to-consumer advertising.

Whether or not these criticisms are valid should be investigated and determined by the reader.

SUMMARY

Today, a variety of positions within the pharmaceutical industry are available for pharmacists. Some positions require a doctor of pharmacy degree, others require advanced training (a residency or fellowship), and other positions require a master of science or doctor of philosophy degree in a basic science. A career in the pharmaceutical industry can be rewarding, and advancement is possible. However, like any job, it has its cons as well.

If you are interested in working for a pharmaceutical or biotechnology company, you may want to do some further reading:

- Pharmaceutical industry 101.[34]
- Getting started in the pharmaceutical industry.[35]
- Endless opportunities in the pharmaceutical industry.[36]

DISCUSSION QUESTIONS AND EXERCISES

1. Put the following areas in which pharmacists work in the pharmaceutical industry in order of your preference:
   a. Sales
   b. Marketing
   c. Medical services
   d. Research
   e. Manufacturing and production
2. In some areas of the pharmaceutical industry where pharmacists work, it is recommended that the pharmacist have education and training beyond the doctor of pharmacy degree. What are these areas?
3. Pharmaceutical companies vary considerably. Some are large, and some are small. Some are more research based, whereas others are based more on sales and marketing. Comment on your preferences and why.
4. How do salaries and benefits for pharmacists working in the pharmaceutical industry compare with positions for pharmacists outside the pharmaceutical industry?
5. If a person does a good job, new opportunities and promotions are commonly available in the pharmaceutical industry. However, a promotion sometimes means relocating to a different city. How comfortable are you with this possibility?
6. Do you think there might be ethical dilemmas when working as a pharmacist in the pharmaceutical industry?
7. Do you feel there is stigma associated with working as a pharmacist for the pharmaceutical industry?
8. Make an appointment to interview a pharmacist working for a pharmaceutical company.
9. What do you feel are the pros and cons of working for the pharmaceutical industry?
10. Based on what you know and have read about working within the pharmaceutical industry, is this something you may want to do? Why or why not?

CHALLENGES

1. The goal of pharmaceutical companies is to stay within the law and make as much money as possible for their investors. They do this by trying to produce the safest, most effective drugs and heavily marketing these drugs to those who have control over their use. For extra credit, and with the permission of your professor, write a concise report on the methods you would use as a pharmacist to determine if the merits of the drugs promoted by drug companies are valid and if there is evidence of the efficacy and safety of a drug.
2. For extra credit, and with the permission of your professor, prepare a concise report comparing and contrasting the pros and cons of working in the pharmaceutical industry with another career choice for a pharmacist.

WEBSITES OF INTEREST

Association for Accessible Medicines (formerly Generic Pharmaceutical Association): http://www.gphaonline.org

Biotech Industry Organization: http://www.bio.org/

Parenteral Drug Association: http://www.pda.org/
Pharmaceutical Research and Manufacturers of America: http://www.phrma.org/

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19 Other Opportunities for Pharmacists

INTRODUCTION

Most pharmacists work in community pharmacy practice, and this is the first choice of newest graduates who do not want to complete a pharmacy residency program. Other common choices for pharmacists are hospital pharmacy, managed care pharmacy, and consultant pharmacy. There are, however, many more opportunities for pharmacists.

This chapter provides an overview of over 20 nontraditional pharmacy opportunities. Some of these jobs are well known, whereas others may come as a surprise to the reader. There is no way of knowing exactly how many pharmacists work in each of these areas. What is known is that pharmacists with nontraditional careers enjoy what they do. If any of these are of interest, you will need to do more investigation to discover more about them.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Identify and explain at least eight nontraditional career pathways for pharmacists.
- As you see it, provide one positive feature and one negative feature of each of the nontraditional pathways listed under the major headings.

Today, pharmacy graduates have diverse opportunities to practice pharmacy.[1] In addition to community and hospital pharmacy jobs, there are many nontraditional opportunities, and the list is expanding.

ALTERNATIVE MEDICINE

Alternative medical therapies are defined functionally as interventions that are neither widely taught in medical schools nor widely available in U.S. hospitals.[2] *Alternative medicines* include herbal medicines, folk remedies, megavitamins, and homeopathy. About one-third of Americans use alternatives medicines that are sometimes called *natural medicines*.[3] The problem is that most of these products have never been tested for effectiveness using accepted research methodology (like double-blind controlled trials).[4] However, pharmacists have an opportunity to be experts in this area and can help patients use these products safely and more effectively.

Herbal Medicines

Herbal medicines are the various parts (seeds, barks, leaves, berries, or roots) of naturally growing plants. These plant parts are thought to contain one or several active ingredients that help to relieve from various ailments. Herbal products can be sold in the United States as "dietary supplements," which is a restriction of the Food and Drug Administration (FDA).

The maker cannot make claims that a dietary supplement can be used to treat, cure, diagnose, or mitigate a specific disease. Only structure–function claims can be made, for example, "improves breathing" or "reduces blood pressure."

The use of herbal medicines by the public is increasing and is a wonderful opportunity for pharmacists to advise patients on which products may work, how to take the medicines, and to report adverse effects.[5]

Folk Remedies

Folk remedies, which are remedies handed down from generation to generation in various ethnic groups, and have existed in the United States for hundreds of years. Various Native American tribes still use these remedies, and folk medicine cures are still commonly used by some people in New England and in mountainous areas of southeastern United States.

Megavitamins

Megavitamin use involves taking large doses (many times the normal daily requirement set by the government) of vitamins and minerals. The theory is that if a little is good, more should be better. However, there is little or no scientific evidence that this theory is true. In fact, overuse of fat soluble vitamins (A, D, E, and K) can lead to toxicity. Although regulated by the FDA, most vitamins and minerals are over-the-counter products that can be sold in any retail outlet. Thus, health food stores and mass merchandisers can sell these products, and no pharmacist is available to advise patients.

Homeopathy

Homeopathy was founded by a German physician, Samuel Hahnemann, over 200 years ago.[6] Homeopathy is based on stimulating the body to recover itself. Homeopathy is also based on likes curing likes. This is done by using minute dilutions (as small as 1 part per million) of a mineral, botanical substance, animal part, microorganism, or other source that, in larger doses, would produce the very symptoms the patient is experiencing.

Homeopathic medicines are drug products made by homeopathic pharmacists using processes described in the *Homeopathic Pharmacopoeia of the United States* (HPUS), the official manufacturing manual recognized by the FDA.[7]

Although many doubt the effectiveness of homeopathy, there is some scientific evidence that it works better than a placebo in at least one condition: perennial allergic rhinitis.[8] However, the study was conducted in only a few patients.

Pharmacists can be helpful to patients who turn to homeopathy. A guide for doing this is available.[9]

Pharmacists and Alternative Medicines

The increased use of alternative medicines affects the pharmacist in several ways. First, every practicing pharmacist must be knowledgeable about these products: their uses, effectiveness, and adverse effects. Second, the sale of effective alternative products and counseling patients on their use can supplement a practice or become full-time work.

Of the 400 pharmacists responding to a survey, 94% said they believed many alternative medicines can be helpful to the health of patients.[10] Concern was expressed about the unregulated nature of the products, including concerns about toxicity, and the need for more evidence that alternative medicine works.

Despite some misgivings pharmacists have about the use of alternative medicines, pharmacies are stocking more and more of the products. Independent community pharmacies are taking more interest in this niche market, and some community pharmacies are starting to include homeopathic products.

It is recommended that pharmacists wanting to specialize in alternative medicines learn more about these products by studying professional journals, taking some coursework (e.g., at Columbia University and the University of Arizona), and completing continuing education programs.

ASSOCIATION MANAGEMENT

Pharmacy associations are to pharmacists what government is to its citizens—they represent, protect, and promote the profession.[11]

Why Consider This Opportunity?

Pharmacists working in *association management* speak of professional growth and personal satisfaction.[12] Job diversity and the opportunity to have a direct impact on the future of the profession are the attractions.

What Do Association Pharmacists Do?

It is estimated that more than 200 pharmacists work for state and national pharmacy associations in the United States. Pharmacists working in professional pharmacy organizations work in the management structure or as staff members of the organization.

Pharmacists working in the administrative part of a professional association use a broad range of administrative skills to help achieve the mission of the organization. Working with the elected leadership of the association, its executives help set up the organization's goals and objectives and continue their achievement by carrying out effective strategies.

A few specific functions pharmacists are providing in associations today include editing, writing, public relations, government affairs, developing practice standards, educational programming, practice information resources, residency and technician training inspections, providing advice on patient safety, drug shortages and counterterrorism, and developing student leaders.

Pharmacist staff members of professional pharmacy organizations use skills in law, clinical pharmacy, journalism, education, and public relations to help serve the profession and its members.

Getting Started

Pharmacy students interested in association management can start exploring this opportunity by visiting a state or national pharmacy organization and asking the pharmacists who work there about their jobs. Some schools of pharmacy offer elective classes in management and pharmacy administration that can help.

Some pharmacy organizations, such as the American Pharmaceutical Association (APhA) and the American Society of Health-System Pharmacists (ASHP), and some national pharmacy fraternities and sororities offer association management internships in the summer. The ASHP, the APhA, and the American Society of Consultant Pharmacists (ASCP) offer 12-month postgraduate residencies in association management.

ENTREPRENEURSHIP AND CONSULTING

Entrepreneurship

Entrepreneurs are usually viewed as individuals who take substantial risk to start new endeavors.[13] The following traits help make for a successful pharmacist entrepreneur[14]:

- Draw inspiration from their unique experiences
- Surround themselves with like-minded individuals
- Use technology to reach more people in new ways
- Strive to advance the practice of pharmacy through their unique skill sets
- Adaptive to change
- View taking action to achieve their dreams as an exciting challenge
- Don't listen to naysayers
- Proactive in helping others and building support systems
- Aren't afraid to adjust to market demands
- Know that innovation takes courage

Consulting

Since pharmacy is knowledge based, pharmacists possess knowledge and know-how about pharmacy, drugs, and drug therapy that can be valuable to others. Pharmacists with specific knowledge and experience can consult on a part- or full-time basis.

Pharmacists have always consulted. However, modern pharmacy consulting started in the early 1970s when federal requirements for pharmacy consulting in long-term care were mandated. The ASCP represents pharmacists interested in pharmacy consulting.

Few pharmacists start out as consultants. Most work for years in traditional or clinical practice and gain valuable experience. Pharmacists sometimes become bored with what they are doing, or they become tired of working for somebody else. They start looking around for something different to do. The same happens when some pharmacists retire from what they have been doing most of their lives. They would still like to work, but not necessarily full time. Consulting is a good way to continue working as much, or as little, as they want. To do consulting, the pharmacist must have some relevant knowledge and, if doing full time, must be bold enough to take the step of not having a guaranteed source of income.

Consulting Services and Clients

To be successful at consulting, the entrepreneurial pharmacist must have some knowledge or know-how needed by others. The following discussion involves services some pharmacists who perform consulting offer, the skills needed to offer these services, and some potential clients for these services.

Education

Many organizations need education that can be provided by a pharmacist or those who can organize educational sessions. The client for these services is usually the pharmaceutical industry. The education is needed within the company, or the company sponsors educational programs for various professional groups, such as physicians, nurses, or pharmacists.

Pharmacists organizing educational programs for the pharmaceutical industry need strong organizational skills, and they need to know who can speak, and speak well, on certain topics. Thus, the educational consultant pharmacist needs to be well networked with others to be successful.

Public Speaking

Pharmacists who have knowledge in an area of interest to others always have opportunities to be hired as public speakers. The clients are professional health-care organizations, who are always looking for interesting speakers for the various educational meetings they sponsor. Speaker bureaus of pharmaceutical companies always need good speakers, and they keep a pool of available speakers who can talk on interesting topics. Public speaking is a good way for consultant pharmacists to keep visible, and it is a chance for pharmacists to display and market their expertise. However, pharmacists who want to be good speakers must be interesting teachers, proficient in audiovisual preparation, and entertaining.

Professional Writing and Editing

Good writers are always needed in the health-care field. The clients are book publishers, journal editors, and companies that publish manuals and educational materials for health-care professionals.

The required essential skills include good writing and communication skills, intellectual curiosity, the willingness to take risks, being open to new ideas and perspectives, and having a fresh approach to subjects. To be a good writer, you need to read—a lot. As Stephen King and Ernest Hemingway have said—you need to take time to read if you want to write.[15,16]

Many journals and magazines have a set range of fees for writing certain types of articles. The person submitting the article can name his or her price but should be willing to accept less in the beginning. This field is low in pay to begin, but fees can become higher once writers get established and become known for their good writing.

Consultant to the Pharmaceutical Industry

Some pharmacists are hired as consultants, on a project basis, by the pharmaceutical industry. Most of these pharmacists have technical knowledge in a basic science or in an area such as regulatory affairs. Some clinical pharmacists are hired as consultants to help with phase 3 and 4 clinical trials.

Some pharmaceutical companies also have community or hospital pharmacy advisory boards that hire well-known pharmacists to help the company market its new products or to advise the company on how it should be approaching physicians and pharmacists about its products.

Patient Self-Care

Some pharmacists have set up consulting practices that help patients with self-care.[17,18] Some of this consulting is done outside the retail pharmacy setting, and pharmacists are paid to aid patients with their self-care needs. The key to this business is having access to a supply of patients who have a high priority for keeping healthy or who have poor access to care. It is also important that the self-care pharmacist knows which products and services patients need. Marketing services to physicians for referrals and to patients for new and repeat business is critical.

Setting Up Services and Providing Staffing

Some pharmacists have developed consulting services based on their pharmacy practice expertise. They provide expertise in setting up systems such as unit dose or intravenous additive services, performing *drug use evaluations* (DUEs), setting up pharmaceutical care, or developing specialized clinical services. Some pharmacists have gone into the staffing business and supply pharmacists and pharmacy technicians on a short-term or long-term basis.

The clients for these services are hospitals and managed care organizations. Sometimes these organizations need education and training. To be a consultant in pharmacy practice, the pharmacist must have expertise in a needed area, strong organizational and time management skills, and the ability to keep on top of everything.

Home Health Services

Home healthcare is the practice that specializes in treating patients in their homes or other residential facilities.[19] Pharmacists begin by offering their expertise in nutritional support and providing home infusions. The clients are home care agencies, hospices, and home infusion facilities. The knowledge needed is that of nutritional support. The skill needed is to convince others that your expertise will strengthen the services they provide to patients.

The Business of Consulting

Legal Status and Accounting: For pharmacists deciding to be consultants on a full-time basis, it is strongly advised that they seek counsel of a certified public accountant (CPA) and incorporate their business. Several options are available, each with pros and cons. This decision adds the greatest layer of protection and the most flexibility.

Insurance: Two kinds of insurance will be needed—professional liability (to protect you) and business (to protect your company).

Proposal Writing: Often, the client will want the pharmacy consultant to provide a proposal for services. These proposals need to be carefully developed.

Fees: It is important that the consultant pharmacist be paid a fair fee for the services delivered. What the pharmacist charges for his or her consulting needs to be competitive, thus discovering what others are charging for similar services even if it is outside pharmacy. Usually, pharmacists charge too little, although some start low and then charge more as experience is gained. The entrepreneurial pharmacists must pay their own employment, Medicare, Social Security, and employment taxes, as well as overhead insurance, accounting fees, supplies, etc. The hourly fee charged may be more than three times the hourly wage if employed by someone else.

Contracts: If possible, it is always important to have a contract or letter of agreement for jobs performed for clients. These can be basic, but must specifically list the work to be performed, the time frame, any deliverables, and the consideration for the work completed.

Risks and Rewards

The risks of trying to do full-time pharmacy consulting involve not knowing when the next paycheck is coming and how much it will be. Business is usually not continuous; it ebbs and flows, so money needs to be set aside to avoid cash flow problems and this can be stressful. Many people are not willing to take these risks. However, successful, entrepreneurial pharmacists repeatedly use words such as *challenging, stimulating*, and *rewarding*. What they enjoy is

solving problems and seeing their ideas carried out. They also enjoy working for themselves, making their own decisions, setting their own schedules.

COMPOUNDING PHARMACY

Compounding pharmacy is defined as practicing as a dispensing community pharmacist with an emphasis on preparing customized dosage forms and prescription medication to meet individual patients' or physicians' needs. About 1% of all prescriptions dispensed in independent pharmacies are compounded.[20]

Compounding pharmacies prepare medications that are not commercially available or become unstable easily. They sometimes take commercially available medications and can alter them to serve the needs of the patient.

Modern-day compounding combines an ageless art with the latest medical knowledge and state-of-the-art technology, allowing specially trained professionals to prepare customized medications to meet each patient's specific needs. Compounding is fundamental to the profession of pharmacy and was a standard means of providing prescription medications before drugs began to be produced in mass quantities by pharmaceutical manufacturers.

The demand for professional compounding has increased as health-care professionals and patients realize that the limited number of strengths and dosage forms that are commercially available do not meet the needs of many patients, and that these patients often have a better response to a customized dosage form that is "just what the doctor ordered." Compounding professionals can prepare the following:

- Unique dosage forms containing the best dose of medication for each individual
- Medication in dosage forms that are not commercially available, such as transdermal delivery
- Gels, troches, and lollipops
- Medications free of problem-causing excipients such as dyes, sugar, lactose, or alcohol
- Combinations of various compatible medications into a single dosage form for easier administration and improved adherence

For those interested, there is an article offering insight into a day in the life of a compounding pharmacist.[21] A compounding pharmacist job description is also available.[22]

FORENSIC PHARMACY

Some pharmacists have expert knowledge of pharmacology, pharmacokinetics, therapeutics, or drug safety, and can be hired as consultants and expert witnesses to provide reviews of legal cases, provide depositions, or testify in trials involving medication. The clients are usually attorneys. This practice is known as *forensic pharmacy*: the application of medication sciences to legal work.[23]

Forensic pharmacists engage in litigation and the regulatory process and sometimes in the criminal justice system, and use expert skills in evaluating drug-related evidence for court cases. To do this work, one must study, be prepared for anything, be unbiased, be knowledgeable about the legal system, and be able to stand the pressure of long depositions and cross-examinations by attorneys.[24]

INFORMATICS

No other field has recently impacted pharmacy so dramatically than *informatics. Pharmacy informatics* is defined by ASHP as the integration and use of knowledge, information, technology, data, and automation in the medication-use process.[25] Clinical informatics practice is meant to streamline patient care and outcomes while enhancing efficiency, accuracy, and safety in the prescribing, dispensing, administration, and use of medications.

The entire field of health-care informatics has exploded for some of the following reasons:

- The current health-care system is decentralized and fragmented.
- The parts of the medication use system need to mesh smoothly to achieve safe and effective medication therapy.
- All pharmacists are impacted by the medication use system—when it is working well and when it is not—and when it is not, they must scramble to make sure each patient's safety is not endangered.
- The desired results are interoperable systems and *electronic health records* (EHRs) that readily provide all health practitioners, in all locations, with access to up-to-date information about a patient's care.

An account on being an informatic pharmacist is available.[26]

MEDICAL EDUCATION AND COMMUNICATIONS

Some pharmacists work for companies that produce various written *medical communications*. Some of these communications can be package inserts for pharmaceutical companies, documentation and manuals for computer software, drug therapy newsletters (e.g., *The Medical Letter*), brochures, handbooks, and advertisements for drugs.

Medical communicators review the literature, explore developments, and interact with medical experts. They must know how to write in an interesting way to keep the reader's attention. Pharmacists going into medical writing also need above-average writing skills and should be able to find information, balance several projects at once, and meet deadlines.

There are some interesting articles about being a pharmacist in the medical education and communication fields.[27–29]

MAIL-ORDER PHARMACY

Patients can mail their prescriptions or have their physician call in a prescription for them to a remote pharmacy. After dispensing, the *mail-order pharmacy* mails the medication to the patient. This is usually legally permissible, even between most states, as long as the pharmacist can reasonably determine that the prescription is legal, is for an FDA-approved drug, and the prescriber is licensed to prescribe in the state where the prescription was written.

Value of Mail-Order Pharmacies

The value of mail-order pharmacies is continuously debated by pharmacists. Those in the business feel that they are meeting patients' needs and providing a fine service both legally and ethically. Patients use and like mail-order pharmacy services for the savings they gain by buying their medication in this manner. However, patients sometimes get anxious about

receiving their medication on time. Some community pharmacists are quick to point out the lack of face-to-face, personal attention and ask whether there is a relationship between the pharmacist working at the mail-order pharmacy and the patient.

What It Is Like Inside a Mail-Order Pharmacy

Mail-order pharmacies are large operations with cutting-edge technology. The following is a description of what you might see inside a mail-order pharmacy:

> Inside the pharmacy, vacuum tubes pop the exact quantity of pills required for an individual's prescription into a procession of plastic trays dispensed with bottles. Machines screw the caps onto the bottles with a force just right for handling by an arthritic senior. Robotic arms zero in on the correct bottle for a patient from thousands of trays and drop it into a waiting, addressed envelope. Conveyor belts carry the envelopes to mail-sorting stations, where they slide off sloped trays into large bags, ready to be taken to the nearby postal depot.[30]

Largest Mail-Order Pharmacy Provider

Many people are surprised to learn that the first (early 1950s) and largest provider of mail-order prescriptions in the United States is the Department of Veterans Affairs (VA): the VA hospitals and medical centers. The VA mails approximately 100 million prescriptions per year, of which 65% are dispensed through automation. How the VA does this is fascinating (see Chapter 6, "Pharmacy Informatics").

The VA has regionalized and automated its large outpatient medication refill program. Instead of each VA medical center refilling and mailing prescriptions, the refills are electronically sent to a regional consolidated mail-order pharmacy (CMOP).

Commercial Mail-Order Pharmacies

The American Association of Retired Persons (AARP) started a commercial mail-order pharmacy in the 1950s. Today, there are over 300 commercial mail-order pharmacy programs. Some of the major commercial mail-order pharmacies are Express Scripts, Caremark, Medco, and Walgreens.

Although mail-order pharmacies have been gaining on the retail pharmacy market share, the use of mail order is starting to drop (see Chapter 8, "Ambulatory [Community] Pharmacy"). This may be because most health plans only allow 90-day dispenses of prescriptions through mail-order pharmacies. There are advantages and disadvantages for consumers using mail-order pharmacies. Advantages include the following:

- *Convenience:* Consumers can get a 90-day supply of each of their medications delivered to their home.
- *Consumers may save money:* Their health plan may have lower copayments for prescription medications obtained through mail order.
- *Consumers can easily order refills:* If the prescription is current, most mail-order pharmacies allow a person to order refills online, by mail, or by phone anytime of the day or night.

Disadvantages include:

Safety issues: Buying medications through the mail from online drugstores that are not reputable puts a person at risk for getting the wrong medication or counterfeit medication.

Mail delivery issues: Although safe and efficient, packages handled by the U.S. Postal Service can get lost or damaged. In addition, there is a small danger of your package being stolen from a rural or suburban mailbox.

Mail-order delivery can be slow: When you use a mail-order pharmacy, it may take as long as 2 weeks to receive your medication shipment. This may be okay if you plan ahead. If you wait until you are almost out of medication before you order a refill, however, you will need to pay for overnight or one-day shipping, which can be expensive.

No face-to-face contact with your pharmacist: One of your most valuable health resources in your community is the pharmacist. If a person takes several medications and uses over-the-counter drugs, the pharmacist can advise them about interactions and side effects.

Mail-Order Practice

Pharmacists working in *mail-order pharmacies* share the same dedication to patients as their retail counterparts. They dispense and consult with professionalism while meeting productivity goals. Their functions include screening prescriptions, calling physicians, answering calls from physicians and patients, dispensing, checking prescriptions for accuracy, calling patients, and improving patient adherence.

Mail-order pharmacies provide toll-free telephone numbers and patient advisory leaflets with every new and refill prescription. Other safety features include pharmacists checking each other on certain types of prescriptions, such as those for warfarin. There are also standards when patients receive their medication. For example, the AARP mail-order pharmacy service expects that patients will receive their medication within 6 days of mailing in a prescription.

There are pros and cons of every pharmacist position, and this is true of working for a mail-order pharmacy. The pros of working for a mail-order pharmacy include flexible schedules (sometimes no weekends, evenings, or holidays), the chance to discuss matters with patients, informal dress codes, and advancement. The major disadvantages are lack of face-to-face contact with patients and the stigma sometimes felt because of competition with retail pharmacies. Other concerns include standing all day and repetition.

What it is like to be a mail-order pharmacist?[31] A sample job description is also available.[32]

NUCLEAR PHARMACY

Many students are not aware of the field of *nuclear pharmacy*, as only a few schools of pharmacy offer elective courses in this subject. The practice of nuclear pharmacy involves tagging, which is attaching low-level radioactivity to a drug.[33] The compounded new product becomes a *radiopharmaceutical*. Radiopharmaceuticals are chiefly employed to aid diagnosis of a disease and to monitor the outcome of drug therapy.[34] The radiopharmaceutical is injected into a patient, and the drug localizes in a target organ depending on which drug is used. A camera is placed over the patient's organ, and the radiation from the radiopharmaceutical exposes the film in the camera. Nuclear medicine physicians read the film to see whether the patient's organ is functioning normally.

Most *radiopharmaceuticals* are prepared fresh each morning; therefore, a nuclear pharmacist's day starts early in the morning. Early tasks involve reviewing the schedule of patients for the day, preparing the radiopharmaceuticals, keeping records, consulting with referring physicians and the nuclear medicine physicians, perhaps providing some teaching, and doing some committee work.

The Nuclear Regulatory Commission (NRC) requires a minimum of 700 contact hours of training (typically 200 hours of didactic instruction and 500 hours of experiential training) to become an "authorized user" of radioactive material. This training can be obtained from some colleges of pharmacy, through residency training, or from one of the three major companies (Mallinckrodt, Nicomed-Amersham, and Syncor) that employ nuclear pharmacists.[34]

Nuclear pharmacy was the first specialty area recognized (in 1978) by the Board of Pharmacy Specialties (BPS).[35] There were 455 board-certified nuclear pharmacists in 2016.

Nuclear pharmacists are satisfied with what they do. One nuclear pharmacist has stated, "I am very happy with my career in nuclear pharmacy. New drugs, better technology, and the demand for improved diagnostic techniques make this industry dynamic. I find the changes mentally stimulating because they put my knowledge of the pure sciences to use."[33]

Two excellent references are provided for those seeking more information about nuclear pharmacy.[36,37]

PHARMACY BENEFIT MANAGEMENT

Pharmacy benefit management (PBM) companies, like CVS-Caremark, manage the pharmacy benefit provided by health plans. PBM companies provide clients with accessible retail pharmacy networks, process drug claims, and review utilization; some provide mail-order pharmacy services.

Most PBM companies hire several pharmacists to undertake numerous functions, such as interpreting which drugs represent a covered benefit, supervising drug formulary content and revision, negotiating rebates with manufacturers, and directing drug utilization review programs. Pharmacists help market contracts that enlist pharmacies that will accept payment from the plan for each prescription dispensed to covered individuals and maintain relations with participating pharmacists and enrolled patients.

PHARMACY LAW

Another interesting area of practice is *pharmacy law*. Pharmacists who earn a law degree can specialize in pharmacy and drug laws. Colleges of pharmacy, drug companies, and professional pharmacy organizations often employ pharmacists with a law degree.

Many articles have been written about being a pharmacist attorney.[38–46] Pharmacist attorneys make major contributions to the profession by keeping up to date, writing, and presenting to practicing pharmacists on new drug and pharmacy laws and regulations and on the movement of the law through legal case reviews.

PHARMACOECONOMICS AND OUTCOMES RESEARCH

Pharmacoeconomics is a tool designed to provide users and decision makers with information about the cost-effectiveness of different pharmacotherapies.[47] Pharmacoeconomics is an emerging field of study for pharmacists. Some colleges of pharmacy offer graduate studies, and there are also residencies and fellowships.

Outcomes research is the process by which different therapies or drug regimens are evaluated to measure the extent to which a goal of therapy or desirable outcome can be reached.[48] Like pharmacoeconomics, graduate studies, residencies, and fellowships are available.

PHARMACOEPIDEMIOLOGY

Pharmacoepidemiology focuses on pharmaceutical care outcomes and the identification of potential or realized drug problems in large populations.[49] Pharmacoepidemiology measures the source, diffusion, use, and effects of drugs in a population and determines the frequency and distribution of drug use outcomes in that population. Pharmacists who are interested in pharmacoepidemiology need strong backgrounds in biostatistics and epidemiology.[50]

Pharmacoepidemiologists perform *observational research*, such as doing case control and cohort studies to test hypotheses about the effects (usually the harmful ones) of drugs. They study if there exists a possible relationship. For example, some observational research questions might be as follows:

- Are people with gastrointestinal (GI) bleeding more likely to be taking nonsteroidal anti-inflammatory drugs (NSAIDs) than those people who do not have GI bleeding? This would be a case control study in which an *odds ratio* (OR) is calculated.
- A cohort study—Are people on NSAIDs more likely to have GI bleeding than people who are not taking NSAIDs? This is a cohort study in which *relative risk* (RR) is calculated.

Observational studies usually use data that has been collected in administrative databases like payment systems, and therefore, there is no patient randomization. Therefore, such studies merely allow peeking into the black box, but not everything can be seen. Therefore, to get a good look into the box, *randomized controlled studies* (RCTs) must be performed to validate the suspicions of observational studies. However, RCTs are much more expensive than observational studies.

PHARMACY MANAGEMENT/LEADERSHIP

Pharmacy Management—Management is another opportunity for pharmacists. Pharmacy managers are found in community pharmacy, hospital pharmacy, managed care pharmacy, and other companies where pharmacists work. The roles of a pharmacy manager are to plan and manage operations, people, facilities, equipment, information systems, and fiscal resources.

To become a pharmacy manager, it is recommended that the person receive supervisory and management training. These can be obtained by earning more academic credits, completing a residency, and/or receiving training by an employer.

Pharmacy Leadership—If you intend to be a leader in pharmacy, like a director of pharmacy, a chief pharmacy officer, or the president of a state or national pharmacy organization, several steps are recommended:

- *Residency training:* Most pharmacy leaders have residency training.
- *Start at the bottom:* Start at the bottom of the management chain—for instance, a supervisor or advancement through promotion.
- *Mentorship:* This step may be the most important—working, watching, talking, and listening to a respected pharmacy leader.

- *Additional training:* Excellent leadership training is available. One such program is the Leadership Academy offered by the ASHP Foundation.[51]
- *Read:* It is important to expand your thinking on leadership and beyond pharmacy, such as occasionally reading the *Harvard Business Review, Journal of Hospital Administration*, and texts on pharmacy management and leadership.[52]
- *Observe:* Watch pharmacy leaders. There will be common characteristics, but also some unique ones. If you spot and admire a unique characteristic of a pharmacy leader, take a page out of their book and put it into your book.
- *Patience:* Becoming a pharmacy leader is a process that cannot be rushed. Go through each step and be patient.

PHARMACOGENOMICS

Pharmacogenomics is the study of how genes affect a person's response to drugs.[53] It is new and combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications and doses that will be tailored to a person's genetic makeup.

Most drugs come in "one size fits all," but they don't work the same way for everyone. It is difficult to know who will benefit from a medication, who will not respond at all, and who will experience adverse drug reactions effects.

Although the field of pharmacogenomics is immature, currently limited, it is expected that pharmacogenomics will allow the development of tailored drugs to treat a wide range of health problems, including cardiovascular disease, Alzheimer disease, cancer, HIV/AIDS, and asthma.

Pharmacists, even with limited training in pharmacogenomics, can help.[54] ASHP has a helpful statement on "The Pharmacist's Role in Clinical Pharmacogenomics."[55]

RESEARCH

The term "research" is broad and so is pharmacy research. Traditionally, most pharmacy research has been about drug discovery, but there is way more opportunities than this. Just a few examples include research into drug delivery (pharmaceutics), adverse drug effects (pharmacoepidemiology), customized drugs (pharmacogenomics), cost-effectiveness (pharmacoeconomics), and pharmacy practice (outcomes), and the list goes on.

What preparation is needed to do pharmacy research? First, a keen interest in investigation. Second, a degree—a PharmD is a bare minimum, or a MS or PhD. Third—training helps, such as a research fellowship in a specific area. If you are interested in doing basic science research, you will need a MS or PhD degree, and maybe postdoctoral training.[56]

VETERINARY PHARMACY

Imagine having patients who cannot verbalize what is wrong with them and are therefore unable to be counseled about their medication. That is what it is like being a veterinary pharmacist—challenging, to say the least.

The difference between a regular pharmacy practice and a *veterinary pharmacy* practice is that the patients are unique and the treatment diverse.[57] Patients can be birds weighing 5 g or elephants weighing over 2000 pounds. Other challenges include varying dosages and responses to the same drug in different species of animals, the names of the drugs being

different from those for humans, and a lot of compounding. However, pharmacists can come up to speed through self-learning and on-the-job training.[58]

Veterinary pharmacists provide value by having a broader knowledge of drug therapy than most veterinarians and by being able to compound medications, develop formularies, control inventory, and set up safe systems of medication distribution.[59] Veterinary pharmacists have also set up a computer network to share information between veterinary pharmacists in the United States and even outside the country.

The job of a veterinary pharmacist is rewarding. The pharmacist and veterinarian can establish a good professional relationship. It allows the pharmacist to be intimately involved with the drug product selection. It is satisfying, both professionally and personally, to know that a pharmacist can make a difference in the success of drug therapy for an animal—both large and small.

For those who would like to learn more about the diseases and regulatory issues of veterinary pharmacy, Creighton University School of Pharmacy offers an online veterinary continuing education course.[60]

SUMMARY

Although most pharmacists work in community and hospital pharmacies, plenty of opportunities exist beyond these traditional practice sites to use the knowledge pharmacist gain in their education, training, and practice experience. Work in nontraditional areas can be challenging, but fulfilling.

DISCUSSION QUESTIONS AND EXERCISES

1. Rate your interest for the following opportunities in pharmacy (1 = low interest, 5 = high interest).
   a. Alternative medicine _____
   b. Consulting _____
   c. Homeopathic pharmacy _____
   d. Jobs with no patient contact _____
   e. Jobs outside pharmacy _____
   f. Mail-order pharmacy _____
   g. Pharmacy leadership/management _____
   h. Pharmacy benefit management _____
   i. Self-care pharmacy practice _____
   j. Veterinary pharmacy _____
   k. Medical education/communications _____
   l. Nuclear pharmacy _____
   m. Pharmacogenomics _____
   n. Pharmacy law _____
   o. Drug/basic science research _____
   p. Informatics _____
   q. Pharmacy practice/outcomes research _____
   r. Pharmacoepidemiology _____
   s. Pharmacoeconomics _____
   t. Association management _____
   u. Compounding pharmacy _____

   v. Forensic pharmacy _____
   w. Pharmacy benefits management _____
2. Circle your top three choices in Question 1.
3. Make appointments to interview pharmacists working in each of your top three areas of interest.
4. From what you know and have read, take the three top areas you selected in Question 2 and discuss the pros and cons of each.
5. Which of the three areas you discussed in Question 4 interests you the most? Why?
6. How does your choice in Question 5 compare with other interests you have in pharmacy?
7. Name three pharmacist positions that require no patient contact.
8. Name three areas outside the pharmacy profession in which pharmacists can work and still use their education and training in pharmacy.

CHALLENGES

1. For extra credit, and with the permission of your professor, select one of the careers described in this chapter and investigate and prepare a concise report about this career. Include the pros and cons and describe what it would take for you to pursue this career. End your report by making a convincing argument regarding why you may pursue this option.
2. Some pharmacists work in jobs where being a pharmacist is not a requirement. For extra credit, and with the permission of your professor, investigate and prepare a concise report with three case studies of pharmacists working in such situations and include why they did this and why they like their jobs.

WEBSITES OF INTEREST

Alternative medicine: http://www.pitt.edu/~cbw/altm.html
Association management: See web addresses in the text in Chapter 16
Compounding pharmacy: http://www.iacprx.org
Consulting: http://www.ascp.com
Informatics: http://www.himss.org/library/pharmacy-informatics
Mail-order pharmacy: http://rxinsider.com/mail_order_pharmacy_jobs.htm
Nuclear pharmacy: http://nuclear.pharmacy.purdue.edu/what.php
Pharmacoeconomics: http://www.ispor.org/
Pharmacoepidemiology: http://www.pharmacoepi.org/
Pharmacogenomics: http://www.aacp.org/governance/SIGS/pharmacogenomins?Pages/default.aspx
Pharmacy law: http://www.aspl.org
Veterinary pharmacy: http://www.svhp.org/

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20 Career Development

INTRODUCTION

Few pharmacists stay in the same job position during their entire career. An average American changes his or her job for every 3.8 years and an average hospital pharmacist for every 4 years.[1] You will change jobs throughout your career, and you may even change the type of work you do as a pharmacist.

This is a great time to be a pharmacist. There is an unprecedented number and variety of career opportunities for pharmacists. Foregoing the opportunities, finding a good job or changing to another job is something that should be done thoughtfully and carefully.

This chapter is about career planning for pharmacists who are beginning their career or for veteran pharmacists looking for a job change. This chapter presents informations about careers, career development, how to assess strengths and preferences, and about being prepared for the next job. It also covers how to find opportunities, how to assess job offers, and how to make a career change.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Define a career.
- Describe the pitfalls of planning for your career.
- Identify the steps in finding a job as a pharmacist.
- Describe how to differentiate yourself from others to find the job you want.
- Describe how social media can help or hurt your chances for a job.
- Write a convincing letter of application and develop a curriculum vitae (CV).
- Explain some do's and don'ts in interviewing.
- Provide the top five mistakes millennials make when interviewing for a job.

CAREER

Having a job and having a career are not the same. Anyone can have a job, but not everyone can have a career. *Webster's Dictionary* defines a career as "a pursuit of progressive achievement, especially in public, business, or professional life." And goes on to say, under the word *career*, "a profession for which one trains and is undertaken as a permanent calling."[2]

Pharmacy is more than a job and more than work for hire. Pharmacy is a profession that should be pursued as if you will never learn enough. Members of the pharmacy profession chose pharmacy, learned a body of specialized knowledge, and prepared for a life pursuit of their profession. Pharmacists are *lifelong learners* who continually improve their practice skills and are proud to be a part of a noble profession.

CAREER PLANNING

To be the most successful, careers need to be planned versus drifting from opportunity to opportunity. Planning involves establishing goals and deciding how to achieve them, then pursuing objectives (important steps) that achieve the goal.

Common Mistakes Students Make

Pharmacy students often make mistakes in career planning.[3] Mistake number one is procrastination. Many students become so involved in coursework and other activities that they do not think about or plan what they would like to do with their degree until it gets close to graduation. Ideally, a pharmacy student should be thinking about what he or she would like to do as a pharmacist as soon as the decision is made to go to school to be a pharmacist. Students should also be exploring various opportunities throughout their time as a student.

Every pharmacy student should be introduced to and should investigate the pros and cons of graduate work in pharmacy during the first year of pharmacy school. Basically, there are two available domains: clinical/social/administrative and pharmaceutical science.

The second mistake pharmacy students often make in career planning is to be too passive. Many students wait for the jobs to come to them in the form of interviewers who come to the campus on "career day" rather than actively looking for good opportunities. Because there are so many opportunities available for new graduates, some students are not challenged to think about their careers. Proactive strategy seeks introductory and advanced practice experiences and internships while in school, where you may want to eventually work. In this way, potential employers get to know you and see your work, and you get to see whether this may be where you eventually work.

The third mistake is for students to make assumptions about what is available in the workplace. Students may only assume positions are available in independent, chain, or hospital pharmacies or that the only positions available are the ones being recruited during campus career day.

The fourth mistake is letting the pressure of paying off school loans overcome the value of pursuing a pharmacy residency, which some students think is just another year of senior clerkships—it is not. A 1-year pharmacy residency is the equivalent of 2–3 years of practice experience and provides training to become a pharmacy leader. It provides increased knowledge and confidence and puts the resident in a position to obtain the best new jobs—the ones that are the most satisfying. Although salaries for residencies are about 50% less than being paid for a full-time job, the money is a lot more than when you were a student, and most residents are able to pay on college loans.

Avoiding Common Pitfalls

The author of an article titled "Choosing Your Career Direction—Before It Chooses You" offered some don'ts for students thinking about careers as pharmacists[3]:

- Don't be driven by what others think you should do with your life.
- Don't assume there is only one right choice.
- Don't assume that career planning is something you do once, and then it is over.
- Don't assume the decision you make just out of pharmacy school will be your only decision about your career.
- Don't wait for an opportunity to find you. Continually seek opportunities and learn all you can about them.

FINDING YOUR JOB AS A PHARMACIST

The first decision to be made, and as early as possible, is to decide what will happen after graduating from pharmacy school. Will you pursue further education, add more training, or gain employment?

More Education

Many of the best opportunities exist for pharmacists with education beyond a doctor of pharmacy degree. Many jobs in the pharmaceutical industry (see Chapter 18, "The Pharmaceutical and Biotechnology Industry") require a master of science (MS) or doctor of philosophy (PhD) degree. A MS or PhD degree in a specific science discipline (pharmaceutical chemistry, pharmacology, pharmacokinetics, or pharmaceutics) can also be obtained and used to find a job in academics (see Chapter 15, "Pharmacy Academia").

Some pharmacists also find that seeking a graduate degree in business administration (MBA) provides more flexibility in finding the ideal job. Some educational degrees that are useful when combined with the doctor of pharmacy degree are the master of public health (MPH) or a law degree (JD).

More Training

Some of the best opportunities in pharmacy are for pharmacists who have advanced training provided by a pharmacy residency or fellowship. Pharmacy residencies provide 1–2 years of intense training in the practice of pharmacy and pharmaceutical care. Pharmacy fellowships provide 2 years of intense training in performing clinical research (see Chapter 2, "The Pharmacist"). Residencies and fellowships help differentiate one pharmacist from another.[4] Many of the top leaders in the pharmacy profession have completed a postgraduate residency or fellowship. Completing additional education or training after graduation helps a pharmacist stay competitive when added educational and training requirements for pharmacists are introduced over the years since graduation.

Gaining Employment

Another possibility is to go directly into the workforce after graduating from pharmacy school. Endless opportunities abound for new pharmacy graduates. However, selecting the correct job is not an easy task. In finding the first or next job, it is important to take charge and put in the necessary time to locate the best job for you. Finding a good job in pharmacy takes good planning and assessment.

Planning

Planning starts with identifying career goals. Most important is putting the goals into written statements. If the goals are not written, they will just become wishes, and likely mean they will not be achieved.

Goals should be practical, achievable within a certain time frame, and as specific as possible. One way to do this is to make two or three short-term goals (achievable within 2 years), two or three intermediate goals (achievable within 10 years), and two or three long-term goals (achievable over a career). Once drafted, goal statements need to be revised and refined over several days and revised annually. Table 20.1 is an example of some goal statements written by one new pharmacy graduate.

Assessment

To set realistic and achievable goals involves knowing yourself and the opportunities available. Learning about the two should take place as close together as possible, but the process starts with self-assessment.

TABLE 20.1
Professional Goals for One New Pharmacy Graduate

Goals Achievable within 2 Years

- Work in a thriving, independent community pharmacy
- Learn about owning and running a small business
- Get involved in a local professional organization

Goals Achievable within 10 Years

- Identify the type of pharmacy I would like to purchase
- Seek advice from a pharmacy administration professor in pharmacy ownership
- Evaluate three to five independent community pharmacies for their potential
- Purchase one store
- Become an officer in the state pharmacy association

Goals Achievable within My Career

- Make the first store into a professional pharmacy where patients and pharmaceutical care are the priorities
- Make the pharmacy successful from business and patient viewpoints
- Be elected president of the state pharmacy association

Self-Assessment

There are different ways of examining yourself for your likes and dislikes, and for your strengths and weaknesses. Several tools are available that can help make self-assessment easier. The first approach is to read *What Color Is Your Parachute?*[5] This is an inexpensive, short, easy-to-use manual that has been in print for many years. An excellent workbook is also available. These will help answer important questions such as—What do I like to do? What am I good at? Where do I want to accomplish it?

The other tool recommended for self-assessment and career planning is the American Pharmaceutical Association (APhA) Pathway Evaluation Program, first developed by Glaxo/Wellcome/Smith Kline Pharmaceutical Company to help pharmacy professionals, especially student pharmacists, in career planning.[6] The program consists of the following three parts:

Briefing document: Pre-workshop, self-assessment exercises; a combination of written and online exercises
Workshop workbook: Materials and exercises to use during a live workshop
Follow-up materials: Exercises and resources to use after completing the workshop

It is highly recommended that the student use this program during his or her first year of pharmacy school, especially while taking a course on Introduction to Pharmacy if one exists. There is even a virtual mentor program. The website for this program is listed at the end of this chapter.

As far as getting to know a job better, there is nothing like finding out about it firsthand. Pharmacy students who can handle coursework and a part-time job should work as pharmacy interns or as pharmacy technicians to become familiar with what various pharmacy jobs have to offer. While in school, students should also schedule their practice experiences at a variety of places where pharmacists work.

Another good way to find out the pros and cons of various jobs in pharmacy is to attend professional pharmacy meetings—local, state, and national—to network with pharmacists.

At these meetings, ask pharmacists where they work, what they do, and what they like and do not like about their job. Most pharmacists love helping pharmacy students find their way.

Finding Opportunities on Your Own

Finding opportunities on your own can be daunting if you are seeking to go beyond finding a job by word of mouth. Here are some tips:

- Attend local, state, and national pharmacy meetings.
- Sign up for the personnel placement service of the American Society of Health-System Pharmacists (ASHP).
- Attend the midyear clinical meeting of the ASHP in early December.
- Go to the Monster.com site (http://www.monster.com).
- Go to Pharmacist.com (http://www.pharmacist.com).

Pharmacist.com has many tools for seeking a good job in pharmacy, including (a) choosing the right employer, (b) 25 tactics for negotiating with your potential employer, (c) networking for career success, (d) successful job interviews, and (e) typical interview questions.

The Importance of Professional Networking

Networking with other pharmacists and professionals is a hallmark of the profession. Meeting and getting to know other pharmacists and professionals helps you gain new knowledge, find new opportunities, and advance your career. Networking can sometimes allow you to help other people by connecting people together. It's not always what you know, but who you know.

The Pros and Cons of Using Social Media in Job Seeking

Social media is a double-edged sword that can help, but can also hurt your chances for gainful employment. One author has said "pharmacy students are especially vulnerable to being their own worst enemy when it comes to online social networking."[7] The author suggests that pharmacy students need to realize they are now in a professional school, and they should ask themselves one question before posting anything online: Is it something you would want pharmacy faculty, your colleagues, a future employer, or your patients to see?

You can find a statement by ASHP on the use of social media by pharmacy professionals.[8] Every student should read this.

Developing Your CV

Putting It Together

Once you identify a preferred job, the next step is to develop a résumé, which in pharmacy is more commonly called a *curriculum vitae*. The CV is a critical document used during job searches. A CV tells employers who you are and what qualifications you have to perform a job. CVs must be carefully composed, presentation perfect, and attractive to stand out from the CV of others.

There are several helpful references on creating an effective CV, one of which is specific for creating a CV of a pharmacist.[9–11]

CVs usually consist of eight categories: the heading, the job objective, education and training, work experiences, honors and awards, activities and interest, references, and contact information.[12]

Heading: Include your formal and complete name (first, middle initial, and last).
Job objective: Include a brief description of your career objective for the job sought. This needs to be carefully thought out and crafted. It should not include clichés such as, "I want to contribute as a valuable member of the health care team." How boring, bland, and useless.

Try answering these questions in the following section[13]:

- First things first—What are you writing? Answer: an objective summary of your qualifications and skills that match the exact position you are applying for.
- Next, what are you? Are you a seasoned pharmacist? Young professional? Recent graduate? Say so.
- How much experience do you have?
- What makes you special? What is your major asset? Skill set?

Be honest and write this section from your heart.

Education and training: Include all formal college education, special course-work, and any residencies and fellowships.
Work experiences: Include any work experiences, paid or unpaid, that would contribute to gaining the job you are seeking. This section should list the job title and a brief summary of a few key responsibilities.
Honors and awards: This needs to be carefully considered. Include only the most worthy accomplishments.
Hobbies and interests: This is a chance to show that you have well-rounded interests. List only two or three.
References: The statement, "references available upon request" does not cut it! In fact, a statement like this can disqualify you. Good references can seal the deal.[14]

For new graduates, it is important to list two job references, a professor who knows your classroom work, and a clerkship preceptor who knows your clinical abilities.

Here are recommendations:

- List only references who have agreed to be references
- Make sure your references agree with the facts you've put in your résumé
- Provide names, current job titles, company affiliations, and phone numbers of your references
- Include a frame of reference—your relationship (I was his mentee for 2 years)
- As a courtesy, call your references after you've had interviews

Students may think their CVs do not show much. At this point in your pharmacy career, the quality of the information is more important than the quantity of information. Here are some deadly sins in formatting a CV and how they can be avoided[15]:

- Typos—an obvious problem.
- Faulty formatting—keep it readable and not "fancy" (adding fonts, shading, etc.).

- Irrelevant job experience—delete anything not in line with the job being sought.
- Weak word choice—banish "helped," "provided," and "worked."
- Boring bullets—don't list work accountabilities from a job description.
- Not including a strong branding statement in your objective—create a dynamic statement description of yourself.
- Length—too short or too long are both problems. It is a good idea to provide no more than one page for every 10 years of experience.

After you have written the CV, set it aside for a while and come back to edit. Be sure to prune out any deadwood and cliché's such as the following:

- "Salary negotiable"—Yes, they know.
- "Responsible for"—Turn into "managed," "led," etc.
- "Experienced in"—Turn into what you achieved.
- "Problem-solving skills"—So does everyone else.
- "Detailed oriented"—This is self-defeating if they find a typo in your CV.
- "Hardworking"—Show, rather than tell. Provide examples where your hard work benefitted your employer.
- "Team player"—Delete. Rather, tell about when you were on a team, what you contributed, and how it worked.
- "Proactive"—Stale. Again, show rather than tell.
- "Objective"—Using "Career Summary" is preferred.

The CV writer and several others should carefully proofread the CV before it is used to find a job. They should look for these strategic mistakes commonly made on CVs[12]:

Aiming too high, too soon: Do not use words such as leader, manager, or supervisor unless you have the background to support their use. Employers favor people who like to start in entry-level jobs and prove they can handle more responsibility.

Weak career objective: This should be "employer oriented." Rather than about yourself, it should be about how the company will benefit from having you as an employee.

Giving all education, training, and work experience equal billing: The education, training, and work experiences should point to your ability to do the job for which you are being considered. Directly related items should receive top billing. Those not related to the job sought should not be stressed.

Burying crucial information: Formatting the CV is critical. The readers should not have to hunt for the information they seek, such as who you are and why they should hire you. The information should be laid out in such a way that it plays like a symphony. It should start out with an attention-getting statement (most likely the job objective statement), flow from movement to movement, and end with a finale. The CV merely gets your foot in the door. Therefore, the CV writer's goal is for the reader not to throw the CV into the trash but to place it in the small pile of "candidates to be interviewed."

Highlighting the irrelevant: This goes back to selecting what needs to be stressed: the special skills the employer may want.

Keeping the employer in the dark: When the CV is written in such a way that it leaves questions in the employer's mind, the applicant may never get a chance to interview and provide answers to those questions.

Some final recommendations for preparing a CV include reading, rereading, and rewriting drafts. Also, share the draft CV with others, especially friends who have experience hiring professional people. Finally, answer this key question: What is the number one reason someone should hire you?

Assessing Opportunities

As soon as there are a few good opportunities to consider, the job seeker should turn their attention to the 20 critical job factors (from APhA Career Pathway Evaluation Program for Pharmacy Professionals) the job seeker scored when job seeking began. Each of the job opportunities should be assessed for each critical job factor and matched to the importance placed on each job factor by the candidate. For example, let us say "job security" was marked as important (score of 8 or higher) by the job seeker. The question is, for each of the opportunities considered, how good is job security?

Not all the job factors will be listed in the employment advertisement. When this happens, the job seeker should write out specific questions that can be asked when interviewing for the job. Before accepting a job offer, all of the job factors important to the job seeker should be assessed.

After going through the job factors for all job opportunities, scoring can be used to see which job provides the best fit for you as an individual. Once this process is complete, you can begin applying for the best-fitting jobs.

Salary is not the most important feature of a job. Having an opportunity to show what you can do is just as important. In addition, the benefit package must be carefully considered even if you are a new graduate and this is your first job as a pharmacist. It is recommended that you look for a benefit package that has the following features. It[16]

- Provides benefits that are important now
- Provides enough flexibility to meet future needs
- Is stable and secure
- Is economically rewarding
- Is within your employer's ability to grant

When handed a list of benefits with explanations, make sure you read it and understand it.[17] People who have worked a long time can be consulted to explain what you may not understand. Next, identify which of the benefits are most important to you now and identify the quality of each benefit important to you. Last, compare the benefits for one job versus other jobs under consideration. Benefits can represent as much as 30% of the total compensation for a job. Therefore, benefits need to be considered with the salary and other job factors that are important to you.

The quality of the work you will be doing, growth in the job, expectations the employer has for you, and the work environment and culture are important considerations. How you think you will be treated by the employer or a supervisor is a critical consideration that is often overlooked before being hired. Do the people working at the place you are considering seem happy? Do they feel comfortable working there? How are they treated? What is the downside of the job, and how important is that to you? Be honest with yourself. Don't just look at the upside of the opportunity.

THE LETTER OF APPLICATION

The letter of application is as important, and perhaps more important than a well-written CV. It may be the only information the initial job screener uses to decide which candidates will be interviewed. Therefore, it must be done carefully.

The letter of application should not say, "I read your advertisement for a pharmacist position. I am a pharmacist. Enclosed is my CV." The letter of application must grab the attention of the reader, but not be so overwhelming that the reader thinks you are too good to be true. The following are 10 tips for writing an outstanding letter of application. These references provide more detail on each tip[18,19]:

- Address the letter to a specific person (not "To Whom It May Concern" or "The Personnel Manager." Use the person's correct title.
- Keep it accurate and concise.
- Express interest in the specific position and the company.
- Show you know something about the company by doing some research.
- Refer to a former conversation, if the intended reader or another employee suggested you apply.
- Sell your value by listing your skills or major accomplishments or both, but do not go overboard.
- Tie your qualifications to the needs of the company.
- Express your potential.
- Toward the end of the letter, repeat the recipient's name to show friendliness.
- Request an interview.
- Ask more than one person to edit it.
- Print it on high-quality paper.
- Spend extra on delivery.

The following is what not to do[20]:

- Overuse the word "I"—don't look self-centered.
- Have a weak opening statement—put the emphasis on their need, not yours.
- Omit your top selling points—the main reason why they need you.
- Make it too long—stick to one page.
- Repeat your CV word for word—this is a selling job, not a rehash of your life.
- Be vague—make sure you state the job for which you are applying.
- Forget to customize—don't use the same letter for each opportunity you are seeking.
- End on a passive note—let them know you will be following up with them.
- Be rude—thank the reader for their time and consideration.
- Forget to sign the letter—not necessary if using email.

The letter of application needs to be clear, concise, and organized. Most important, the letter should be composed in such a way that the reader cannot wait to read the CV enclosed with the letter.

The goal of writing a letter of application and submitting your CV is to gain an interview. A carefully crafted letter of application and a good-looking CV with good references can do that.

THE INTERVIEW

First things first. Please understand—interviews are pitches and the product is you.[21] Second, you must respect the recruiter.[22] This means you must sell yourself and understand the interviewer will determine whether you are successful at doing that. Therefore, don't

- Get personal
- Use slang

- Use your cell phone while being interviewed (turn it off or leave it in your car)
- Lie

Most people hate interviewing for a job. Often, they do not know what to expect or don't understand the process. Many people make mistakes. The following are some things to avoid[23]:

- You are late and do not bother to call ahead.
- You dress in your best jeans and polo shirt.
- You smell of smoke, heavy cologne, or perfume.
- You interrupt the receptionist while she is answering calls.
- You give the interviewer a "dead fish" handshake and greeting.
- You demonstrate ignorance about the hiring company.
- You answer questions with rambling thoughts and verbal pauses.
- You use everyday language and speech patterns.
- You have poor eye contact with the interviewer.
- You ask only self-serving questions.
- You fail to address the questions asked.

In another article, the top five interview mistakes millennials make are[24]

- Inappropriate attire (75%)
- Have posted questionable social media content (70%)
- Have not done their homework (62%)
- Don't ask enough questions (60%)
- Overconfident in themselves (60%)
- Checking phone/texting during interview or when in presence of company employees (30%)

How you dress for an interview matters. Unless the prospective employer tells you otherwise, you should dress in your "Sunday best" clothes. An excellent explanation of proper dress for an interview is available.[25]

Interviewing is hard work and not enjoyed by many people. That may be because they do not understand the interviewing process. The interviewer and the person being interviewed have different goals that need to be satisfied to have a successful interview.

The goal of the interviewer is to find out whether the person being interviewed is qualified to do the job. If the candidate is qualified, the next goal of the interviewer is to find the strengths and weaknesses of the candidate. The interviewer will try to discover the quality of past work performed and how well the candidate will fit with other employees.

The questions the interviewer uses for the interview will be in seven areas, which are presented next with a few example requests or questions for each[26]:

1. *Basic interview questions*
   - Tell me about yourself.
   - What are your weaknesses?
2. *Behavioral interview questions*
   - Give me an example of a time that you felt you went above and beyond the call of duty at work.
   - Can you describe a time when your work was criticized?
3. *Salary questions*
   - What salary are you seeking?
   - How would you respond if the interviewer said, "That is awfully high?"

4. *Career development questions*
   - What are you seeking in terms of career development?
   - How do you want to improve yourself in the next year?
5. *Getting started questions*
   - What do you see yourself doing within the first 30 days of this job?
   - How would you go about establishing credibility with your fellow workers?
6. *More "about you" questions*
   - How would you describe your work style?
   - Tell me about your proudest achievement.
7. *Brainteaser question examples*
   - How many times do the hands of a clock overlap in a day?
   - With your eyes closed, tell me step by step how to tie my shoes.

A more extensive list of typical interview questions is available.[27]

If the interviewer is satisfied with the candidate's responses, the interviewer may shift to telling the candidate about the job and why he or she should work there. This is a good sign during the interview.

The primary goal of the person being interviewed is to find out as much as possible about the job. If the job sounds good, the other goal is to impress the interviewer that you are the right person for the job, but not in a boastful way.

The interviewer has all the power in the interview and will conduct the interview the way he or she sees fit. A good interview is when there is a two-way conversation rather than questions by the interviewer and answers by the job candidate. If the interview is conducted using the latter method, time may expire before the candidate's goals can be achieved. If this is the case, about two-thirds of the way through the interview, the candidate should be assertive in a respectful way and start asking questions about the job.

It is a good idea to have a list of questions. Ask if it is okay to take notes. It is always good to ask whether there is a *job description* available. It is the job of the person being interviewed to understand the job and to get a feel for the employer. The person being interviewed also needs to feel he or she has convinced the interviewer that he or she (the candidate) is able to get the job done and is the best person for the job.

The following are some final tips on how to ace a pharmacy job interview[28]:

- Prepare, prepare, prepare.
- Keep your answers short.
- When in doubt, overdress.
- Say to the interviewer, "I really want this job."
- Follow promptly with a handwritten thank you letter using appropriate stationery.

One last bit of advice. Special considerations are in play if you are interviewed by a group, or if you are interviewed alongside your competition for the job. These considerations go beyond the scope of this book, so the best strategy is to do some research on these situations.

GOT AN OFFER?

Some people get so excited about getting an offer for a job that they just accept the offer as given. "About 80% of employers stated that the job applicant who negotiates in a professional manner would make the best impression on them, compared with applicants who just accept the first offer or applicants that use an overly aggressive style when negotiating."[29]

The following are some tips to obtain the best offer:

- Get a written job offer before conducting any salary negotiations—This is when they want you the most.
- Avoid answering questions about your current or previous salary, or salary expectations—This is trap that can work against you.
- Conduct research to determine your market value—To see whether the offer is in the "ball park."
- Set a salary range—Your minimum and desired/plausible maximum.
- Establish your best alternative to a negotiated agreement—Look for other offers to use as leverage.
- Give yourself time—Don't feel pressured—sleep on it.
- Choose your battles—Where are you willing to be flexible, inflexible? Don't quibble about little things.
- Keep it professional—Listen, consider, ask good questions.
- Remember to consider nonmonetary benefits—Job title, location, start date, relocation, education, equipment, development funds, etc. These can add up and be helpful.
- Get your final offer in writing—Then send your letter of acceptance.

CHANGING JOBS

After working as a pharmacist for some time, your job may no longer be challenging or the environment may have changed and no longer be to your liking. Perhaps you would like to try something new and different. You ideally should be moving from a negative experience to a positive experience or from a positive experience to an even more positive one.

No matter how bad your current job may get, it is ill-advised to jump into another job right away without some self-assessment and planning. It is important to go through the same steps as previously listed for finding the first job. However, there needs to be more reflective thinking about the jobs you have had as a pharmacist. What did you like? What did you not like? What are your strengths? What are your weaknesses? One of the best tools for helping with this reflective thinking exercise is the *What Color Is Your Parachute* workbook.[30]

The potential job change may be coming at an important point in your career. What is it that you want to do in pharmacy? Are you headed in the right direction? Do you want to make a major change such as moving from community to hospital pharmacy? Some unhappy pharmacists are just in the wrong setting.

One approach is to list all the jobs you know pharmacists do. The Pathways Program mentioned can help. Make sure the list is comprehensive. Circle those jobs you think you would like to explore further.[6] You should be open minded and should not discount opportunities that you may not be qualified for now.

After brainstorming about potential career choices, put the jobs in order of preference, and for the first three, ask yourself these questions[31]:

- What skills are necessary for this job?
- Which of these skills do I possess now?
- Which skills do I need?

- Where can I learn these skills?
- How long will it take me to learn these skills?
- How much will it cost to invest in my future?
- When will I start to learn these skills?
- Will it be worth it?

If a major change is what is needed, do you need more education or training? If you have a bachelor of science pharmacy degree, what about applying for a nontraditional doctor of pharmacy program? What about doing a midcareer residency?[32] It is never too late.

Differentiation

The best jobs go to the people with the most education and experience or to those with a special set of skills. The key to finding the best jobs is to differentiate. Differentiation is the development of competencies which collectively create a quality distinction. What will set you apart from others who are seeking the same job? It might be completing a residency or fellowship. It might be some specific experience or certification in a specialized area. Diversification, knowing a little bit about many different areas of pharmacy practice, also works.

Changing from One Job to a Similar Job?

Some pharmacists just change job sites rather than thinking about changing the kind and quality of the work they do. One wonders whether this fits the definition of a career. For this strategy to work, you must like the quality of the work you are doing, like the environment, and like the salary and benefits.

Finding a New Job

Finding opportunities when you would like to make a change is similar to when you seek a first job. You hunt the newspapers and professional journals, go to local pharmacy meetings, and most of all, network with friends who may be aware of good opportunities. There is also one other avenue usually not used by new graduates: the use of an *employment agency*. Using a good employment agency that specializes in health-care opportunities can be invaluable. There might be a small application fee to use an employment agency; however, the employer usually pays the agency for connecting you to the employer. A well-designed, up-to-date CV will be needed no matter the approach used to find a new job.

CHANGING CAREERS

What if you wake up one day and find that you no longer like dealing with sick people? Or, you no longer like being a pharmacist? What can you do? Answer—plenty!

Many jobs pharmacists hold have no patient contact. Many management positions, most jobs in the pharmaceutical industry, and positions in the government have no patient contact. Companies that make and sell pharmacy software, companies that publish information about drugs, and professional pharmacy organizations need pharmacists, and none of these positions involve patient contact.

What can you do if you are a pharmacist and do not want to practice pharmacy? An interesting book by Rucker can help.[33] Useful information is provided for pharmacists in the

predicament of no longer wanting to practice pharmacy, yet wanting to use their background to do something useful and rewarding. Professor Rucker was able to identify 260 nonpharmacist job titles held by pharmacists.

Some examples of nonpharmacist jobs being done by pharmacists include developing cosmetics, buying drugs for a drug wholesale company, editing a pharmacy journal, performing legal work as a pharmacist–attorney, and working in a pharmacy library.

FOR MORE INFORMATION

For those interested in more information about career opportunities, Pfizer Pharmaceuticals has published an interesting book that covers 70 job titles held by pharmacists.[34] Each job is described by someone doing the job at the time the book was published. These stories are invaluable to someone wanting to know more about a specific pharmacist job. Another excellent publication, *Survival Strategies for Your New Career*, has been published by the ASHP.[35]

SUMMARY

Being a pharmacist means being a part of a profession. Being a professional means you have a career rather than just a job. Having a career means continually striving to improve in your chosen profession and taking your oath seriously. This does not mean you need to continue doing the same job forever. Growth sometimes means having to go on to different and perhaps more challenging opportunities. When this happens, good planning and self-assessment make the change easier and success more likely.

DISCUSSION QUESTIONS AND EXERCISES

1. Rate your interest in the following areas (5 = high, 1 = low):
   a. Caring for patients
   b. Interpreting and using data
   c. Presenting information
   d. Problem solving
   e. Teaching
   f. Discovering new knowledge
   g. Helping others
2. Circle your top three choices in Question 1. Which areas in pharmacy do you feel best match your top three interests?
3. Review a newspaper and two pharmacy journals listing jobs for pharmacists.
4. Make an appointment to interview a pharmacy resident by telephone or in person.
5. From what you know and have read about pharmacy residencies, what are the benefits of doing a residency?
6. Make an appointment to interview someone who interviews pharmacists for jobs. What are the important things they look for in job candidates?
7. Someone offers you just what you are looking for as your first pharmacy position, but the salary is much less than expected. Discuss how you would handle this and if you would take the job.
8. You discover you are unhappy in your current job. What is the first thing you should do?

9. Assume that when you graduate there are no positions in community or hospital pharmacy. List the three career choices you would be most interested in pursuing.
10. You are retiring from a career in pharmacy. What would you want your greatest accomplishment in pharmacy to be?

CHALLENGES

1. For extra credit, and with the permission of your professor, prepare a CV following the instructions in this chapter.
2. For extra credit, and with the permission of your professor, complete the APhA Career Pathway Evaluation Program for Pharmacy Professionals Program (see link in the next section).

WEBSITES OF INTEREST

APhA Career Pathway Evaluation Program for Pharmacy Professionals: https://www.pharmacist.com/sites/default/files/files/Pathway_Workshop_workbook_070807.pdf
CareerPharm: http://www.careerpharm.com/
Monster.com: http://www.monster.com/
APhA Career Center: http://www.pharmacist.com/career-center
APhA Career Option Profiles: http://www.pharmacist.com/career-option-profiles

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