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## The Value Driven Pharmacist: Basics of Access, Cost, and Quality 2nd Edition

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# **THE VALUE DRIVEN PHARMACIST**

**BASICS OF ACCESS, COST AND QUALITY**

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# INTRODUCTION TO ACCESS, COST, AND QUALITY

The United States healthcare system is complex and sometimes controversial. Despite attempts to improve quality of healthcare and access to it, costs in the United States (US) are high and continuing to rise. Projections suggest US health expenditures could exceed \$4 trillion by the year 2020, or approximately 20% of the US gross domestic product.<sup>1</sup> Conservative models have estimated that waste accounted for nearly 20% of total US expenditures in 2011, or approximately \$500 billion.<sup>2</sup> Despite spending more than other countries on healthcare, the US falls short on improving overall health and wellbeing as a nation.

A 2017 study by the Commonwealth Fund ranked the US last (11<sup>th</sup> out of 11) in overall health care among other industrialized countries. Despite spending the most per capita, the US ranked 5<sup>th</sup> in care process, 10<sup>th</sup> in administrative equity and last 11<sup>th</sup> in access, equity, and health care outcomes.<sup>3</sup> A 2016 report by the Centers for Medicare and Medicaid Services (CMS) showed that the annual National Healthcare Expenditures (NHE) for the year reached \$3.3 trillion dollars, an average of over \$10,300 per person.<sup>4</sup> The CMS report also shows that the US had spent 17.9% of its gross domestic product (GDP) on healthcare in 2016, which far exceeds the amount spent by any other country in the world.<sup>4</sup> The following chapters will discuss how cost, access, and quality are impacted in interactions between patients, payers, and providers.

Access, cost, and quality are three major factors used to evaluate healthcare systems.<sup>5</sup> Countries maintaining a good balance between these components have more effective healthcare systems. Optimizing the balance can be difficult because changes or improvements to one may come at the expense of the others.

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# SECTION 1

## ACCESS

Access to care is fundamental in allowing patients to achieve successful outcomes. Access may be defined as reaching necessary providers and being able to pay for the care needed. Patient-centered medical homes (PCMH) and neighborhoods focus on the needs of patients as a central component to delivery of care. This may include multidisciplinary team-based care, email communication directly with providers, and flexibility through extended hours or seven-days a week appointment options. PCMH provide key components for coordination of patient care and are usually a component of Accountable Care Organizations (ACOs) discussed in **Section 2**.

Providers must be prepared for patient-centered collaborative care. Successful patient outcomes must be achieved regardless of the patient's health literacy, health status, and socioeconomic considerations. Studies have shown that a positive relationship exists between health literacy levels and an individual's knowledge of available health services and payment, and results in improved overall health outcomes.<sup>1</sup> Individuals who understand their payer coverage are more likely to successfully navigate their financial benefits. Providers, including pharmacists, can help bridge the literacy gaps that may exist between patients and payers.

Pharmacists can clinically and financially assist patients with low health literacy. Community pharmacists are an easily accessible source of clinical knowledge. They may assist patients transition home after an inpatient stay, including navigating new providers and understanding the care necessary for a new diagnosis. The ability to consider the economic, social and cultural issues of the patient population they serve will likely increase pharmacists' success and satisfaction with their profession.

Ultimately, pharmacists have the clinical knowledge to meet heightened demands for patient-centered care and contribute to the growing need for access, cost, and quality-minded health care providers. They will have interactions with different types of providers. These interactions range from providing education, recommending drug therapy, or answering questions. In general, interactions are for the ultimate benefit of the patients and are aimed at improving patient care.

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# CHAPTER 1

## WHO PROVIDES THE CARE?

Author: Trish Devine PharmD

A multitude of healthcare professionals provide patient care. With nearly 18 million workers, healthcare providers/professionals are considered among the largest groups of employees in the US and they comprise the fastest growing sector of the US economy.<sup>1</sup> Furthermore, they constitute one of the most gifted, well-educated, highly-compensated, and diverse groups of employees in the nation.<sup>2</sup> In this section, the similarities and differences between the most frequently encountered healthcare professionals will be covered. While many of these providers have traditionally been considered providers of either inpatient or outpatient care; however, many provide direct patient care in both settings.

### PHYSICIANS

Physicians are at the center of the healthcare setting and play one of the biggest roles in providing care to patients.<sup>1</sup> Physicians diagnose conditions, examine patients, order and evaluate diagnostic tests, and prescribe medications.<sup>3</sup> Physicians must complete many steps in their training in order to practice. First, they must graduate from an accredited medical school with either a Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO) degree. Most complete at least four years of undergraduate study then complete four additional years of medical school to earn this degree. After completing their degree, prospective physicians complete a residency where they gain on-the-job training and may become specialized in certain areas. These residencies typically take between three and eight years.<sup>1</sup> After they complete the residency, physicians then take an examination to become licensed to provide direct patient care in a particular state.<sup>1</sup>

There are many different types of physicians. Generally, physicians are categorized as MDs or DOs. MDs practice allopathic medicine, which focuses on using medical treatment as active intervention to treat and counter an illness or disease.<sup>2</sup> Most MDs are specialists in one particular area, such as cardiology, emergency medicine, oncology, surgery, or urology. DOs practice osteopathic medicine, which focuses on preventative measures and treating the whole patient with a special emphasis on the musculoskeletal system of the body.<sup>4</sup> Most DOs are primary care providers (also known as “generalists”), which means they practice family medicine, general medicine, general internal medicine, or general pediatric medicine.<sup>2</sup>

Psychiatrists and ophthalmologists are medical doctors (MD or DO) who are sometimes confused with psychologist and optometrist respectively. Psychiatrists specialize in mental health, including substance use disorders, are qualified to assess both the mental and physical aspects of psychological problems and can prescribe medication for treatment. Clinical psychologist have a masters or doctorate degree in psychology and specialize in emotional and behavior mental health diseases. In most states, they are only allowed to use talk therapy as treatment. A few states allow psychologists to prescribe some psychiatric medications if they have met the required training.<sup>5</sup> Patients must be seen by a psychiatrist or other medical doctor to receive medication treatment. Ophthalmologists are medical doctors who specialize in eye and vision care whereas optometrist complete an undergraduate degree and four years at a college of optometry obtaining a doctor of optometry (OD) degree. The scope of practice varies by state but in general an optometrist are licensed to provide primary vision care, nonsurgical management of eye diseases including medication treatment.<sup>6</sup>

## **DENTISTS**

Dentistry is a branch of medicine that is involved with the study, diagnosis, prevention, and treatment of diseases, disorders, and conditions of the oral cavity and structures in the jaw area. Dentists are doctors specializing in oral health who have earned either a Doctor of Dental Medicine (DMD) degree or a Doctor of Dental Surgery (DDS) degree. Dentists primarily work in private outpatient practice but some work in the inpatient setting.<sup>7</sup>

## **PHYSICIAN ASSISTANTS**

Another important component of the inpatient care team is the physician assistant (PA). PAs must be associated with and practice under the direction of a physician. The supervision does not need to be direct and the physician may either be on or off site.<sup>1,8</sup> They may examine patients, diagnose illnesses and injuries, and prescribe medications according to the laws of the state where they practice. Most PAs complete two to three years of training and receive a master's degree.<sup>2</sup> After completing a PA program, a PA must become licensed in order to practice. PAs become certified (PA-C) by passing a national certifying examination and are licensed in the state which they practice.<sup>3,9</sup>

## **NURSES**

Often considered the front line of inpatient care, nurses are the largest group of healthcare professionals.<sup>9</sup> There are many different types of nurses and the level of care they can deliver depends on their degree. The first type of nurse is a Licensed Practical Nurse (LPN). These nurses provide for the basic needs of patients and are asked to take vital signs (such as blood

pressure, heart rate, pulse, etc.), assist with activities of daily living (ADLs), make observations, and keep records. They typically have a high school diploma, followed by completion of a one year nursing program and passage of a state licensing exam.<sup>1</sup>

Another type of nurse is a registered nurse (RN). RNs must also be licensed in the state in which they provide care and obtain their level in one of three ways: a 2-3 year hospital diploma program, a 2-3 year associate's degree in nursing (ADN) from a community college, or a 4 year Bachelor of Science degree in nursing (BSN) from a college or university. After becoming licensed and depending on their level of practice and expertise, nurses may do all or any of the following: administer medications, record progression of a patient's condition, provide patient education, perform medical procedures, and assist physicians.<sup>9</sup>

Nurses can specialize in specific fields of nursing. It may take more schooling or training depending on the speciality. Some of the areas of speciality include but not limited to: neonatal, critical care, dialysis, pain management and pediatric nursing.<sup>10</sup>

## **ADVANCED PRACTICE NURSES**

If a registered nurse decides to receive advanced training and education beyond the level of an RN, they may become an advanced practice nurse (APN).<sup>1</sup> There are four different types of APNs: nurse practitioner (NP), clinical nurse specialist (CNS), certified nurse midwife (CNM), and certified nurse anesthetist (CNA). APNs, as outlined by state laws, are typically allowed to provide direct patient care and often serve as an intermediary between doctors and RNs.<sup>8</sup>

Comprising the largest group of the APNs, nurse practitioners (NPs) are registered nurses who obtain a master of science in nursing (MSN) degree.<sup>1</sup> Working closely with physicians under collaborative practice agreements but not necessarily always under their direct supervision, NPs can do many things that a physician can do.<sup>8</sup> These duties include evaluating patients, diagnosing and treating common conditions, providing patient education and resources, and prescribing most types of medications depending on the laws in their respective states.<sup>2,8</sup> Along with becoming certified (NP-C), nurse practitioners can also specialize in certain areas, including geriatrics, pediatrics, or family care. NPs and PAs are often favorably viewed by patients due to their increased accessibility and amount of time they spend with their patients. Both NPs and PAs are cost-effective alternatives to physicians in regards to treating common conditions and educating patients about different disease states.<sup>1</sup>

## **MEDICAL ASSISTANTS**

Some of the fastest growing healthcare-related occupations are the medical assistant (MA), certified medical assistant (CMA) and registered medical assistant (RMA).<sup>11</sup> MAs are normally found on the “front lines” of physicians’ offices and routinely perform administrative tasks including scheduling appointments, greeting patients, answering phone calls, ordering supplies, and filing medical records. Some may also assist the healthcare professional with clinical duties, such as preparing patients for surgery/examination, recording vital signs, taking medication histories, collecting and preparing lab specimens, and calling prescriptions into pharmacies. MAs may receive formal training by attending vocational-technical high schools or community colleges. Others may attend colleges or universities where they receive either a one-year certificate or a two-year associate’s degree. Still others may have a high school degree or equivalent and receive on-the-job training.

A medical assistant may become certified by passing a national exam. Medical assistants have quickly become crucial members of healthcare teams and their roles are expected to expand with the proliferation of physician’s offices.<sup>11</sup>

## **PHARMACISTS**

Pharmacists are the health professional most accessible to the public. They have been traditionally perceived as engaged only in the community setting, dispensing medications, counseling patients, and providing medical advice and expertise. However, pharmacists have also been working in hospitals, nursing homes, medical industries and other settings for many years. Roles of the pharmacists have evolved over the years to provide high quality care for patients and the general public. Pharmacists work closely with other members of medical teams to enhance patient care, making drug recommendations based on evidence-based medicine and therapeutic guidelines, monitoring lab results and patient-specific responses to therapies, and educating patients and their families on disease states and their medications.<sup>12</sup> Pharmacists also participate in health promotion through health-related campaigns, community group education, and health fairs.<sup>12</sup>

All pharmacists, regardless of setting, must receive a doctor of pharmacy (PharmD) degree from an accredited institution and licensed in their state to practice pharmacy.<sup>13</sup> After graduation, a prospective pharmacist gains licensure by successfully completing the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Exam (MPJE) or an equivalent state-level law exam.<sup>8</sup>

After receiving licensure, pharmacists may pursue residency programs. Residents are

exposed to different facets of practice and learn about the many career paths available to pharmacists today. During a one-year residency (Post-Graduate Year 1 or PGY1), pharmacy residents are generally trained in a variety of areas within the residency setting. Most pharmacy residency programs are hospital based; however, there is an increasing number of residency opportunities in community and managed care areas. Usually a second year of a residency program (Post-Graduate Year 2 or PGY2) is specialized in a certain area, such as pediatrics, ambulatory care, critical care, infectious diseases, cardiology, and many others.<sup>8</sup>

In addition to residencies, pharmacists can obtain disease-specific multidisciplinary certification. Pharmacists can voluntarily become certified in certain disease states, such as diabetes, asthma, anticoagulation, and dyslipidemia.<sup>12</sup> For example, a pharmacist can become a “Certified Diabetes Educator” in order to help diabetic patients learn about and understand their condition, as well as help them to manage the condition and their medications. Certifications can be obtained through national programs that involves didactic, professional diabetes patient experience and exams. This type of certification is also available to other healthcare professionals.

More specifically, pharmacists can become board-certified in a specialty practice area of pharmacy through The Board of Pharmacy Specialties’ (BPS) post-licensure certification program. BPS board certification is considered the gold standard when it comes to determining a pharmacist’s qualifications and capabilities within a specialty area. The BPS currently offers eight distinct specialty areas, including: Ambulatory Care, Critical Care, Nuclear, Nutrition Support, Oncology, Pediatric, Pharmacotherapy, and Psychiatric pharmacy.<sup>14</sup> Pharmacists must practice at least three to four years in the speciality area and pass a speciality certification examination to become a board-certified pharmacy specialist (BCPS) and must be recertified every seven years.<sup>15</sup> Becoming BPS board certified enables pharmacists affirm their knowledge and skills to provide more comprehensive patient care in a specific area, be recognized for their expertise by other healthcare professional, employers, patients and insurers. With more opportunities to provide direct patient care in inpatient and outpatient settings, pharmacists are seeing their roles expanding and are moving closer to being recognized as providers rather than just “drug experts.”

## **ALLIED HEALTH PROFESSIONALS**

An allied health professional is someone who has received special training and earned a certification or degree in a science related to healthcare and has responsibility for the delivery of health or related services. This does not include anyone who has received a degree in medicine, dentistry, veterinary medicine, optometry, podiatry, chiropractic, pharmacy,

psychology, or equivalent. Allied health professionals can be divided into two categories: technicians/assistants and therapists/technologists. Technicians and assistants generally receive less than two years of postsecondary education and require supervision. Examples are physical therapy assistants, medical laboratory technicians and respiratory therapy technicians. Therapists and technologists receive more advanced training and education and are responsible for evaluation, diagnosis and development of treatment plans and can practice independently from a physician in some states.<sup>16</sup>

## Therapists & Technologists

*Occupational therapists* (OTs) work with individuals who have conditions that are mentally, physically, emotionally or developmentally disabling. A master's degree is the typical minimum requirement for entry into this field.<sup>17</sup>

*Physical therapists* (PTs) help injured or ill people improve their movement and manage their pain. These therapists are often an important part of the rehabilitation and treatment of patients with chronic conditions, illnesses, or injuries. A Doctor of Physical Therapy (DPT) degree and license is required to practice.<sup>17</sup>

*Respiratory therapists* (RTs) care for patients who have trouble breathing, from a chronic respiratory disease, such as asthma or emphysema, or emergency care, such as heart attack or drowning. Patients range from premature infants with undeveloped lungs to elderly patients with diseased lungs. Respiratory therapists typically need an associate's degree, though some have bachelor's degrees, and a state license is required in all states except Alaska.<sup>17</sup>

*Speech therapists* or *pathologists* assess, diagnose, treat, and help to prevent communication and swallowing disorders in patients. Speech, language, and swallowing disorders result from a variety of causes, such as a stroke, brain injury, hearing loss, developmental delay, Parkinson's disease, cleft palate, or autism. Speech-language pathologists typically need at least a master's degree and must be licensed in most states.<sup>17</sup>

*Audiologists* diagnose, manage, and treat a patient's hearing, balance, or ear problems. Audiologists need a doctoral degree and all states require a license.<sup>17</sup>

*Dietitians* and *nutritionists* are experts in the use of food and nutrition to promote health and manage disease. They advise people on what to eat to lead a healthy lifestyle or achieve a specific health-related goal. Most dietitians and nutritionists have a bachelor's degree and have completed supervised training through an internship. Many states require dietitians and nutritionists to be licensed.<sup>17</sup>



*Social workers* help people solve and cope with problems in their everyday lives. Social workers may work with children, people with disabilities, and people with serious illnesses. Their work varies based on the type of client. There are child and family, clinical, school, healthcare, and mental health social workers. Social workers assess clients' situations, and support networks to determine their needs. They help clients adjust to changes and challenges in their lives, such as illness, divorce, or unemployment by providing community resources, such as food stamps, child care, and healthcare to assist and improve a client's well-being. Most social workers need a bachelor's degree in social work, while clinical social workers must have a master's degree and 2 years of post-master's experience in a supervised clinical setting. Clinical social workers must also be licensed in the state in which they practice.<sup>18</sup>

*Counselors* provide support and advice to people. There are many different kinds of counselors, including substance abuse and behavioral disorder counselors who advise people suffering from alcoholism, drug addiction, eating disorders, or other behavioral problems. Genetic counselors assess individual or family risk for a variety of inherited conditions. They provide information and support to other healthcare providers or to individuals and families concerned with the risk of genetic disorder and birth defects. Most positions require a bachelor's degree, though educational requirements can vary from a certification to a master's degree depending on the employer.<sup>17</sup>

## **ADVANCED PRACTITIONERS**

Centers for Medicare and Medicaid Services (CMS) and the US Department of Justice's Drug Enforcement Administration (DEA) use different terminology to identify non-physician healthcare providers such as nurse practitioners, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the state in which they practice. The term "mid-level practitioner" is used by the DEA, while CMS uses "non-physician practitioner." There is a movement to change this nomenclature, as the descriptor "mid-level" does not represent the advanced degrees earned by these health care providers. Patients may feel they will not receive high quality care if they are seen by a "mid-level or non-physician practitioner" instead of by an advanced practitioner or their actual degree title.<sup>19,20</sup>

## **HOSPITALISTS**

Society of Hospital Medicine defines a hospitalist as a physician, nurse practitioner or physician assistant who is engaged in clinical care, teaching, research, and/or leadership in the field of hospital medicine. Hospitalists coordinate the care of patients' in hospital. They

organize the communication between different providers caring for a patient, and serve as the point of contact for other doctors and nurses for questions, updates, and provides safe transitions of care within the hospital and from the hospital to the community. Hospitalist are the main point person for patients and family members to contact for patient care questions.<sup>22</sup>

## **CREDENTIALING AND PRIVILEGES**

Each medical staff member who provides medical services in a hospital setting and for health insurance holders must meet the credentialing and privileging standards of a nationally recognized accrediting/certifying body such as the Joint Commission, the American Association for Ambulatory Health Care, or the Centers for Medicare and Medicaid Services. Medical staff includes physicians (MDs and DOs), dentists, physician assistants and nurse practitioners, and those defined by the hospital's policies and procedures manual and bylaws.<sup>23</sup>

Credentialing is the primary source verification of a healthcare practitioner's education, training, work experience, and license. A variety of resources are used to verify this information, including but not limited to direct communication with educational and training institutions, past and current hospital affiliations and employers, peer reference letters, certification boards and licensing agencies.<sup>23</sup>

Privileging is granting approval for an individual to provide specific aspects of patient care within a specific institution. Examples of privileges include admitting, prescribing, and performing procedures. In some instances, healthcare providers may be credentialed, trained, and licensed to provide certain care but may have their practice limited by the privileges granted within a hospital.<sup>23</sup> For example, a physician assistant specializing in pediatrics may only be granted privileges to the pediatric unit and would not be able to admit a patient to other areas of the hospital. Healthcare providers go through similar processes at all hospitals where they want to practice and each hospital makes an independent decision regarding privileges.<sup>6,24</sup>

## **INTERPROFESSIONAL EDUCATION AND HEALTH CARE TEAMS**

According to the World Health Organization (WHO), "inter-professional education occurs when students from two or more professions learn about, from, and with each other to enable effective collaboration and improve health outcomes. Once students understand how to work inter-professionally, they are ready to enter the workplace as members of the collaborative practice team. This key step moves health systems from fragmentation to a position of

unity.”<sup>25</sup>

Interprofessional healthcare teams are composed of an array of healthcare professionals who bring their specialized knowledge, experience and skills to work together to provide optimal care for patients. Many organizations interprofessional healthcare teams consist of a nurse, pharmacist, physician, social worker and therapist. Members of an Interprofessional team communicate and work together, as colleagues, to provide quality, individualized care for patients.<sup>26</sup>

In the United States, an Inter-Professional Education Collaborative (IPEC) was formed in 2009, with five health professional associations represented allopathic and osteopathic medicine, dentistry, nursing, pharmacy, and public health to promote a more consistent approach to inter-professional education (IPE) and improve population health outcomes. By 2017, fourteen additional health care professional associations became members representing over 20 professions including podiatry, physical therapy, occupational therapy, psychological medicine, veterinary medicine, physician assistant, optometry, allied health and social work.<sup>27</sup> IPEC developed four interprofessional collaborative practice competency domains for future health professionals in training. The four domains with their general competency statement are:

*Values/Ethics for interprofessional Practice-* Work with individuals of other professions to maintain a climate of mutual respect and shared value.

*Roles/Responsibilities-* Use the knowledge of one’s own role and those of other professions to appropriately assess and address the healthcare needs of the patients and populations served.

*Interprofessional Communication-* Communicate with patients, families, communities, and other health professionals in a responsive and responsible manner that supports a team approach to the maintenance of health and the treatment of disease.

*Teams and Teamwork-* Apply relationship-building values and the principles of team dynamics to perform effectively in different team roles to plan and deliver patient-centered care that is safe, timely, efficient, effective, and equitable.<sup>27</sup>

The accreditation council for pharmacy education has included Interprofessional Education in its Standards. Schools of pharmacy must include IPE in their curriculum for accreditation.<sup>28</sup> In an effort to enhance quality and meet the evolving needs of patients, interprofessional team based delivery of health care is used.

Interprofessional teams' goal is to provide patient-centered care. There is evidence that shows including patient preferences into patient care improves outcomes.<sup>29</sup> Interprofessional or multi-disciplinary teams have been a part of health care delivery in hospitals for a long time. Accountable Care Organizations and Patient-Centered Medical Homes are beginning to utilize interprofessional teams to improve patient care and decrease health care costs.<sup>6</sup> Interprofessional team practice arrangements vary from inpatient to outpatient teams as well as from patient to patient depending on individual needs. The central goal of an integrated health care practice is to provide the most effective, accessible, and efficient care to the patient, based upon clinical and patient-focused outcome measures or assessments.<sup>30</sup>

# GLOSSARY

## **Medical Provider Credentialing**

A detailed process that reviews doctors' qualifications and career history including their education, training, residency and licenses, as well as any specialty certificates.

## **Medical Provider Privileges**

Defines a physician's scope of practice and the clinical services he or she may provide.

## **Patient-Centered Care**

Identify, respect, and care about patients' differences, values, preferences, and expressed needs; relieve pain and suffering; coordinate continuous care; listen to, clearly inform, communicate with, and educate patients; share decision-making and management; and continuously advocate disease prevention, wellness and promotion of healthy lifestyles, including a focus on population health.

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# CHAPTER 2

## HEALTHCARE SETTINGS

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Healthcare is provided in a variety of settings usually categorized as inpatient or outpatient. **Table 2-1** displays examples of inpatient and outpatient facilities and more details are provided in this chapter. Examples of facilities that provide inpatient services include hospitals and nursing homes. Various facilities that provide outpatient care include physician offices and urgent care centers.

Healthcare Settings	
Inpatient	Outpatient
<ul style="list-style-type: none"> <li>• Hospitals</li> <li>• Mental institutions</li> <li>• Nursing homes</li> <li>• Long-term acute care facilities</li> <li>• Long-term skilled nursing facilities</li> <li>• Inpatient rehabilitation centers</li> </ul>	<ul style="list-style-type: none"> <li>• Physicians' offices</li> <li>• Urgent care centers</li> <li>• Emergency departments</li> <li>• Home health agencies</li> <li>• Outpatient surgery centers</li> <li>• Rehabilitation centers</li> <li>• Dialysis centers</li> <li>• Sports medicine clinics</li> <li>• Chemotherapy centers</li> </ul>

**Table 2-1.** Examples of inpatient and outpatient facilities

While these general distinctions exists, a facility may function as an inpatient or outpatient setting depending on the type of treatment being given and admission status of an individual patient. For example, inpatient facilities, such as hospitals, may have outpatient offices and provide outpatient services, such as surgeries, rehabilitation, and ambulatory clinics, without admittance to the hospital.<sup>1</sup> Determining whether someone is admitted as an “inpatient” or seen at the facility as an “outpatient” impacts how bills will be submitted and paid.



## INPATIENT CARE

Not everyone who goes to the hospital is considered an inpatient. Based on various factors, such as the prescriber's judgement of the situation, seriousness of the condition, and medical necessity for hospital services, the physician will choose whether or not to order admission for a patient.<sup>1</sup> The decision to admit may not be immediate. A patient in a hospital bed may be considered an observational outpatient (sometimes termed "obs") to allow physicians time to run tests and/or make further evaluations before they decide whether to fully admit as an inpatient or discharge to home or another facility. Patients can only be considered observational (i.e., outpatient) for less than 24 hours before a decision must be made on whether they will be admitted. This observation may or may not include an overnight stay and the observation can occur anywhere in the hospital, including the ED.<sup>1</sup>

A patient will typically be admitted if the patient is expected to need at least two days of hospital care that can be provided by the facility.<sup>1</sup> If the physician determines that the patient does not need to be admitted, they will discharge the patient from their care. However, if the physician has ordered admission, the hospital must then formally accept the order and admit the patient as an inpatient. Hospitals may only allow physicians to have admitting privileges excluding other practitioners.<sup>2</sup>

### Types of Institutions

#### *Hospitals*

Hospitals are commonly recognized as the provider for acute care services. Hospitals can be classified in a number of different ways, including type of service provided, ownership, and average length of stay.<sup>3</sup> Type of service includes two main types of hospitals: general and specialty.<sup>3</sup> General hospitals, such as Massachusetts General Hospital, provide a wide range of services with few limits. These services include surgeries, labor and delivery, and treatment of most of acute disorders or illnesses. Specialty hospitals, such as Peyton Manning Children's Hospital or MD Anderson Cancer Center, focus on specific types of patients or specific illnesses or diseases.<sup>3</sup>

There are two primary types of hospital ownership: public and private. Public hospitals may be owned by the federal, state, or local government.<sup>4</sup> The federal government owns and operates federal hospitals, such as the Veterans Administration (VA).<sup>5</sup> The VA consists of hospitals, clinics, and nursing homes that provide care and services solely for retired United States armed forces veterans.<sup>5</sup> Other examples of federal hospitals and networks include Indian Health Services, which provides healthcare for Native Americans.<sup>4</sup> Facilities owned

and funded by state governments typically include long-term facilities for psychiatric patients and those with chemical dependency and addictions. Local governments, such as counties, also fund and operate hospitals. These hospitals are usually general hospitals that are open to anyone, regardless of insurance or their ability to pay for care.<sup>5</sup> Often thought of as “safety-net” hospitals, these facilities often focus on providing services to underserved populations at reduced costs.

Private hospitals typically only provide care to patients who are part of their private network, except for emergencies.<sup>5</sup> Private hospitals are named because of their private source of funding. They are not government operated and may be either non-profit or for-profit.<sup>4,5</sup> Non-profit hospitals are frequently affiliated with charitable organizations or religious denominations.<sup>4</sup> As a non-profit hospital, the government does not require them to pay taxes. Profits are reinvested in operating expenses, hospital improvement, or donated to the community rather than given to shareholders or private investors.<sup>3</sup> For-profit hospitals are owned by private corporations. A portion of their profits are used for operations and making improvements and some of their profits are disbursed to owners and investors via dividends.<sup>3</sup>

Hospitals may also be classified by how long patients are expected to stay in the facility. Short-term hospitals, also known as acute care hospitals, care for their patients for an average of less than thirty days.<sup>6</sup> Patients are admitted for short-term needs, such as routine surgery or an acute illness like pneumonia, receive the care they need, and are discharged home. Long term acute care hospitals provide care for patients who need to stay for an average of thirty or more days.<sup>3</sup>

#### *Long Term Acute Care Facilities (LTAC)*

In the past, patients would stay in a general hospital for their entire acute critical illness episode, including time needed for recovery.<sup>7</sup> With the advent of LTAC facilities, patients who need additional care are transitioned to these facilities.<sup>8</sup> Patients moved to LTAC facilities typically do not need as much intensive care as they previously received for their injury or condition from an acute care hospital, but they still have needs for ongoing care that they cannot receive outside of a facility.<sup>7</sup> Some of the services typically offered at LTAC facilities include respiratory therapy, head trauma treatment, and intensive pain management.<sup>8</sup> With the additional time and care, patients have been shown to have experienced improvement in their conditions and fewer re-admittances for similar or related conditions.<sup>8</sup> LTAC hospitals have proven to be successful in reducing costs and improving patient outcomes.

RS was admitted to an inpatient facility following a serious motor vehicle accident. RS had damage to several internal organs and is still on a ventilator. He has been transferred to a LTAC facility until he can be weaned from the ventilator and begin rehabilitation.

### *Nursing Facilities*

Nursing facilities, more commonly known as nursing homes, provides long term nursing care without the level of medical attention or specialty provided at LTAC facilities.<sup>8</sup> This type of long term care may involve around-the-clock nursing, custodial care or both. Skilled care is care administered when direct medical attention is needed and provided by a licensed medical professional in a certified facility. Custodial care may be performed by someone without professional medical skills either at home or in a facility. Custodial care provides assistance with activities for daily living (ADLs), like eating and bathing, and not direct medical treatments.

### *Inpatient Rehabilitation Centers*

Sometimes when patients are past their acute illness they still need functional assistance but not medical assistance. This functional therapy is provided by occupational therapists, physical therapists, or speech language pathologists. The goal of these therapies is to assist the patient in returning to as much of their normal functioning as quickly as possible.

## **OUTPATIENT CARE**

### *Physician Offices and Integrated Care Models*

As often portrayed on TV, physician offices traditionally featured a physician, a nurse, and office staff. While some of these sole practitioner offices still exist today, integrated care offices are becoming more common. These primary care practice models have multiple physicians and other practitioners, such as pharmacists, physician assistants, nurse practitioners, and social workers to meet the needs of their patients.

In the spirit of providing value based care, there has been increased interest in healthcare delivery models that are more patient-focused. These models include Patient-Centered Medical Homes (PCMHs). These practices represent a primary care delivery model focused on comprehensive, coordinated, and integrated management of all aspects of a patient's health.<sup>9</sup>

## Emergency Departments

Emergency departments (EDs) and various outpatient clinics may be part of a hospital or health system. Many patients with limited resources use the ED for nonurgent care, resulting in around 10 million nonurgent visits per year.

## Urgent Care Centers

Urgent care centers are walk-in clinics that offer a variety of services during convenient hours. Although they are not quite as equipped for emergencies as EDs, urgent care centers can be used when doctors' offices are closed and are much cheaper than EDs.

## Retail Clinics

Often seen in pharmacies and grocery stores, retail clinics are operated for patient convenience. Physicians are not required and they are staffed by nurse practitioners or physician assistants.

## Ambulatory Surgery Centers

Some minor surgeries don't require an overnight stay. Approximately two-thirds of surgeries performed in the last 10 years were outpatient surgeries.<sup>9</sup>

## Other Outpatient Models

Other models of outpatient care include community health centers, charitable clinics, local government health departments, home health, hospice, telemedicine, and complementary/alternative medicine.

## Why are Patients Increasingly Seeking Outpatient Services?

Since the 1980s, the volume of outpatient services delivered has grown considerably. Advances in medicine and technology have enabled us to provide more advanced treatments in outpatient settings. The introduction of the Medicare Prospective Payment System in 1983 changed the way hospitals were reimbursed for inpatient hospitalizations and encouraged shorter lengths of stay.<sup>3</sup> This provided incentive to continue treatment in outpatient settings without payment restrictions.<sup>10</sup>

Increased use of outpatient services and fewer doctors pursuing primary care practice provides an opportunity for pharmacists to increase their involvement in the primary care setting. Residencies are now available and the Board of Pharmacy Specialties offers a

specialty certification in ambulatory care pharmacy practice. Similar to outpatient care, ambulatory care includes all health-related services in which patients walk to seek their care.<sup>11</sup>

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# CHAPTER 3

## ROLES OF AMBULATORY CARE PHARMACISTS

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Ambulatory care pharmacists may practice in a variety of settings, but similar skill sets are utilized throughout different practices. This section will review general pharmacy services which will be helpful in learning how they are applied in specific ambulatory care settings.

### MEDICATION HISTORY AND RECONCILIATION

Before managing a new patient, pharmacists should obtain a comprehensive list of medications the patient is currently taking, which is referred to as the patient's medication history.<sup>1</sup> A medication history should include both prescription and over-the-counter medications, such as herbal products and nutritional supplements. Vaccines and injectable drugs may also be added to the list. It is important to note the route, frequency, and time that the patient is taking the medications. Additionally, any drug allergies and adverse reactions to drugs should be recorded.<sup>1,2</sup>

A medication history can be obtained in several ways. You may be able to consult a patient on what medications they are taking, particularly if they carry a list of their medications with them and are able to say what they are or are not taking. However, speaking with the patient is not always possible or the patient may be confused about their medications.<sup>2</sup> In these instances, there are several other options. The patient's regular community pharmacy may have a list of prescriptions filled recently by the patient, which may indicate the patient is currently taking those medications. Prescribers may also be contacted to determine what the patient has been prescribed and should be currently taking. If the patient is coming from a hospital, it may be possible to obtain from the hospital the patient's prescriptions at discharge.<sup>1,2</sup>

After this information has been acquired and documented, the process of medication reconciliation may begin. The Joint Commission defines medication reconciliation as:

“the process of comparing a patient's medication orders to all of the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. It should be done at every transition of care in which new medications are ordered or existing orders are

rewritten. Transitions in care include changes in setting, service, practitioner, or level of care.”<sup>2</sup>

In medication reconciliation, a pharmacist looks for discrepancies in the patient’s drug list. During this exercise, the pharmacist may find several possible errors: inappropriate drug therapy, duplicate therapy, drug-drug interactions, drug-disease state interactions, or incorrect doses.<sup>1,2</sup>

Medication reconciliation is an important process in patient care. **Table 3-1** includes medication history discrepancies that may lead to issues in patient care.

Discrepancy	Result
A medication is listed in the patient’s history that the patient is no longer taking	This medication may continue to be dispensed to the patient <ul style="list-style-type: none"><li>• Could lead to duplicate therapy or drug interactions</li></ul>
The incorrect strength of a drug is listed	The patient may be getting too high or too low of a dose <ul style="list-style-type: none"><li>• Could lead to adverse side effects (dose too high) or inadequate therapy (dose too low)</li></ul>
The patient’s medication list may be incomplete and does not include all the medications the patient is taking	The pharmacist may not be able to identify all possible drug interactions <ul style="list-style-type: none"><li>• Meds not listed may interact with other meds</li></ul> Medications may be added that interact with medications not listed <ul style="list-style-type: none"><li>• Could cause drug adverse effects or decrease the effectiveness of drug therapy</li></ul>
How the patient is taking the medication may be incorrectly listed	If the patient is taking the medication more or less than listed, the patient may be getting too much or too little of the drug <ul style="list-style-type: none"><li>• Could lead to adverse side effects or inadequate therapy</li></ul>



Discrepancy	Result
	<p>If the patient is taking the medication at a different time of day than listed, the pharmacist may be unable to identify inadequate therapy or side effects related to the time of day</p> <ul style="list-style-type: none"> <li>• Could decrease effectiveness of drug therapy or side effects (e.g. if a sedating drug were given in the morning)</li> </ul> <p>The pharmacist may not be able to identify if the medication interacts with other medications the patient is taking</p> <ul style="list-style-type: none"> <li>• Certain drugs need to be separated from one</li> <li>• another and taken at different times</li> </ul>
The incorrect dosage form of a medication is listed	<p>The patient may be getting inadequate drug therapy</p> <ul style="list-style-type: none"> <li>• Example: If an immediate release formulation is given instead of an extended release formulation, patient may not be getting enough drug</li> </ul>

**Table 3-1.** Medication history discrepancies

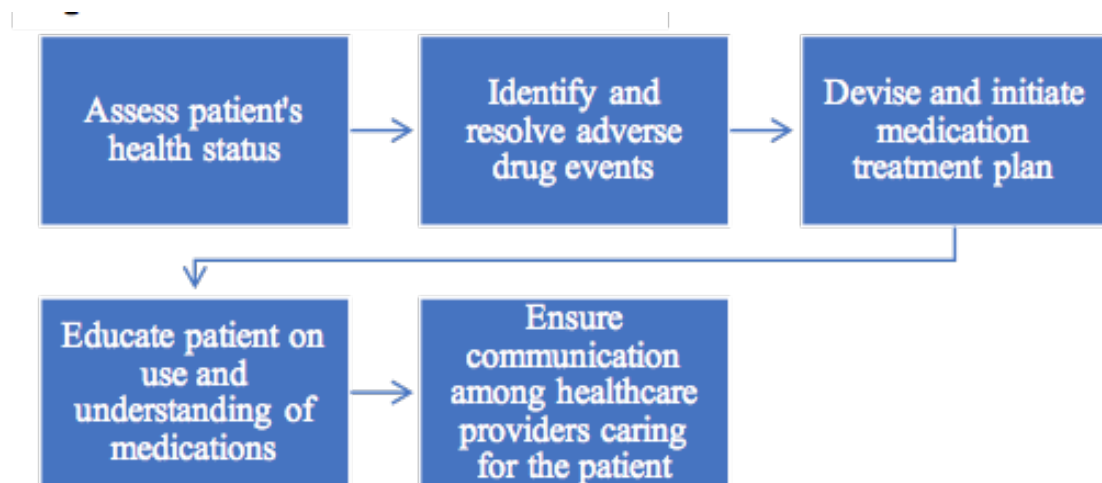
By obtaining a thorough medication history and carefully checking through it, pharmacists can help to reconcile these and other errors that may have gone unnoticed.

## MEDICATION THERAPY MANAGEMENT

Medication therapy management (MTM) involves a scope of activities with the goal of optimizing health outcomes for patients and helping patients manage their medications. Pharmacists and other healthcare professionals providing patient care are included in this process (**Figure 3-1**). Many patients may be eligible for MTM; however, patients who benefit most from MTM services include elderly patients, patients taking multiple medications, and patients with multiple or complex disease states.<sup>4</sup> These patients may have more difficulty managing their medications and pharmacists can help with this task.

In ambulatory care, MTM services are generally provided via one-on-one patient

appointments.<sup>4</sup> Patients may be referred to an ambulatory care pharmacist by their health plan, physician, or other healthcare providers. Medication therapy management services are generally done in person but may also be provided over the phone. Although both in-person and phone appointments are possible, face-to-face interactions allow the pharmacist to visually observe the patient for potential health problems. Regardless of the type of visit, an MTM appointment typically includes a medication therapy review, developing an action plan, and referral to other health care providers.<sup>3,4</sup>



**Figure 3-1.** The MTM process<sup>3</sup>

### Medication Therapy Review

Pharmacists review patient information and drug therapies to identify any medication-related problems.<sup>4</sup> After obtaining an accurate medication history, the pharmacist can identify if problems or side effects experienced by the patient are related to their drug therapy.<sup>5</sup> During this time, the pharmacist may also address patient adherence and identify barriers that may be preventing patients from taking medications as they should. Any issues the patient is experiencing could stem from incorrect use of the medications rather than the drug therapy itself; therefore, it is the pharmacist's responsibility to identify the source of medication-related problems.

## Developing a Plan

After the pharmacist has identified drug-related problems, a plan for resolving the issues is then developed.<sup>4</sup> During this process, the pharmacist works with the patient and the physician/healthcare provider to determine possible options for fixing the drug-related problems. These options may include discontinuing therapy that is ineffective for the patient or is causing side effects the patient cannot tolerate, adding drugs onto inadequate drug therapy, or adjusting doses. Medications that are discontinued may also be replaced with medications that can provide the same type of therapy. In other cases, drugs may be added onto current drug therapy if the patient has a health concern not being managed. The drug dose may also be adjusted according to the needs of the patient. Any type of drug therapy changes should be discussed and explained to the patient.<sup>4</sup>

## Referral

Medication therapy management services include referral to other healthcare providers as deemed appropriate.<sup>4</sup> These providers should be consulted if a patient's care goes beyond the extent of the pharmacist's scope of practice. In these instances, the patient should be referred to the appropriate provider.<sup>4</sup>

Situations that may require referral to another health care provider
The patient is experiencing a medical problem outside of the pharmacist's scope of practice
The patient is experiencing any type of medical emergency
The patient needs medication adjustments unable to be made by the pharmacist

**Table 3-2.** Situations requiring referral.

## DRUG INFORMATION SERVICES

Another service commonly provided by ambulatory care pharmacists is providing drug information.<sup>6</sup> As experts in medication knowledge, pharmacists are able to provide accurate drug information to both patients and healthcare providers. Pharmacists utilize primary

literature and medication databases to provide accurate drug information. Educating patients on their disease states and medications enables patients to better manage their health, and providing drug information to healthcare providers can help them to care for patients more effectively.<sup>6</sup>

## **DISEASE STATE MANAGEMENT**

Many medications are used to treat chronic disease states. Pharmacist responsibilities include managing patient medications which translates into managing chronic disease. Disease state management may be accomplished through patient visits with a pharmacist and can occur in a variety of settings including, but not limited to: physician offices, pharmacist-managed disease state clinics, or community pharmacies. In pharmacist-managed clinics, the pharmacist is independently responsible for providing primary care via protocol with a physician, which includes ordering lab tests, modifying drug therapy, and following up with patients.<sup>14</sup> Helping patients with their medication regimens can help to optimize disease state outcomes, such as:

- In one smoking cessation group clinic, pharmacists were able to assist patients in quitting smoking, with 47.6% of patients smoke-free at 3 months and 52.4% of patients smoke-free at 6 months.<sup>19</sup>
- A pharmacist-managed spirometry clinic resulted in pulmonary drug regimen changes in 80% of patients, with referral to physicians or further diagnostic testing in 27.4% of patients.<sup>18</sup>
- A study on pharmacist-managed hypertension clinics resulted in 81% of patients reaching their blood pressure goals versus only 12% of patients who did not meet with a pharmacist.<sup>21</sup>

Pharmacy services in ambulatory clinics may focus on a single disease state, such as diabetes, or may be focused around multiple conditions related to a high risk medication, such as warfarin.<sup>7</sup> Medication management services can be expanded further when pharmacists work in collaboration with other healthcare professionals.

### **Collaborative Drug Therapy Management**

Collaborative drug therapy management (CDTM) has been defined as a formal partnership between a pharmacist and physician or group of pharmacists and physicians to allow pharmacists to manage a patient's drug therapy.<sup>8</sup> CDTM agreements allow pharmacists to expand their scope of practice by allowing them to perform services they would not be allowed

to perform without a CDTM agreement. CDTM can help improve patient outcomes, increase patient satisfaction, and lower costs.

Potential Problem	Pharmacist Intervention
Medication adverse events	Pharmacists may identify drug interactions, resolve side effects, identify inappropriate medications or doses
Limited patient access to healthcare practitioners	Pharmacists may help provide care to patients, lessening patient load for physicians
High healthcare costs	Pharmacists can reduce costs by optimizing medication use <ul style="list-style-type: none"><li>• Can identify unnecessary or inappropriate medications</li><li>• Ensuring patient adherence to medications can help prevent hospital admissions</li></ul>

**Table 3-3.** CDTM Benefits<sup>9</sup>

Ambulatory care pharmacists utilize CDTM agreements to work collaboratively with physicians to enhance patient care. Based on the pharmacist's scope of practice in their state, responsibilities of a pharmacist under CDTM agreements may include implementing or modifying drug therapy, ordering and evaluating drug-therapy related laboratory tests, and administering medications such as immunizations. However, these responsibilities may vary depending on the legal agreement and scope of practice.<sup>8,9</sup>

## ADMINISTRATION

In some clinics, particularly those providing services to underserved populations, ambulatory care pharmacists may be asked to assist with developing drug formularies and monitoring prescribing habits. A formulary is a list of medications and related drug information that is continually updated and reviewed by physicians, pharmacists, and other healthcare professionals.<sup>10,11</sup> For health plans, a formulary includes all the prescription medications covered by the plan. Hospitals also have drug formularies, which include drugs that the

hospital carries. Formularies are developed by identifying the most medically appropriate and cost-effective drug therapy options. Pharmacists play a key role in this process by continually reviewing primary literature and guidelines on medications to determine the most appropriate drug therapies to include in formularies and relaying findings to physicians and other healthcare professionals.<sup>10,11</sup>

### PREVENTATIVE CARE / WELLNESS SCREENINGS

In addition to helping patients manage existing chronic disease, pharmacists may also help to prevent disease. For example, an annual wellness visit (AWV) may serve as an annual health screening for patients. Medicare Part B covers the patient's cost and provides reimbursement for the practitioner providing this service. AWV occur in a physician office and during these visits, patients are assessed to determine if they have risk factors for certain disease states and may be referred to health education or other preventive services.<sup>12, 13</sup>



**Figure 3-3.** Elements of an AWV<sup>12</sup>

### DIRECT PATIENT CARE

Direct patient care is one of the primary services performed by ambulatory care pharmacists.

CDTM agreements facilitate pharmacist-independent and team-based patient care services.<sup>14</sup> **Table 3-4** outlines the pharmacist's role in various clinic types, which can be provided by pharmacist-independent or team-based care.

#### Pharmacist-Independent Care

Ambulatory care pharmacists may be independently responsible for providing patient care, generally when working collaboratively under a physician.<sup>14</sup> This is most commonly seen in disease state management with CDTM in place. When a pharmacist is working independently to care for a patient, responsibilities may include completing medication histories, physically assessing the patient, ordering lab tests, adjusting medications, and following up with the patient.<sup>15</sup> Additionally, based on the collaborative agreement in place, pharmacists may also authorize refills of certain medications and provide immunizations.<sup>15</sup>

#### Team-Based Care

Ambulatory pharmacists may also work as a member of a team with other healthcare professionals to provide care for a patient.<sup>14</sup> In this setting, pharmacists may meet with the patient at the same time as other healthcare providers. During shared appointments, pharmacists are able to address medication questions and concerns brought up by the patient or the other healthcare providers.<sup>15</sup> Pharmacists may still have independent responsibilities in this setting, such as obtaining medication histories and performing medication reviews.<sup>14</sup>

Clinic Type	Pharmacist Role
Diabetes <sup>9,16</sup>	<ul style="list-style-type: none"><li>• Help patients set self-management goals<ul style="list-style-type: none"><li>◦ Blood pressure and A1C targets</li><li>◦ Investigate barriers to achieving these goals</li></ul></li><li>• Adjust medications to help achieve these goals</li><li>• Provide diet and exercise education</li></ul>
Anticoagulation <sup>17</sup> (primarily warfarin)	<ul style="list-style-type: none"><li>• Adjust warfarin doses</li><li>• Assess for drug interactions or diet changes that may affect warfarin therapy</li><li>• Interpret INR results to see if dose adjustments need to be made to keep patients in therapeutic range</li></ul>

Clinic Type	Pharmacist Role
Pulmonary <sup>18</sup>	<ul style="list-style-type: none"> <li>• Provide spirometry tests to evaluate patient pulmonary functions</li> <li>• Identify respiratory problems related to inadequate medication therapy</li> <li>• Counsel on proper inhaler and nebulizer use</li> </ul>
Smoking Cessation <sup>19</sup>	<ul style="list-style-type: none"> <li>• Instruct on both prescription and over-the-counter medications to help quit smoking</li> <li>• Provide strategies and tips in quitting</li> <li>• Follow up with patient to ensure no relapse</li> </ul>
Heart Failure <sup>20</sup>	<ul style="list-style-type: none"> <li>• Ensure patient is not taking medications that may worsen heart failure</li> <li>• Inform patient's primary care provider of any inappropriately prescribed drugs</li> </ul>
Hypertension <sup>21</sup>	<ul style="list-style-type: none"> <li>• Take patient's blood pressure</li> <li>• Suggest adjustments to patient's medications based on blood pressure results</li> <li>• Diet and lifestyle counseling</li> </ul>
Behavioral Health <sup>9</sup>	<ul style="list-style-type: none"> <li>• Help to adjust or initiate psychiatric medications <ul style="list-style-type: none"> <li>◦ Disease states include depression, schizophrenia, and bipolar disorder</li> <li>◦ Consider special populations such as geriatrics and pediatrics</li> </ul> </li> </ul>
HIV <sup>22</sup>	<ul style="list-style-type: none"> <li>• Help to optimize treatment regimens <ul style="list-style-type: none"> <li>◦ Analyze patterns of resistance to the HIV virus</li> </ul> </li> <li>• Ensure patients have access to medications</li> </ul>
Hepatitis C <sup>23</sup>	<ul style="list-style-type: none"> <li>• Manage drug interactions</li> <li>• Assess appropriateness of treatment regimens based on patient genotypes</li> </ul>

**Table 3-4.** Pharmacist's role based on clinic type



## CARE COORDINATION

### Transitions of Care

Transitions of care refers to the movement of a patient from one setting of care (hospital, ambulatory care practice, long-term care, home health, rehabilitation facility) to another.<sup>24</sup> Transitions of care may also apply to patients who are leaving a healthcare setting to go home. When patients leave one healthcare setting and move to another, it is important that they are receiving continuous care. Care should be coordinated between all healthcare professionals providing care to the patient. When patients are transferred from one setting to another, adverse events may occur, often caused by medication errors. Recent studies have shown that 54% of patients experienced medication errors upon hospital admission; a significant percentage of these errors (39%-45%) were found to be potentially harmful to the patient.<sup>25</sup> Patients who are admitted to a care facility, such as a hospital, may leave with a different prescribed medication regimen than what they had previously. If these changes are not adequately communicated between healthcare providers, the patient may end up receiving inappropriate and/or duplicate drug therapy. This is why it is important for healthcare providers to effectively communicate any changes in drug therapy.<sup>24,25</sup>

Pharmacists may play a significant role in facilitating a patient's transition of care in collaboration with other health care providers such as, physicians, nurse practitioners, clinical nurse specialists, or physician assistants.<sup>24,26</sup> Obtaining a patient's complete medication history in order to accurately perform medication reconciliation is important in reducing medication errors.<sup>27</sup> The patient's medication list should be reconciled again upon discharge to another healthcare facility and should be available for the next healthcare providers taking care of the patient. Patient adherence to new drug regimens is also important and can be improved through disease state education and medication education. Educating the patient about their condition, medication, how to take the medication, and potential side effects can improve medication adherence rates. Disease state education can help a patient understand their new diagnosis and the risks involved can help motivate patients towards better adherence. Immediate patient follow-up is another task in which pharmacists can help.<sup>26</sup> Care transition pharmacists make contact with the patient within a few days of discharge from the inpatient setting. This quick initial contact can help answer questions the patient may have and help them to better manage their new diagnosis effectively. In addition to these services, pharmacists can also integrate MTM services and medication counseling services. In some practices, pharmacists are able to continue following the patient if the patient's chronic conditions match those in which the pharmacist manages at the clinic. Pharmacists provide a unique, medication-specific approach to transitions of care, which has

been shown to decrease hospital admissions, readmissions, and ED visits.<sup>24,27</sup>

### CASE 3-1

Dr. Jones is a local physician whose patient population consists largely of diabetic and atrial fibrillation patients. Many of his patients appear not to be adequately managed in their disease states. Additionally, Dr. Jones has a high patient load which prevents him from seeing his patients as often as he should, resulting in poor outcomes, trouble managing appointments, and difficulty bringing in new patients. Due to poor performance scores, Dr. Jones is at risk for facing penalties and/or not receiving full reimbursement amounts with his payers.

**What are opportunities for ambulatory care pharmacists in this scenario? What services could be provided?**

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# SECTION 2

## COST

There are many reasons healthcare costs so much in the United States, but the answers usually fall into two categories: costs due to the healthcare system itself and costs due to the nature of disease and society.<sup>1</sup> Costs caused by the healthcare system can be attributed to insurance used as insulation, lack of transparency, and lack of standardization and coordination.<sup>1</sup> Insurance was originally designed to protect against high, catastrophic costs that could lead to medical bankruptcy or significant financial loss. Insurance as insulation attempts to assist consumers with even low cost expenses, increasing the cost of insurance because providers can no longer calculate costs based solely on the risk of catastrophic events. This more extensive coverage relies heavily on private negotiations and opaque contracts to control costs.

The American healthcare system is a private, competitive, market-driven system with limited government regulation, price controls, and salary caps. Many other countries have centralized negotiation programs where companies compete for contracts by offering lower prices.<sup>2</sup> In the United States, private and government payers may negotiate prices with healthcare administrators without involvement of the patient or healthcare provider. Therefore, price does not equal cost or reimbursement for a particular healthcare service or product. This lack of transparency allows for variable prices for similar services and further impacts competition. Prices for drugs, office visits, and procedures are typically higher in the United States than any other country. These costs support innovation, advanced technology, attractive facilities, and higher salaries of healthcare providers. A 2013 Gallup Poll suggests that Americans have more positive feelings about their personal healthcare than the country's healthcare.<sup>3</sup> Approximately 2/3 of Americans rate their personal healthcare coverage as excellent or good and about 1/3 give the country's healthcare coverage a high rating.<sup>3</sup> 59% of respondents indicated they were satisfied with the cost of their own healthcare.<sup>3</sup>

Costs related to the nature of disease and society include costs of chronic disease care, end of life care, unhealthy behaviors, and health literacy.<sup>1</sup> According to the Agency for Healthcare Research and Quality (AHRQ), in 2013, 5% of the US population account for 48.7% of spending with an estimated annual mean expenditure of \$43,253.<sup>4</sup> The lack of incentive for preventive care and unhealthy lifestyles leads to an increase of chronic disease. The

expectation of insurance payment for chronic disease management is part of the systemic costs of increased perception of insurance as insulation. Attitudes toward prevention and healthy lifestyle are part of the costs related to the nature of disease and society. Societal views on extensive end of life care contributes significantly to healthcare spending, especially as the baby boomer population ages. Other factors that impact the cost of care will be discussed later.

Until the early twentieth century, insurance for routine healthcare did not exist. The first modern group health insurance plan was formed in 1929. A group of teachers in Dallas, Texas negotiated a contract with a local hospital for services in exchange for a fixed monthly fee.<sup>5</sup> This arrangement led to the startup of organizations such as Blue Cross and Blue Shield which offered similar insurance programs. Offered only by some employers, insurance was generally purchased by the patient consumer and having insurance was uncommon. This changed during World War II when the federal government imposed wage freezes. At the time, employers could not raise salaries but could offer benefits to employees and employers competed for workers by offering better benefits packages. A key component was new or improved health insurance plans. This led to major demand and growth for private employer-based health insurance and by the late 1950s the majority of Americans had some amount of healthcare coverage. However, those who were unemployed, self-employed, or employed by small employers were unable to afford the care they needed. In response, Medicare and Medicaid were created in 1965 providing public funding for healthcare coverage for the elderly and indigent.<sup>5</sup> Each of these coverage options may use one or more payment structures, including fee for services, network negotiations, capitated payments, or salaried providers.

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# CHAPTER 4

## FROM INSURANCE BASICS TO PLAN SELECTION

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By purchasing insurance, plan members are buying protection from a large debt in the event of a catastrophic need for medical care. However current practice in using insurance to cover non-catastrophic expenses causes higher premiums and may decrease the amount available to pay for covered expenses.

On average, a three day hospital stay can cost about \$30,000 and a reasonable question might be how health insurance companies pay for the large bills.<sup>1</sup> The insurance company's job is to spend money to benefit the most members without having to raise premiums or deny additional services. This includes using profits to pay competitive salaries to employees. The business of health insurance in the United States relates as much to finance as it does to healthcare. Plan members pay for insurance through regular premiums and insurance companies invest that money to pay for illnesses that happen to anyone in the group. Proper investing and money management provides the best coverage to cost ratio for beneficiaries.

Insurance is paid via premiums, deductibles, co-payments, and co-insurance amounts. Premiums are a monthly payment to ensure the member stays covered under a plan (like a basic phone bill without usage charges). Many insurance plans require patients to pay a deductible at the beginning of each year of coverage, typically January 1. A deductible is the total amount a member must spend on their care per policy period (generally one year) before insurance will begin to cover their portion. Therefore, beneficiaries pay for coverage but the insurance doesn't work right away. Depending on the plan, deductibles may only apply to certain types of care. For instance, if the deductible does not apply to prescriptions, the patient does not have to pay the deductible first for prescriptions.

Once a patient has met their deductible, they may continue to have to pay a portion of their bills until they have reached their out-of-pocket maximum. Having beneficiaries paying some of their own costs, cost sharing has been shown to engage them in keeping costs low. It also helps to keep the costs of premiums down by decreasing insurance company spending. The patient will pay a portion of costs through co-pays, which are flat fees, and co-insurance, which is a percentage of total charges. Insurance will cover the remainder of the bill.



Health insurance plans negotiate prices and have out-of-pocket maximums to help prevent members from going bankrupt despite having insurance. Once the out-of-pocket maximum is reached, insurance will cover 100% of a member's healthcare costs for the rest of the year.<sup>1</sup>

## **PATIENT TO PAYER CONNECTIONS**

Fundamental knowledge of insurance terminology is necessary for navigating patient to payer interactions. The primary purpose of health insurance is to help protect an individual from financial risks of medical expenses, which can often be very high, and to help avoid significant financial loss.<sup>1</sup> Health insurance in the United States usually includes both medical insurance (doctor and hospital coverage) as well as prescription coverage. A common misconception is the belief that insurance will pay for all health care expenses that occur.<sup>2</sup>

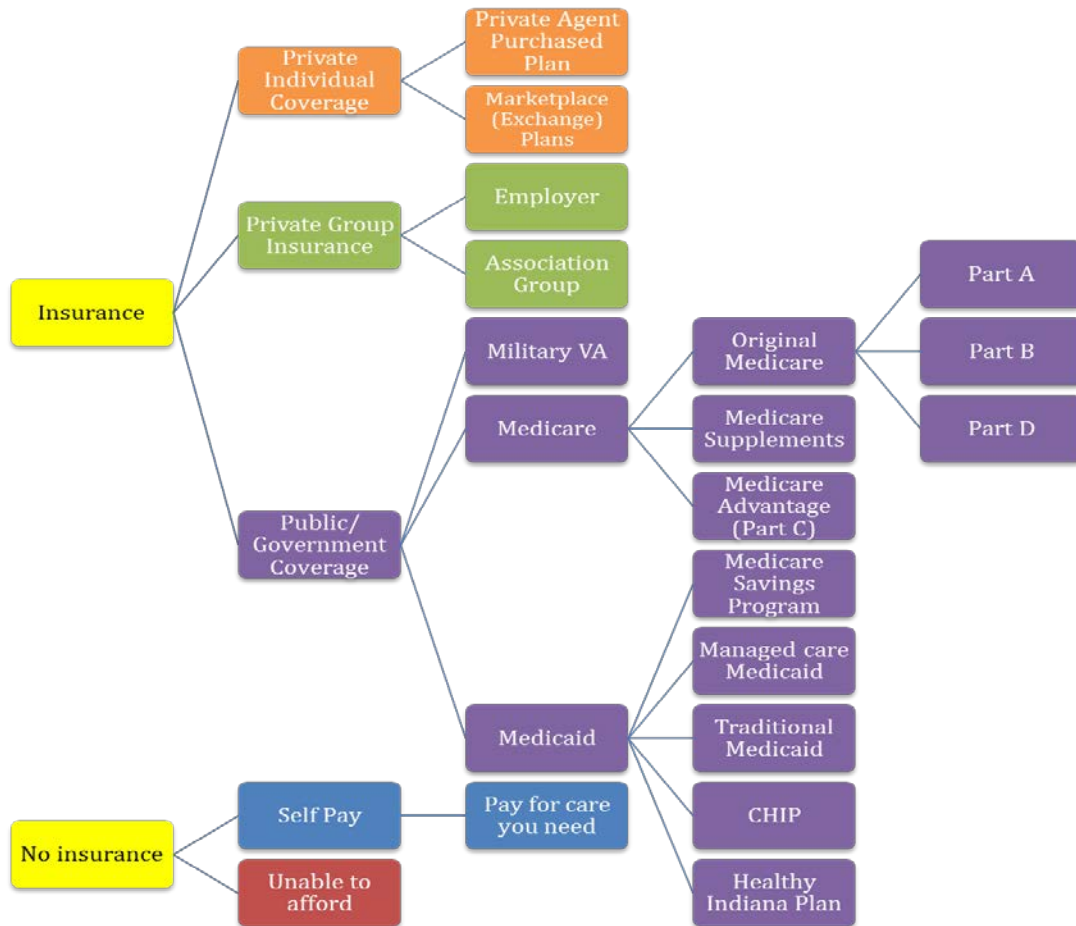
Health insurance plans identify services or expenses that are covered or eligible for insurance payment.<sup>3</sup> It may also list items that are excluded, where an individual will pay any expenses incurred without insurance help. When a health care provider or patient submits these expenses to the insurance company for processing (send in the bill), the expenses are referred to as claims. Additional vocabulary such as deductible, coinsurance, etc. is defined in the glossary.

### Types of Insurance Coverage

**Figure 4-1** below provides an overview of the primary types of health insurance coverage available in the US.<sup>3</sup> Health insurance may be purchased privately, either individually or as part of a group, or publicly, through state or federal government. Employer coverage, a form of group coverage, is the most common type of private insurance.<sup>3</sup>

Employers who offer health insurance plans to their employees generally offer better coverage at a cheaper rate than if the employee were to purchase it on their own as an individual policy. Employers may also choose to cover a portion of the premium for each employee. The employees then pay their portion of the premium through paycheck deductions.<sup>3</sup>

Others are not able to obtain employer health insurance. These individuals may not work enough hours to qualify for employer coverage, are unemployed or work for a small employer who does not offer regular group coverage. These individuals can purchase private coverage through the health insurance marketplace (online) or from private agents.



**Figure 4-1.** An overview of the types of insurance coverage available to Americans

## IN-DEPTH LOOK AT THE MARKETPLACE

### Marketplace

The Patient Protection and Affordable Care Act, PPACA, created a new, private insurance marketplace in all 50 states and the District of Columbia.<sup>4</sup> Some states created their own marketplace and others utilize the federal health insurance marketplace. These marketplaces include a central online location, called the Small Business Health Options (SHOP) Exchange, that enable individuals and small groups to shop for private health insurance plans.<sup>4,5</sup> Here, small businesses, currently defined by the federal government as 50 or fewer full time equivalent (FTEs) employees, can set up accounts to allow individuals to compare available plans specifically selected by the small employer.<sup>5</sup> In the SHOP, individuals have

fewer options than on the individual marketplace, but the employer pays a portion of the premium.<sup>5</sup>

People who select insurance plans through the individual health insurance marketplace may be eligible for tax credits to help cover their premium. These credits are based on the person's income.<sup>6</sup> Some individuals may also choose to self-pay for medical bills, rather than pay for insurance coverage. However, this choice will result in penalty taxes the individual will be required to pay, unless they qualify for a tax exemption.<sup>6</sup>

Marketplace exchanges support individual access and comparison of health insurance coverage. Resources are available to help individuals navigate the exchanges. HealthCare.gov offers a wide variety of information regarding navigation and utility of the federal health insurance marketplace. Individuals can apply online, by phone, via a paper application, or with in-person help using a tool on HealthCare.gov, which enables individuals to enter their location information, and select the type of coverage they are searching.<sup>6,7</sup>

### Function and Navigation

Individuals can enroll in plans during yearly open enrollment periods (OEP) that is set by the federal government.<sup>6</sup> During this timeframe, individuals may browse and enroll in a health insurance plan for the following year. Enrollment outside of the OEP cannot occur unless the patient, also known as a beneficiary, qualifies for a special enrollment period.<sup>6</sup> Special enrollment periods occur over a 60 day period following particular life events that result in a change of family status, such as marriage, childbirth, or after the loss of prior health coverage.<sup>6</sup>

HealthCare.gov offers screening tools to help individuals determine if they are eligible for either Medicaid, Children's Health Insurance Program (CHIP), or a special enrollment period. Both Medicaid and CHIP are discussed later in this chapter.

### Marketplace Plans

The federal health insurance marketplace categorizes insurance plans into four "metals" or "medals": Bronze, Silver, Gold, and Platinum. Although a common misconception, the "metals" do not reflect or categorize plans according to quality or amount of care provided by each plan.<sup>8</sup> Each metal level reflects the cost of monthly plan premiums and the portion of costs for care or services, such as hospital visits or prescriptions, that the patient will be expected to pay.<sup>8</sup> "Metal" categories are defined in [Figure 4-2](#).<sup>9</sup>

“Metal” Federal Health Insurance Marketplace Categories	
Bronze	<ul style="list-style-type: none"> <li>• Health plan covers approximately 60% of total average costs</li> <li>• Beneficiary covers approximately 40% of total average costs</li> </ul>
Silver	<ul style="list-style-type: none"> <li>• Health plan covers approximately 70% of total average costs</li> <li>• Beneficiary covers approximately 30% of total average costs</li> </ul>
Gold	<ul style="list-style-type: none"> <li>• Health plan covers approximately 80% of total average costs</li> <li>• Beneficiary covers approximately 20% of total average costs</li> </ul>
Platinum	<ul style="list-style-type: none"> <li>• Health plan covers approximately 90% of total average costs</li> <li>• Beneficiary covers approximately 10% of total average costs</li> </ul>

**Figure 4-2.** “Metal” insurance plans for the federal health insurance marketplace

Catastrophic health plans, often referred to as a ‘fifth category’ within the marketplace, exist for individuals under 30 years of age or those who have a hardship exemption.<sup>9</sup> Hardship exemptions are a set of specific criteria, such as being homeless, experiencing domestic violence, or facing substantial medical debt, that enable an individual from having to obtain health insurance coverage for a particular period of time.<sup>9,10</sup> Catastrophic plans focus their benefits on high medical costs such as serious injury or hospitalization rather than outpatient, chronic care.<sup>10</sup> Under these Catastrophic plans, health insurance companies pay less than 60% of the total average costs of care, placing more payment responsibilities on the patient.<sup>9</sup> These plans are an option for younger individuals who are healthier and do not utilize their insurance coverage on a regular basis.<sup>10</sup> Individuals under hardship exemptions are eligible, regardless of age or income, to purchase a Catastrophic health plan, but are not required.<sup>10</sup>

#### Public/Government Insurance Coverage Options

Individuals who have a very limited income and significant medical need may obtain health insurance through the state government Medicaid program. Medicaid is a collection of programs available for different levels of need. Medicaid provides health insurance options for low-income families and children, pregnant women, the elderly, and people with disabilities. Low income in most states is defined as at or below 133 percent of the federal poverty level.<sup>11</sup> Some states have expanded their Medicaid programs to cover all adults below 138% (133%+/-5%) levels.<sup>11</sup> Medicaid recipients typically don’t pay a premium and copays are low to nonexistent since coverage is funded by the state and federal government.

Although each state administers their own program, the federal government provides some financial support to assist with Medicaid funding. The federal government also sets minimum guidance standards, such as criteria for enrollment and evaluation of claims, Medicaid programs must follow to ensure some consistency of coverage between state programs.<sup>11</sup> Therefore, though all states must meet minimum standards, Medicaid benefits vary between states based on individual state budgets and overall population need.

Individuals who are over 65, disabled for 24 months or longer, have End Stage Renal Disease (ESRD), and/or ALS (amyotrophic lateral sclerosis or Lou Gehrig's disease) qualify for another government program called Medicare.<sup>12</sup> It is important to note that individuals may qualify for both Medicaid and Medicare. **Table 4-3** describes the different types of Medicare programs available to patients.<sup>12</sup>

Types of Medicare	
Medicare Part A & B ("Original Medicare")	Original Medicare is a fee-for-service health plan that has two parts: Part A (Hospital Insurance) and Part B (Medical Insurance). After the member pays a deductible, Medicare pays its share of the Medicare-approved amount, and the member pays their share (coinsurance and deductibles).
Medicare Part C ("Medicare Advantage")	Medicare health plan that contracts with Medicare and uses managed care arrangements with providers to provide Part A and Part B benefits to Medicare patient. Medicare Advantage Plans include Health Maintenance Organizations, Preferred Provider Organizations, Private Fee-for-Service Plans, Special Needs Plans, and Medicare Medical Savings Account Plans. Patients choose either Medicare Advantage or Original Medicare. Most Medicare Advantage Plans offer prescription drug coverage.
Medicare Part D	A separate program that helps pay for prescription medications for people with Medicare. All Medicare Part D plans are offered through private insurance or prescription benefit companies, there

is no “original” Medicare Part D plans offered by the federal government. There are two ways to get Medicare prescription drug coverage: through a stand alone Medicare Prescription Drug Plan or a Medicare Advantage Plan that includes medication coverage.

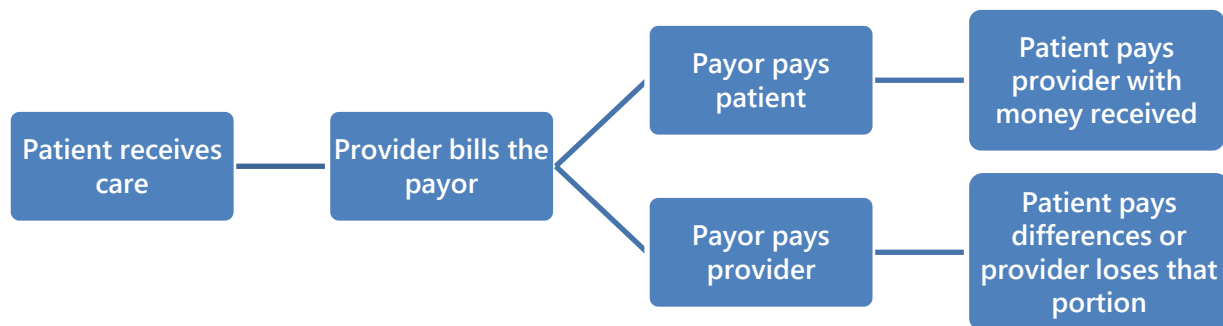
**Table 4-3.** Types of Medicare

Other examples of government-funded programs include federal coverage through the Department of Defense for military members and their families and coverage for veterans through the Veterans’ Administration (VA).<sup>12</sup> Government-funded coverage may also be referred to as public health coverage.

## RELATIONSHIPS BETWEEN PAYERS AND PROVIDERS

### Fee-For-Service (FFS)

Before the 1970s, Medicare and private insurance primarily offered insurance, called indemnity insurance, that used a fee-for-service model. Fee-for-service means that each item or expense would be itemized to one or more bills. Providers would be paid a specified amount for each service amount established by each insurer. In the fee-for-service model, the patient chooses their own providers and has no restrictions on the use of specialty services. Providers who receive reimbursement directly from payers may then charge the patient what the insurance did not cover. This is referred to as balanced billing because the patient is billed for the remaining balance.<sup>13</sup> This is demonstrated in figure 4-4.



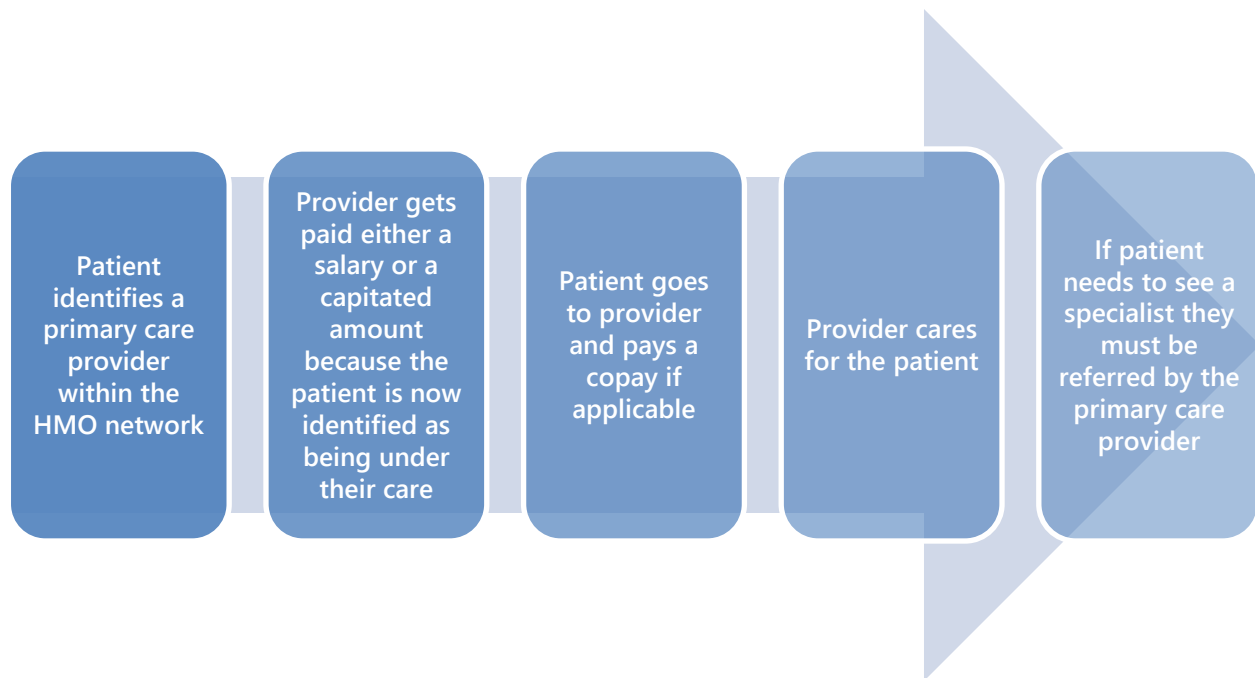
**Figure 4-4.** Fee for service model

In 1973, President Richard Nixon signed a law to help control the rising healthcare costs.<sup>14</sup> With this law, a model for a managed care organization (MCO) was initiated.<sup>15</sup> An MCO is a private insurance company with agreements in place with selected healthcare administrators and providers. This agreement is settled before patient care is delivered and outlines negotiated prices and payment arrangements. MCOs lower costs for patients by limiting their healthcare provider options to only those with an agreement. There are several types of MCOs, including: Health Management Organizations (HMOs), Preferred Provider Organizations (PPOs), and Point of Service (POS) plans.<sup>14</sup> The options described below outline the financial agreements between healthcare providers or administrators and payers in managed care coverage. This is important to help patients understand their coverage and to help providers understand how they will be reimbursed.

### **HEALTH MAINTENANCE ORGANIZATION (HMO)**

Healthcare providers within an HMO network are usually paid by salary or a capitated (per person, per year) amount, allowing the HMO to exert more connection and possibly control over the providers and their healthcare decisions. Therefore, patients can only receive healthcare services from providers in the HMO network.<sup>14</sup> If a patient uses a provider that is not an HMO provider, their insurance plan will not pay for any services from that provider and the patient is responsible for all associated costs.

Under an HMO plan, a patient is usually required to choose a primary care provider (PCP) who serves as a gatekeeper for their care.<sup>13</sup> As gatekeeper, the PCP provides primary care and is the only provider who can refer the patient to specialists for care beyond the PCP's scope of practice.<sup>13</sup> This is demonstrated in Figure 4-5.

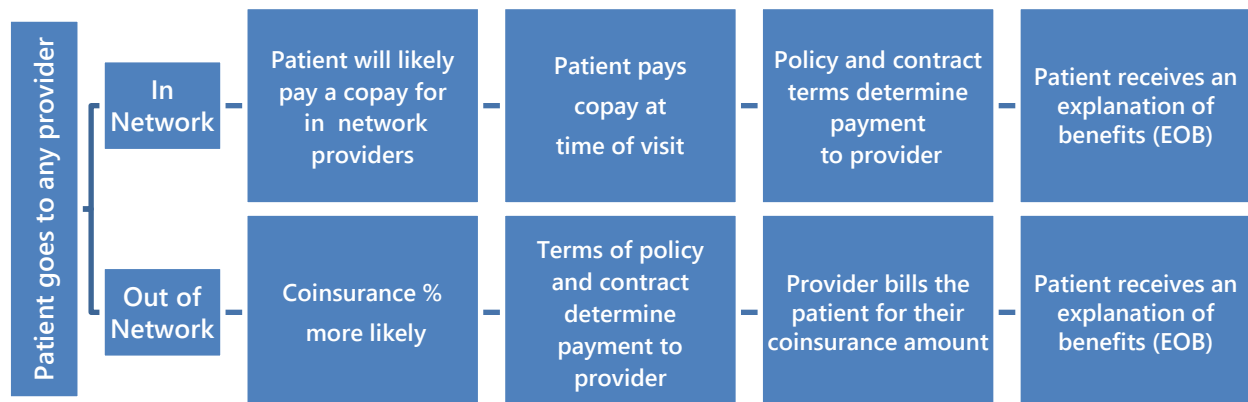


**Figure 4-5.** Health maintenance organization model

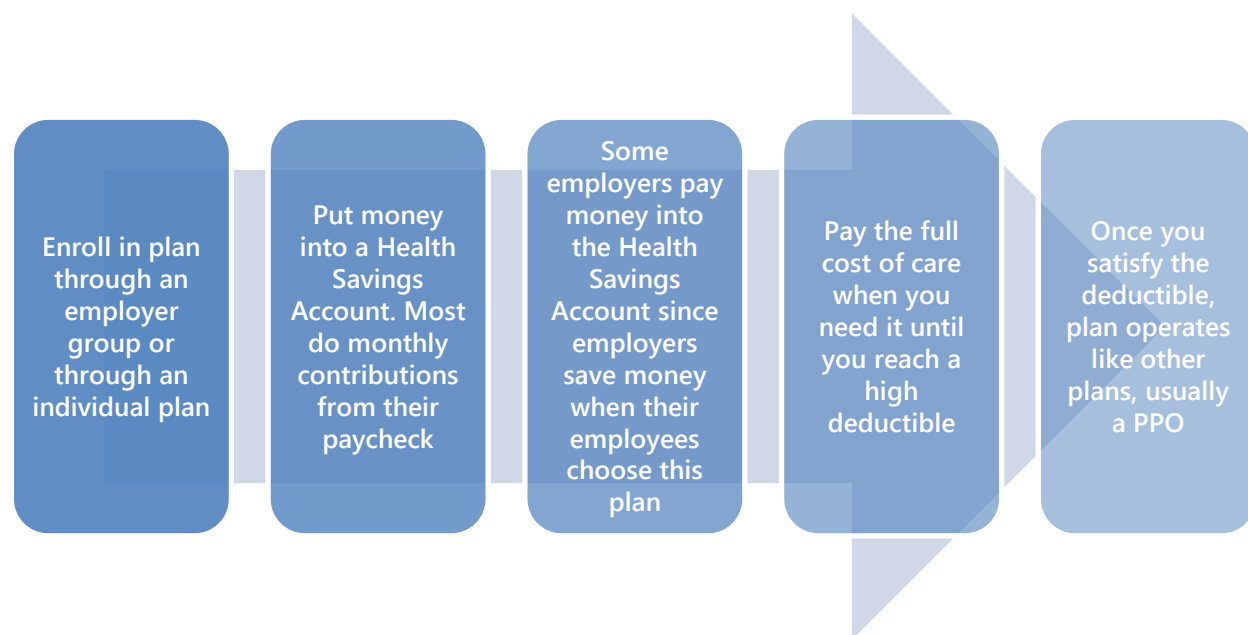
#### **PREFERRED PROVIDER ORGANIZATION (PPO)**

In a PPO, a patient has a preferred in-network list of providers from which to choose. If a patient chooses to see a provider who is out-of-network, it is more expensive than seeing a provider that is in-network but there will be some coverage from the insurer. In-network providers offer services at discounted rates in exchange for increased business from that insurance company. High deductibles may be options within PPOs (**Figures 4-6 and 4-7**), which can be offset by putting money into a tax-free account referred to as a Health Savings Account (HSA).





**Figure 4-6.** PPO plan without a high deductible



**Figure 4-7.** PPO plan with a high deductible

### POINT OF SERVICE (POS)

A POS may be considered a combination of an HMO and PPO.<sup>14</sup> In these plans, a patient is typically required to choose a primary care provider (PCP) similar to an HMO. The PCP

coordinates the patient's care and can refer them for additional services. At this point, the patient can choose to receive point of service (POS) care from a less expensive in-network or more expensive out-of-network provider.<sup>14</sup> The out-of-network providers are more expensive because they are reimbursed on a fee-for-service basis.

In summary, managed care attempts to limit healthcare costs by steering patients toward specific providers and controlling the number and variety of paid for services. A lack of provider knowledge of costs, limited patient knowledge about the care they need, and third-party negotiations have made it difficult for patients embrace managed care. A trend toward a new structure, called accountable care, integrates healthcare providers to consider cost versus benefit with a focus on outcomes and value to patients.

## **ACCOUNTABLE CARE**

The intent of the Patient Protection and Affordable Care Act (PPACA) was to shift from paying providers for the amount of care, fee-for-service, to paying providers based on the quality and value of the care they provide. The goal of pay-for-performance is to improve patient outcomes, enhance the quality of patient care, and reduce overall system costs.<sup>13,16</sup> Instead of having payers lead the decisions, the PPACA directed health care providers to be accountable for their patient care. This was done through changes to reimbursement for providers. New payment structures are based on measures of improving clinical outcomes, increasing overall patient satisfaction with the provider, minimizing adverse events, or decreasing length of stay and treatment times.<sup>17</sup>

### **Accountable Care Organizations**

The PPACA established a new model to encourage and support accountable care: the accountable care organization (ACO). ACOs consist of groups of physicians, hospitals, and other health care providers. The ultimate goals of ACOs are to increase the use of evidence-based quality measures, actively engage patients in their care, and coordinate patient care between providers.<sup>16</sup> Coordinated care is intended to provide patients with the right care, avoid unnecessary duplication, and improve patient outcomes.<sup>8</sup>

Medicare provides coverage to individuals who are at least 65 years old or those of any age who are permanently disabled. A new payment model, the Medicare Shared Savings Program, offers financial incentives to certain ACOs. Providers must meet different criteria but if they are successful and improving outcomes while cutting costs, they received a portion of the money saved back. To help measure success and determine reimbursement, ACOs are required to submit information to the Centers for Medicare & Medicaid Services (CMS) on

quality measures which together comprise four domains: Patient/Caregiver Experience, Care Coordination/Patient Safety, Preventative Health, and At-Risk Populations.<sup>18</sup> Looking at the domains, it is easy to see how the focus on both the patient experience and clinical care connects to providing value based care.

### Accountable Care and Pharmacists

The sustainability of ACOs is dependent on how well they can control costs through coordinated care while improving healthcare quality. Pharmacists are in a position to help ACOs succeed. The pharmacist's role in accountable care will continue to include optimizing treatment choices, considering cost, ensuring medications are being prescribed and used properly, reducing medication-related adverse events, and helping other providers manage chronic disease states.<sup>16,19</sup>

For example, think about a patient who has high cholesterol. The outcome of treatment is to lower the cholesterol. Lowering cholesterol may be done by changes in diet and exercise and by medications. This patient is self-employed and has a fee-for-service plan. Each time the physician meets with the patient and orders a lab test, it will be paid for by the insurance company and the patient will pay a portion of the cost. If the physician is concerned the patient is at risk of a heart attack, they may be very aggressive may order frequent tests, prescribe new medications, and schedule regular appointments because each item will be paid. The physician is free to make clinical judgment without any review.

The patient changes jobs and now has employer coverage using a health maintenance organization (HMO). The physician the patient had been seeing is not in network, so he must go to a different provider. After making an appointment with the new physician, the patient learns this will be his primary care provider who will decide what additional care the patient needs. This is the gatekeeper and the name appears on the patient's insurance card. This physician is focused on maintaining the patient's health and limiting the use of expensive laboratory tests and medications to reduce cost for the HMO and the patient. This physician recommends more extensive exercise and nutrition. The physician makes recommendations based on the guidelines and policies provided by the HMO. The physician's payment and employment is based on following the HMO criteria and managing cost and risk to the HMO.

The patient now retires and enrolls in Medicare. The patient changes physicians to one that takes Medicare. This physician is part of an accountable care organization (ACO). This physician knows that his reimbursement is based on the patient achieving his cholesterol goal and staying out of the hospital. He implements a diet, exercise and medication plan that fits

nationally recognized guidelines and the physician's clinical experience. The physician considers the costs of care and balances that with maximizing the benefits for the patient. The physician considers what quality measures exist for patients with high cholesterol and set goals for the patient that match this goal. If this and other patients meet their quality measures for cholesterol management, the physician will receive the remainder of his reimbursement.

This is a simplified approach to understanding the difference between payment structures to clearly delineate how healthcare providers may be impacted. It is not likely that a provider would change their treatment by the type of insurance coverage but different settings are likely to place different emphasis on treatment options. There is certainly overlap between what drives different providers and their use of quality measures, national guidelines, payer guidelines, and clinical experience.



**Figure 4-8. Transition from Fee for Service to Accountable Care.**

### Fee for Services versus Managed Care Organizations

As discussed, there are three primary forms or categories of health insurance plans:

1. fee-for-service
2. health maintenance organizations
3. preferred provider organizations.<sup>2,3</sup>

Traditional fee-for-service plans are often the most expensive coverage options but offer patients the most flexibility when choosing health care providers.<sup>3</sup> Health maintenance organizations (HMOs) offer lower co-pays for patients than traditional fee-for-service plans and cover most costs for preventative care, but patients are only allowed to use a limited number of health care providers and facilities except in emergency situations.<sup>3,20</sup> HMOs require their patients to select a primary care provider in order to receive coverage.<sup>3,20,21</sup>

Additionally, HMOs may require referrals from a single primary care provider, also known as a gatekeeper, to see providers outside of the plan's network.<sup>20</sup> Point-of-service options may also be offered by some HMOs and allow patients to receive care outside the preferred network, but at a higher, out-of-pocket cost through higher premiums.<sup>20</sup>

Preferred provider organizations (PPOs) offer lower co-pays than traditional fee-for-service plans and provide more flexibility to patients when selecting health care providers or facilities.<sup>20</sup> PPOs typically provide the most coverage for providers within network but allow patients to receive care out-of-network at higher costs and usually do not require referrals for such care.<sup>21,22</sup> Unlike HMOs, PPOs do not require patients to choose a primary care provider.<sup>3,22</sup>

### Comparing and Selecting Health Insurance Plans

Ultimately, selecting a health care insurance plan requires evaluation by the individual seeking coverage. They must first understand the types of coverage available to them, such as private or public. Based on the type of coverage, different forms of reimbursement (HMO, PPO, fee-for-service) may impact a patient's choice.<sup>20,21,22</sup> A patient's current health status, health behaviors, and financial situation must also be considered when selecting insurance plans. Acceptance of risk should also be taken into consideration.<sup>21</sup> Like a warranty plan for an appliance, paying for more insurance coverage decreases the risk that an individual would have to pay out of pocket for unplanned medical expenses. Alternatively, if patients do not wish to pay for coverage they may not need, they may want to reduce the amount of coverage they select. Patients not expecting to go to the doctor may select a plan with lower monthly premiums but less coverage.<sup>6,9</sup> However, a healthy patient wishing to avoid the expense of unexpected healthcare services may choose to pay higher premiums under a private insurance plan to ensure better coverage.

Less coverage may be defined in different ways: it may mean the insurance plan covers fewer expenses or that the insurance company covers the same number of expenses but the patient must pay more out of pocket.<sup>6,9</sup> Paying a higher cost share may mean a patient pays 30% instead of 20% of the medical cost, for example.<sup>6,9</sup> Insurance plans may also have different coverage for different levels of care, referring to the location of where care was received.<sup>6</sup> For instance, a patient with a fever and flu symptoms would likely pay much more for a visit to the ED than an urgent care. The same visit would cost even less at a physician's office.

In choosing a plan, the patient should be aware of how networks function. Based on the plan they choose, they may have little to no coverage at certain providers who are out of

network.<sup>20,21,22</sup> If there is a certain provider or service needed, the patient should make sure it is covered under their intended plan. By limiting the number of providers that a patient can receive care from allows the insurance company to reduce expenses and pass that savings on to the patient.<sup>20,21,22</sup> For example, seeing a primary care physician for a physical may be covered, whereas seeing a renal specialist for the same physical may not be covered. This helps direct patients to the most appropriate provider for their care need.

Some plans may offer tax-exempt Health Savings Accounts (HSAs) or Flexible Spending Accounts (FSAs).<sup>23</sup> These accounts enable patients to deposit and save money, tax-free, to help pay for future medical expenses. Typically, a percentage of a patient's paycheck will be directly pulled and deposited into the accounts.<sup>23</sup> This is a great way to save money and manage healthcare costs. Since the accounts are commonly used with high-deductible policies, patients typically pay higher costs upfront and track their expenses more carefully.<sup>23</sup>

It is important to determine if the plan includes prescription drug coverage, especially if the patient is currently taking prescription medications. Patients should consider a health insurance company's formulary when selecting plans to better determine their prescription coverage needs and/or costs.<sup>24,25,26</sup> Medications or brands not on the formulary can be much more expensive or may not be covered at all. Sometimes the plan will place formulary restrictions on certain medications and only cover them after the patient has completed a step therapy or other type of prior authorization, discussed later in this chapter, to prove the medication is medically necessary.<sup>24,25,26</sup>

Ultimately, premiums, deductibles, and benefits must be weighed and balanced. Patients who need high cost prescriptions may purchase a different plan than a person who primarily needs support for wellness and emergency care.

### Explanations of Benefits

Explanations of benefits are sent to patients by the insurance company to explain their health insurance coverage. These explanations of benefits (EOBs) outline what claims were covered, the negotiated contracted price for the medication, the amount owed by the patient, the amount paid by the insurance company and the reason for any claim rejections, where the insurance company refuses to cover a particular medication and/or therapy.

### Fees for Not Having Health Insurance

As set in the PPACA, individuals may be subject to penalties should they not have health insurance coverage. Individuals who can afford health insurance but choose not to purchase

coverage are required to pay a fee called the Individual Shared Responsibility Payment, also known as a penalty, fine, or individual mandate.<sup>25,28</sup> Individuals without coverage are required to pay the fee for any month they, their spouse, or their tax dependents do not have health insurance coverage that qualifies as minimum essential coverage.<sup>28</sup> Payments are required upon filing for federal tax returns for the year coverage was not held.<sup>28</sup> Fees are calculated per person as a percentage of an individual's household income. HealthCare.gov provides resources to estimate mandated fees.

Exemptions for the Individual Shared Responsibility payment may be available for qualifying individuals. An individual must meet one of the following criteria, (see **Figure 4-9**), to be exempt, which prevents them from holding minimum health insurance coverage:<sup>26</sup>

Have no affordable coverage options due to the fact that the minimum required costs for the annual premium rises more than 8% above the household income<sup>10</sup>

Have gap in health coverage lasting less than 3 consecutive months<sup>10</sup>

Qualify for an exemption for at least one various reason, such as having a hardship that prevents an individual from obtaining coverage or belonging to a group explicitly exempt from the health insurance coverage requirement<sup>10</sup>

**Figure 4-9.** Criteria for exemptions for Individual Shared Responsibility payment

Simply holding insurance coverage may not enable an individual to avoid penalties. Under the PPACA, health insurance coverage must meet minimum comprehensive benefit standards.<sup>5</sup> **Figure 4-10** outlines these essential health benefit standards.<sup>29</sup>

Essential Health Benefits	
Ambulatory Patient Services (outpatient care, non-hospital admittance)	Mental Health/Substance Use Disorder Services (counseling, psychotherapy, etc.)
Emergency Services	Laboratory Services
Hospitalizations (surgery, overnight stays, etc.)	Pregnancy, Maternity, and Newborn Care
Prescription Drugs	Rehabilitative/Habilitative Services/Devices (help gain or recover mental/physical skills)
Pediatric Services (oral, vision, etc.)	Preventative/Wellness Services and Chronic Disease Management

**Figure 4-10.** Essential Health Benefits

All marketplace plans meet minimum standards.<sup>4,28,29</sup> Most plans obtained through employer, government, or state programs also meet minimum standards.<sup>28</sup> Providers should advise patients who wish to purchase insurance outside of these programs to ensure all coverage requirements are being met. HealthCare.gov can be used to help identify whether a plan meets minimum standards.

Pharmacists in different practice settings may assist patients and providers in making the most of their insurance benefits including plan and benefit selection. While this chapter has focused on medical (hospital and office visit) benefits. The next chapter will focus on pharmacy benefits (outpatient prescription) benefit.



# GLOSSARY

## Annual Limit

The maximum amount a member's insurance company will pay for healthcare in a year. These caps may be placed on particular services such as hospitalizations as dollar limits or number of services such as number of therapy appointments. After the annual limit is reached, the member must pay all associated healthcare costs for the rest of the year.

## Beneficiary

A patient who is insured under a specific insurance policy. This could be the primary cardholder or any dependents.

## Benefits

The health care items or services covered by a health insurance plan. Covered benefits are defined in the health insurance plan's coverage documents such as the policy or certificate.

## Claim

A request for payment (bill) that the member or their healthcare provider submits to the health insurer for healthcare products or services.

## Coinsurance

The percent the patient pays (for example, 20%) of the allowed amount for a covered healthcare service or product.

## Copayment

A fixed amount (for example, \$15) paid for a covered healthcare service, usually when the service is provided.

## Covered Expense

A healthcare service or product that is covered as part of the specific insurance plan. A covered expense does not mean it is covered at 100%, but instead that some amount of coverage will be provided.

## Deductible

The amount the patient must pay towards a covered health care product or service before the

health insurance plan begins to pay. For example, if the deductible is \$1,000, the plan won't pay anything until the member has paid \$1,000 for covered services. If a covered expense is NOT subject to deductible, then the patient will not have to pay the deductible first.

### **Dependent**

A child or other patient that benefits from the insurance policy but is not the cardholder. One type of beneficiary.

### **Excluded Services**

Health care services that the health insurance or plan doesn't pay for or cover. This may also be referred to as non-covered.

### **Flexible Spending Account (FSA)**

An arrangement set up through the employer to allow employees to designate money from their paycheck to be used for healthcare before taxes are taken out. This makes the use of these funds tax free. The member decides how much of their pre-tax wages are taken out of their paycheck and put into an FSA. Unlike an HAS, there is no carry-over of FSA funds at the end of the plan year.

### **Formulary**

A list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits.

### **Health Savings Account (HSA)**

A savings account that can be set up at a bank for patients enrolled in a High Deductible Health Plan. The funds contributed to the account aren't subject to federal income tax at the time of deposit. Funds must be used to pay for qualified medical expenses. Unlike a Flexible Spending Account (FSA), funds roll over year to year if they are not spent.

### **Lifetime Limit**

The maximum amount that an insurance company will pay during a person's lifetime. After a lifetime limit is reached, the insurance plan will no longer pay for covered services. The PPACA eliminated lifetime limits from most insurance plans.

### **Member**

A member is a patient who benefits from an insurance plan. Member is another word for

beneficiary. Member is more likely to be used with managed care plans.

### **Network**

The list of all facilities, providers and suppliers the health insurer or plan has contracted with to provide health care services.

### **Out-of-Pocket Maximum**

The most the member will have to pay for covered services in a policy period (usually one year). After reaching this amount, the health plan will pay 100% for covered essential health benefits until the annual or lifetime limit is reached. The calculation towards out-of-pocket maximum includes the yearly deductible and may also include any cost sharing after the deductible. It doesn't have to count premiums, out-of-network cost-sharing, or non-covered expenses.

### **Preauthorization**

A decision by the health insurer or plan that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary. Sometimes called prior authorization, prior approval or precertification. Your health insurance or plan may require preauthorization for certain services before the member receives them, except in an emergency. Preauthorization is not a guarantee that the health insurance or plan will cover the cost.

### **Premium**

The amount that must be paid to keep coverage under a health insurance or plan. The member and/or employer usually pay it monthly, quarterly or yearly.

### **Readmission**

When a patient returns to the hospital shortly after being discharged this is considered a readmission. This is usually counted if it is within 30 days of the discharge. It may count if it is for the same condition or another condition.

### **Reimbursement**

Reimbursement is the amount a payer provides to the health care provider in response to a claim. For managed care plans, reimbursement amount may be based on the terms of the contract. Usual, customary and reasonable amounts may apply to fee for service plans.

## Referral

A written order from a primary care doctor for the member to see a specialist or get certain medical services. In many Health Maintenance Organizations (HMOs), a referral is necessary receiving medical care from anyone except the primary care doctor. Without getting a referral first, the plan may not pay for the services.

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# CHAPTER 5

## PRESCRIPTION INSURANCE

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When patients are choosing health insurance, pharmacy or outpatient prescription benefits are usually part of the health insurance package. Medicare Part D is the exception that focuses only on outpatient pharmacy benefits. In this chapter, more detail will be provided on prescription benefits. While prescription benefits are only part of a health insurance package, they may be the most used component of a person's plan and careful consideration should be given to what they cover.

### PHARMACY BENEFIT MANAGERS

Functioning as a third-party administrator of prescription drug programs, pharmacy benefit managers (PBMs) are companies (not individuals) often hired to help design, manage, and maintain formularies for insurance companies.<sup>1,2</sup> However, PBMs may also be utilized to form contracts with pharmacies, negotiate discounts and rebates with medication manufacturers, and process payment for prescription medication claims. PBMs can help maintain or reduce pharmacy costs of insurance plans, while providing value and flexibility to patients. Some PBMs may offer additional resources that provide patients with information, such as lower-cost therapeutic alternatives, medication therapy management, and mail order services.<sup>1,2</sup>

Pharmacists are often employed by PBMs to provide high quality medication therapy management for members within an insurance plan while considering the pharmacoeconomic implications as well.<sup>1,2</sup> Managed care pharmacists perform a variety of roles including medication distribution and dispensing, patient safety monitoring, clinical program development, business operations, analysis of therapeutic outcomes, and formulary management.<sup>1,2</sup>

### FORMULARIES

Most health insurance plans utilize a formulary, which is a list of particular medications that ensures drug products are used in a rational, safe, and cost-effective manner. Formularies can be either open or closed.<sup>3</sup> Insurance plans with open formularies pay for all medications, even those not on the formulary. Closed formularies only provide coverage for medications that are

listed on the health insurance plan's formulary.<sup>3</sup> The medication listed on a formulary is often organized into tiers. These tiers will represent different levels of payment by the insurance company and the patient. Generally preferred medications will be cheaper than non-preferred agents as well as generic medications cheaper than brand name. Preferred refers to products that are identified by the insurance company as those that may produce more value or cost savings.

Formularies are typically developed by pharmacy and therapeutics (P&T) committees, which are made up of primary care and specialty physicians, pharmacists, nurses, legal experts, and other health care professionals.<sup>3</sup> As mentioned previously, the goal of this committee is to provide a formulary that represents the optimal therapy for patients based on evidence-based efficacy and safety information. Additionally, elements such as cost and ease of delivery are considered when determining which medications should be on a formulary, which are discussed further in **Chapter 6**.<sup>4</sup>

## **PRIOR AUTHORIZATIONS**

Health insurance plans have implemented prior authorizations (PAs) to ensure efficacious and safe medications are being covered, optimizing patient outcomes. A PA requires physicians to provide explanations and/or documentations to justify the use of specific medications for a patient.<sup>4</sup> Insurances use this information to determine whether they will approve or deny coverage of the medication. This helps ensure medications are administered according to recommended therapeutic guidelines and provides better control over costs for health insurance plans.<sup>4</sup> PAs may also be used to limit the use of high risk medications or institute other quality measures set by different quality organizations.<sup>4</sup>

For example, a patient presents a prescription for Crestor® to their community pharmacy, which submits a claim to the patient's health insurance plan. Unfortunately, the brand name medication is not covered by their insurance plan and the claim is rejected or unpaid. Since brand name medications are not on the formulary, the patient may choose to have their prescriber submit a PA to their insurance plan. The prescriber may then do one of two things:

1. Deem the generic medication for Crestor® (rosuvastatin) equally effective for the patient's condition
2. Deem the generic medication to be non-equivalent and not effective for the patient's condition

Should the prescriber choose option 2, they must request pre-approval from the insurance plan to cover the brand medication. Thus, the provider submits the appropriate



documentation and/or explanation (to the insurance plan) that Crestor® is medically necessary and more beneficial/effective, than the generic medication, for their patient. The patient's insurance will then review the prescriber's request for pre-approval and will determine whether or not the medication will qualify for coverage under the patient's health insurance plan.

In this example, the brand name medication was deemed medically necessary by the patient's insurance, and a PA for medication coverage was granted. It is important to note that had the patient's insurance found no medical need for the brand name medication, the patient would then face several options:

1. Try the generic medication under physician approval
2. Try a different medication under physician approval
3. Pay cash for the full cost of the brand name medication not covered by their insurance plan

Other options may exist based upon the particular situation and patient factors.

Guidelines and administrative policies for PA's may vary between insurance plans and companies. Although prior authorizations may be time consuming and frustrating for consumers and health providers, they can help minimize overall health care costs by helping avoid inappropriate medication use and promote utilization of evidence-based medication therapy when used appropriately.<sup>4</sup>

Prior authorizations can be implemented in a variety of ways. Some prior authorizations require additional clinical patient information, such as diagnosis and laboratory results, before a providers is allowed to prescribe that medication.<sup>4</sup> **Figure 5-1**, identifies common types of prior authorizations that may be utilized.<sup>4,5</sup>

Types of Prior Authorization	
Indication	<ul style="list-style-type: none"> <li>• Off-label</li> <li>• One indication vs. another</li> </ul>
Prescriber Coverage for Particular Medication	<ul style="list-style-type: none"> <li>• Specialist vs. Primary Care Physican</li> </ul>
Quantities outside FDA-Approval	<ul style="list-style-type: none"> <li>• Duration of therapy</li> <li>• Days supply</li> <li>• Maximum daily dose limits</li> </ul>
Non-step Therapy	<ul style="list-style-type: none"> <li>• Utilizing second-line, more complex, and/or more expensive options/alternatives before first line options</li> </ul>
Medications outside of patient's health insurance plan's formulary	
High misuse or abuse potential medications	

**Figure 5-1.** Types of prior authorizations

In another example, a patient presents a prescription to their community pharmacist for a migraine medication, which they have been prescribed to take four times daily. However, their insurance company rejects the submitted claim. According to their formulary, the insurance plan will only cover (or pay) for the migraine medication to be taken three times daily. The patient may then choose to have their prescriber submit a PA to their insurance plan. Should the prescriber provide appropriate documentation and/or explanation that proves taking the migraine medication four times daily is medically necessary, the insurance plan may issue a PA for coverage of medication costs.

## EXCEPTION AND APPEALS PROCESS

Prior authorizations may also be referred to as exceptions. Insurance plans can evaluate coverage based on individual patient cases to determine whether or not coverage exceptions will be made.<sup>4</sup> Patients may also request an exception when an insurance plan executes a change to their formulary and their medication is no longer covered.<sup>16</sup>

Insurance plans differ on the amount of time it takes them to review an exception. Some plans, such as Medicare Part D, offer expedited requests based on prescriber recommendations for the patient's overall health.<sup>5</sup> In the event that coverage exceptions or PAs are denied, patients may complete an appeal to request further evaluation or re-evaluation of their original exception.<sup>5</sup> Because certain exceptions must be initiated by the

payer, completed by the prescriber, and reviewed by the payer, the response time can vary. If possible, pharmacists can assist patients by suggesting an alternative medication to avoid this lengthy process.

## HOW TO READ AN INSURANCE CARD

Although insurance cards may look different, they often contain similar information needed to complete claim submissions for payment. In order to submit a claim to an insurance plan, a patient's member identification, BIN, Group, and PCN number are necessary. Should a member's coverage be expired or not active until a later date, submitted claims will not be reviewed for coverage. Help phone numbers are typically found on the back of an insurance card and may be utilized for various issues, such as when insurance card components are missing or claims are rejected. **Figure 5-2** defines common components of an insurance card, whereas **Figures 5-3** and **5-4** are examples of what an insurance card may look like.<sup>6,7</sup>

Components of an Insurance Card	
Member Identification Number	<ul style="list-style-type: none"><li>• Used to identify the individual covered or "holding" the insurance</li><li>• Numbers may be similar for other covered under the original card holder</li></ul>
Group Number	<ul style="list-style-type: none"><li>• Used to track specific benefits of the insurance plan</li><li>• Helps identify the individual covered under the insurance plan</li></ul>
BIN Number	<ul style="list-style-type: none"><li>• Unique six digit number that identifies the third party processor</li><li>• Third party processors may contract with multiple companies, which utilize the same BIN number</li></ul>
PCN Number	<ul style="list-style-type: none"><li>• Help identify different plans via utilization of numbers or letters</li></ul>
Plan Type	<ul style="list-style-type: none"><li>• May have either HMO, PPO, HAS, Open, or other words/labels to describe the type of network the insurance plan maintains</li></ul>
Phone Numbers	<ul style="list-style-type: none"><li>• Help lines, information, questions, etc.</li></ul>
Effective Date	<ul style="list-style-type: none"><li>• Date the coverage became active</li></ul>

**Figure 5-2.** Components of an insurance card

**INSURANCE COMPANY NAME**

Plan type **4**

Effective date

Prescription Group # XXXXX

Prescription Copay **7**  
\$15.00 Generic  
\$20.00 Name brand

Member Name: Jane Doe **1**

Member Number: XXX-XX-XXX **2**

Group Number: XXXXX-XXX **3**

PCP Copay \$15.00  
Specialist Copay \$25.00  
Emergency Room Copay \$75.00 **5**

Member Service: 800-XXX-XXXX **6**

**Figure 5-3.** Sample insurance card<sup>6</sup>

**ABC INSURANCE**  
PARTNERS

PPO

1) Policy Number  
356M59557

2) Group Number  
1234567

Group Name  
XYZ COMPANY

Member Name  
SUSAN J. SAMPLE

3) Office Visit Copay: \$15  
Specialist: \$15  
Emergency Room: \$150  
Urgent Care: \$50  
Rx: \$10/20/40

4) Network Coinsurance:

5) In 90%/10%  
Out 80%/20%

6) Med/Rx Deductible Applies

1. Policy number  
2. Group number  
3. Copay amounts  
4. Coinsurance amounts  
5. In network  
6. Out of network

**Figure 5-4.** Sample insurance card<sup>7</sup>

## SUBMITTING CLAIMS

Pharmacy claims are most often transmitted at the point of sale. Usually, when a patient brings a prescription to the pharmacy, a pharmacist, technician, or intern will either access their insurance information stored within their pharmacy computer (entered from prior

transactions) or enter/update their insurance card information. The pharmacy's computer system will transmit the patient's claim electronically to the insurance company or pharmacy benefit manager. This digital information will be processed electronically and information will be sent back to the pharmacy to determine whether or not the patient is currently enrolled under the entered insurance plan, if the prescription is covered under the plan, what amount the patient owes for the prescription, and what amount of reimbursement the pharmacy can expect to receive for the prescription. Although the information can be viewed within the pharmacy's computer system, the amount owed by the patient and saved by the insurance is typically printed along with the patient prescription label, which are packaged with the medication and distributed to the patient.

If a prescription is not covered, the pharmacy staff can communicate with the patient and prescriber to help determine what steps should be taken. Patients may decide to pay cash or a discount price (using eligible discount cards or coupons), but most often patients will choose to work with the physician and/or pharmacist to determine alternative therapies which may be covered through the insurance or available at cheaper costs for the patient. If a prior authorization process is required, the pharmacy staff will communicate that to the prescriber's office and/or staff electronically. At this point, the prescriber will need to complete the prior authorization process with the patient's insurance company before the pharmacy can re-submit a claim. Most prior authorizations are completed within 72 hours.

## **LOWER COST SUPPORT/ASSISTANCE**

Inability to afford medications is a major cause of non-adherence.<sup>8</sup> Uninsured patients lacking prescription and/or health insurance entirely and in need of assistance paying for their medications have several options. Many pharmacies offer free or discounted prescriptions for products such as vitamins, antidiabetic agents, antihypertensive medications, and antibiotics. Underserved medical clinics may also provide limited medications at no cost.

Patient assistance programs are available for certain medications. Individuals who qualify can receive free or discounted medications for a particular period of time. Websites such as NeedyMeds.org, RxAssist.org, and PPARX.org can be used to determine if an assistance program is available for a given medication and what that programs' eligibility criteria might be. Patients who qualify may even apply for a program using these websites.

Patients can also lower costs with discount cards. Although most discount cards have similar formatting and claims information, discount cards are not insurance cards. Offered by a

number of companies, discount cards offer savings on a variety of medications. Unfortunately, most discount cards cannot be combined with insurance coverage. Discount cards may hold the most utility for consumers when a particular medication is not covered by their insurance. In this situation, a discount card may be used in place of the insurance card. Most online medication coupons work the same way as a discount card and hold the same limitations, but resemble a regular merchandise coupon. Medication coupons are often specific to one medication, whereas discount cards can be applied to a variety of medications. Advertising claims for discount cards and medication coupons can be misleading, as most consumers do not understand the implications regarding their use.

Manufacturer assistance cards, also known as co-pay assistance cards, can be found on manufacturer websites. Unlike discount cards or coupons, most manufacturer assistance cards can be used with an individual's health insurance coverage. Although benefits vary between medication manufacturers, most manufacturer assistance cards offer a one time or twelve-month savings program. However, manufacturers will often set a maximum annual savings limit and most manufacturer assistance cards must be pre-ordered or downloaded, printed, and brought into community pharmacies by the patient. This may create some barriers for individuals lacking access to online resources. Unfortunately, most pharmacies do not have access to manufacturer assistance cards, but some physicians' offices may provide them or are willing to help patients locate them.

Uninsured patients are not the only patients who may need assistance. Underinsured patients, who have minimal health and/or prescription insurance coverage, also may have just as much difficulty affording medications.<sup>9,10</sup> There are various resources available for such patients. Families with children can go to [InsureKidsNow.org](http://InsureKidsNow.org) to check if their child is eligible for Children's Health Insurance Program (CHIP).<sup>11</sup> CHIP is jointly funded by the state and federal government and provides health and prescription coverage to low-income children and, in some states, pregnant women who do not qualify for Medicaid.<sup>11</sup>

Patients with Medicare Part D may qualify for low-income subsidy or "Extra Help" and can apply online at [Socialsecurity.gov/extrahelp](http://Socialsecurity.gov/extrahelp).<sup>17</sup> Both full and partial help is available through the federal government, but states often offer additional programs as well. State based programs are usually referred to as State Pharmaceutical Assistance Programs (SPAPs).<sup>5,9,10</sup> Finally, patients can also be referred to a local State Health Insurance Assistance Program (SHIP) office when they are in need of advice about prescription and/or health insurance or extra assistance.

## **CONCLUSION**

In order to compare medical and prescription insurance coverage it is helpful to first consider the type of coverage that are available options and then the payer-provider relationship. Ultimately, understanding the details of the coverage can allow beneficiaries to select the best coverage for them. Pharmacists can help patients and caregivers compare prescription drug coverage and educate them about the different insurance terms.

# GLOSSARY

## Benefits

Items, services, or payments covered in full or part by the insurance company for the beneficiary

## Co-insurance

A percentage fee paid by an individual for health care services

## Co-payment/Co-pay

Flat fees that must be paid by an individual for particular services, like a visit to a primary care physician

## Deductibles

A set amount that one must pay each year before the insurance company will begin to pay on healthcare costs for an individual

## Formulary

List of particular medications available for coverage by insurance companies that have been demonstrated as safe, effective, and providing the highest cost-benefits for patients

## Health Literacy

The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions

## Member

Individual enrolled under a particular health insurance plan

## Network

Group of healthcare providers who provide services that are eligible for coverage under an insurance plan

## Out-of-Pocket Limits/Maximum

Maximum amounts a patient, also known as a beneficiary, has to pay out of their own pocket for covered health care expenses



## **Pharmacoeconomic**

A branch of economics that compares pharmaceutical products and treatment strategies through analysis of cost-benefit, cost-effectiveness, cost-of-illness, cost-minimization, and cost-utility

## **Premium**

What one must pay in order to have insurance coverage

## **Prior Authorization**

Insurance requirement that physicians provide explanation and/or documentations to support the use of a specific medication therapy in order to determine medical necessity and appropriate therapy

## **Step Therapy**

A treatment approach that utilizes the most cost-effective medication therapy and then progresses to alternative therapies, which may be more expensive or lack comprehensive research evaluating efficacy, to better control costs for insurance providers

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# CHAPTER 6

## PHARMACY AND THERAPEUTICS COMMITTEE

Author: Joe Jordan, PharmD, BCPS

**Chapter 5** discusses access issues for patients including affordability and limits on access such as prior authorization. This chapter explains how and why access to different medications may be restricted on a formulary developed by a Pharmacy and Therapeutics Committee.

While drug formularies have reportedly existed in the United States for over 200 years, their roles and purposes have changed, reflecting the increased complexity of the medications themselves, the healthcare systems within practice settings, and the roles and responsibilities of stewards of these lists.<sup>1</sup> A common name given to a group responsible for oversight of a formulary is the Pharmacy and Therapeutics (P&T) committee. As the name implies, this committee involves pharmacists and those involved in the therapeutic application of these products. A typical committee is comprised of those who prescribe drugs (e.g. physicians), those who purchase and prepare drugs (e.g. pharmacists) and those who administer drugs (e.g. nurses), in addition to other personnel depending on setting (e.g. finance or risk management). Membership will vary based on practice setting but is usually representative of the primary medical services provided within that health care system. In addition to determining formulary selection criteria, P&T committees also oversee how products are purchased, stored, ordered, prepared/dispensed, administered, and monitored. Any policies or protocols addressing medication use, such as adverse drug event monitoring and reporting and approval of guidelines or care pathways, also fall under the P&T committee oversight. In the outpatient setting, prescription drug plans have their own P&T committees that use specific formulary management tools, such as prior authorization, step therapy, and copayment tiers.<sup>2-3</sup>

A formulary, by definition, is a “continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health”.<sup>2</sup> The term medication has been interpreted broadly in some settings to include all products delivered in the context of care for diagnosis, prevention, and treatment. Given this definition, agents such as alternative remedies (herbals and supplements), nonprescription products, blood derivatives, and contrast media would also be included in some settings.<sup>3</sup> While formularies

previously operated more as inventory control, now they are intended to function as systems to insure that drug products are used in a rational, safe, and cost-effective manner to support affordable and sustainable drug benefits.<sup>4,5</sup> These systems are used in hospitals, home care, and long-term care settings, in addition to payer settings such as Medicare, Medicaid, insurance companies, and managed care organizations.

## DRUG FORMULARY EVALUATION

In order for a formulary to have the best available medications available for use, it must be confident in the process of review of the medications.<sup>6-7</sup> The first step for inclusion of a given drug on a drug formulary is through evaluation of evidence. Common elements of a drug review note the FDA approved indications and potential areas of off-label use, a review of the differences with similar agents on formulary with respect to pharmacokinetics and pharmacodynamics, a critique of individual trials used to support a therapeutic benefit, analysis of potential for harm incorporating both drug and formulation characteristics, and ultimately cost.<sup>3</sup> **Table 5-1** expands on common elements within a new drug review. A P&T committee could simply decide to add or not add to a formulary, but more commonly will offer recommendations for additional criteria, such as strategies for ensuring appropriate use.

Questions to consider when determining whether to add drugs to a formulary should be based on quality of evidence and comparisons to therapeutic alternatives. One model cited in the literature is the Formulary Leveraged Improved Prescribing (FLIP) Project.<sup>7</sup> In this model, five areas are addressed when reviewing a drug.

Evidence of Need – Is this Drug Truly Needed? <sup>5</sup>

Depending on your setting of practice and the prevalence of conditions commonly treated by your practitioners, some indications of drugs may not be relevant. For example, glucarpidase, an antidote to methotrexate toxicity, is probably not needed in a community hospital that mostly sees patients in need of orthopedic and cardiovascular procedures. However, tranexamic acid, an agent used off-label to reduce postoperative blood loss, may be of interest to this setting. It is always worthwhile to reflect on what is available on your formulary and to describe the shortcomings of existing therapy with respect to safety, tolerability, or effectiveness. Framing your search based on shortcomings of existing therapy will help with discerning value, if any, of the drug you are considering.

Efficacy – What is the Evidence to Support Claims for Drug? <sup>5</sup>

This is where being able to read, appraise, and apply clinical studies becomes particularly

important. Depending on sources of information, claims of efficacy will be considered differently if coming from high- or low-quality studies or those with high versus marginal differences. For example, a single-center, uncontrolled trial showing improvement in pain scores and decreased hospital length of stay is less generalizable than a multi-center, randomized, active-controlled trial demonstrating these same endpoints. Similar to the question of evidence of need, individual evidence should be assessed for relevance to the population you treat. There may be potential for off-label use of a product and it is important to note what evidence, if any, is available to support this since it may factor into decisions to restrict or regulate use.

#### Safety – What are the Safety Issues that Should be Weighed? <sup>5</sup>

In addition to the safety information present in the labeling of a drug (e.g. contraindications, warnings, adverse effects), the potential for medication errors once it becomes available on formulary should be taken into consideration. The potential for look-alike/sound-alike errors or complicated administration or preparation requirements are a few examples of potential safety concerns beyond the package insert. As drugs are studied in relatively small sample sizes in relation to the size of the population they will be used, it is worth noting any safety signals or areas under review that may become more apparent once a drug is used in a larger population. Lastly, it is worth comparing the safety composite of the drug under review with existing therapeutic options on formulary.

#### Misuse Impact Potential – What is the Potential for Misuse or Overuse? <sup>5</sup>

This question begins to address the issues of pharmaceutical advertisements and detailing. If a drug is heavily marketed to consumers or prescribers, there may be unrealistic expectations leading to demand for use in areas where the product may or may not be needed. Off-label use of drugs is very common and this is an area that a P&T committee should periodically review to ensure that products are being used optimally based on evidence of safety and effectiveness rather than on unrealistic expectations.

#### Cost Issues – Is the Drug Worth the Costs?

A common theme that arises with approval of new drugs is that while they must demonstrate that they can have an effect in a carefully controlled trial setting, these effects may or may not be seen in the uncontrolled real world when they are used in general practice. While a cost may be appropriate based on perceived utility in a controlled study, these costs may be considered excessive if a drug fails to demonstrate effect in a variety of patients in the general population with a given disease. Additional cost factors to consider include preparation and

storage costs, monitoring costs, and labor costs with administering product.

After preparing a review, the information gathered is commonly shared among other healthcare professionals who would be impacted because they prescribe or would administer the product. From a cost standpoint, it is not unusual to have a financial party assess the relative cost-benefit of the potential impact on use of resources outside of pharmacy. Decisions about a drug are often driven based on the final composite analysis of benefit, risk, and cost in relation to agents on formulary. If it provides an improvement in benefit, risk, or cost and the other variables are not impacted (or improved) then a drug will likely be added to formulary. Similarly, if it worsens benefit, risk, or cost and other variables are not impacted (or worsen), then a drug likely won't be added to formulary. However, it is rare that final analyses are this clean and there is usually some trade-off amongst these variables. When drugs are added to formulary with potential increased risk of safety and/or cost, it is not uncommon to have additional criteria to ensure they are used in a safe and cost-effective manner.

## **STRATEGIES FOR MANAGING THE FORMULARY**

Ensuring medications are used in an optimal manner often involves educational, managerial, or regulatory strategies.<sup>3</sup> Multi-disciplinary development of these strategies will increase the likelihood of success instead of creating them from one practitioner's perspective.<sup>3,7-9</sup>

Educational strategies are intended to inform or persuade healthcare practitioners to use a medication in a particular manner. Examples of this approach could be provision of a newsletter, preparation of consultative review documents, or one-on-one clinical supervision or consultation. This approach is often received well by clinicians who don't perceive it as restrictive. A practical application of this could be providing an algorithm of how to treat a patient with blood pressure or high cholesterol. However, this approach is one of the least effective when trying to change behavior or practice. If a medication is not being used optimally from a benefit versus risk or cost standpoint, this approach will likely not result in changes in how that medication is used. For example, if a given clinician is adamant about using a PCSK9 inhibitor (~\$14,000 per year) first line in their hyperlipidemia patients, providing an algorithm that has this class used after statin therapy won't force them to change.

Another approach is to use managerial strategies to guide or structure decisions. Guided strategies allow the product to be used, but with hardwire processes so they are used in particular way. Examples of this approach include clinical protocols or order sets, use of

tiered or step-wise approach, procurement selection based on cost, therapeutic interchanges, protocols converting intravenous to oral administration, and patient cost-sharing. Some examples could include converting all ACE inhibitors to lisinopril at an equivalent blood pressure dose (i.e. therapeutic interchange) or using an oral proton pump inhibitor instead of an IV proton pump inhibitor (i.e. IV to PO interchange) when patients can absorb oral therapies. This approach is less well-received by clinicians than educational strategies because it involves barriers or requiring them to “follow the rules” if they wish to use a particular medication or class of medications. The managerial strategy is commonly, but not always, employed because of cost or safety concerns. If multiple medications are available to treat a given condition and differences, if any, are considered marginal, then steering therapy to least costly agents first is an example of a tiered approach. Another simple approach that pharmacy can take is to procure a generic instead of a branded medication. In order to limit formulary options or possibly save on costs, therapeutic interchanges may allow for one medication to be used in place of another either within its therapeutic class or even out of the same class. This is commonly seen in hospital settings and requires approval by a P&T committee.

Lastly, a less-accepted approach, but very effective, is to introduce restrictions or limitations. Examples of this regulatory approach could include banning certain drugs from an institution, requiring prior authorization before use of medications, or restricting use of medications to a certain provider. Limiting providers from writing for more than five continuous days of ketorolac therapy or restricting daily doses of acetaminophen to <3 or 4 grams is an effective way to ensure safe use of these medications. Restricting use of an antimicrobial to an infectious disease physician or requiring that certain criteria be met before certain medications can be used (i.e. prior authorization) are often disliked by clinicians but can help ensure appropriate use.

## **SUMMARY**

A P&T committee is a multidisciplinary group of professionals within an organization that oversee the selection and use of medications. The goal of this committee is to provide a formulary that represents the optimal therapy for patients based on relative efficacy and safety. As medications and healthcare systems become more complex and costly, P&T committees are focusing efforts to ensure medications on formulary are used efficiently by providing strategies for appropriate use.<sup>2,3</sup>

<b>Uses/indications</b>	FDA approved indications, other potential uses based on clinical trials or agents with similar mechanisms of action
<b>Pharmacology</b>	Summary of drug and/or drug class noting similarities or differences within a class or versus other agents with similar indications
<b>Pharmacokinetics</b>	Depth varies depending on disease state. For example, infectious disease drugs may have more coverage in this area than a blood pressure drug. Highlight absorption, distribution, metabolism, elimination (ADME) of drug and note information on specific subsets of patients (e.g. renal & hepatic dysfunction, male vs female, pediatric vs adult vs elderly, bariatric vs normal weight)
<b>Guidelines and/or systematic reviews</b>	Review indications of drug noting prevalence of disease, current approaches to therapy, and areas of need. Note role of current therapy in the disease approaches, if known.
<b>Comparative efficacy</b>	Review clinical trials of drug noting quality of study methods, relevance of populations studied, applicability of outcomes evaluated and magnitude and precision of results. Contrast findings with other therapies available for indication
<b>Comparative safety</b>	Highlight contraindications, warnings/precautions, drug interactions and adverse reactions that a practitioner needs to be aware of to effectively manage a patient on this drug. Note actions that a clinician can take to mitigate risks as well as similarities and differences with other drugs within class or drugs approved for same indication. Contrast findings with other therapies available for indication
<b>Monitoring</b>	Recommended laboratory or other types of monitoring necessary for patients to be effectively and safely managed
<b>Dosing and administration</b>	Recommended dosing regimens both for FDA indicated and potential off-label use. Special populations such as pediatrics, organ impairment (i.e. renal, hepatic), or obesity may have different



	dosing strategies available from the literature. Compatibility information for parenteral products and splitting or compounding information for oral products would go here.
<b>Availability</b>	How product is supplied noting specialty distribution programs, when applicable. Some products are not orderable through normal supply chains and are shipped directly to patients.
<b>Pharmaco-economic analysis</b>	In addition to the acquisition cost of drug, presenting cost as a function of per unit dose, per day, or per duration of therapy in relation to other therapies. If available, note potential economic impact on other areas such as consumption of additional labs/supplies or ED/hospital visits.
<b>Potential misuse impact</b>	If approved, is there significant education required to ensure product is used optimally (i.e. safely and efficaciously). Are there medication errors associated with this drug or this class and can policies or procedures be put into place to mitigate these. Is product likely to be used in off-label areas

**Table 5-1.** Common elements of drug monograph

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# CHAPTER 7

## BILLING AND REIMBURSEMENT FOR THE AMBULATORY CARE PHARMACIST

Author: Jessica Wilhoite, PharmD, BCACP

**Chapter 6** discusses the variety of contractual arrangements that managed care companies make with healthcare providers such as networks, capitation fees, and salaried payment. That chapter also introduced the concept of coordinated providers under Accountable Care Organizations (ACOs). Medical insurers contract with physicians and hospitals through networks, capitation and bundled payment models of reimbursement. This section will outline how pharmacists are impacted by these payment arrangements.

Pharmacists are usually paid as hourly or salaried employees of the pharmacy chain or independent pharmacy that employs them. It is almost always the pharmacy, hospital, or clinic, not the pharmacist, who negotiates with third party payers such as private insurers and pharmacy benefit managers. In the retail/community setting, claims are transmitted electronically when the patient fills a prescription and payment for each prescription is calculated at the point of sale. The pharmacist is removed from the contractual process but the bottom line is impacted by each prescription rejection.

In the hospital setting, the charges for all services are added together for the patient's stay. This list is often referred to as the charge master, which is then billed to the insurance company or government payer based on the contractual arrangement between that hospital and payer. This is usually done after the patient is discharged, although a pre-authorization may be requested to verify the patient has coverage and payment is likely. As discussed in **Chapter 6**, the charges may be fee-for-service or may be submitted each day as a daily total (per diem) or one total for the whole hospital stay (per episode).<sup>1</sup>

Hospitals and physician practices may be owned by the payer, as with a Health Maintenance Organization (HMO). The healthcare providers in the physician practice, including the ambulatory care pharmacist, are likely paid salary by the payer itself. In this case, a global budget is created for hospital and administrators who are responsible for charging against a budget and for appropriate use of funds.<sup>1</sup> Hospital administrators who are unable to manage budgets appropriately will likely lose their jobs. With the movement towards accountable care and value-based payments, new contractual arrangements linking patient outcomes and

quality measures to payment are changing reimbursement structures.

Ambulatory care pharmacy practice is one of the fastest evolving pharmacy sectors as the profession is continuously changing to include delivery of comprehensive clinical, consultative, and educational patient care services.<sup>2</sup> Challenges in providing such services still remain; pharmacists lack provider status, as they are not recognized under Title XVIII of the Social Security Act, resulting in reimbursement ineligibility under Medicare Part B.<sup>3</sup> One way health care professionals generate income is through billing for their services. Because pharmacists are not recognized as providers by many payers, including Medicare Part B, billing for clinical pharmacy services in the outpatient setting can be complex. Billing is the process of documenting services rendered to patients, and sending a bill for the eligible service to the third party payer for reimbursement. Services are separated into numerical codes, which correlate to the varying complexity of the services. Providers report these numerical codes to third-party payers in order to receive reimbursement for their services.

Reimbursement is a dollar amount which is returned to the organization for properly performing, documenting, and billing for services. Reimbursement amounts for the same services can differ between payers. This means that a health care provider can be paid different amounts for performing the same service, depending on the third party payer. Medicare reevaluates and recalculates reimbursement amounts for outpatient services annually and makes that data publicly available. In general, Medicaid reimburses about half that of Medicare and private payers reimburse 20% more.<sup>4</sup> Billing also includes cost-sharing, which represents the patient's copay. The next section will focus on both direct and indirect billing methods utilized to receive reimbursement for ambulatory care pharmacy clinical services.

## PROVIDER STATUS

Provider status is granted to healthcare providers who provide patient assessments, bill for their services, and receive reimbursement. The diversity of healthcare professionals included in a provider network can vary between private third party payers and the Centers for Medicare and Medicaid Services (CMS). Third party payers define a provider network to ensure quality healthcare is delivered to patients by qualified health care professionals. A summary of third party payer types, and pharmacist billing opportunities for each type can be found in [Table 7-1](#).

### Medicare

Title XVIII of the social security act recognizes health care providers eligible to receive

reimbursement from Medicare Part B. Such providers are listed in **Figure 7-1**. As mentioned previously, pharmacists are not recognized as providers under Title XVIII; therefore, lack ability to receive reimbursement for their services in the outpatient setting.<sup>3</sup>

Physician Assistants	Nurse Practitioners	Clinical Nurse Specialists	Certified Nurse Midwives
Clinical Psychologists	Clinical Social Workers	Physical Therapists	Occupational Therapists

**Figure 7-1.** Non-physician providers eligible for reimbursement from Medicare Part B

Additionally, Medicare Part D, which provides prescription benefits, gives variable options for patients to choose a prescription drug benefit plan to best suit their needs. Regardless of which plan is chosen, it is required that all plans offer medication therapy management (MTM) services to their beneficiaries. MTM services can be provided by pharmacists or other qualified providers and is reimbursable by Medicare Part D when the service is provided in the community pharmacy setting.<sup>2</sup>

### State Programs

Individual states have the ability to enact legislation to allow pharmacists to bill for services and receive reimbursement. A state legislature can trump the federal social security act and allow pharmacists to have provider status in that state. In May 2015, Washington became the first state to sign legislation requiring pharmacists be included in health insurance provider networks.<sup>5</sup> At the time of this writing, 38 states designate pharmacists as providers in at least one statute or Medicare provision.<sup>6</sup>

### Private Third-Party Payers

Generally, most private third-party payers follow CMS rules and regulations; however, pharmacists have worked directly with commercial third-party payers to create contracts for

payment of their services. There is no obligation for a commercial payer to recognize pharmacists as providers and it is up to their discretion whether they include or exclude pharmacists from their provider network.

Self-insured employers are another third-party payer in which pharmacists may directly bill. Self-insured employers are businesses where the employer pays out-of-pocket for their employee's healthcare expenses, handling all paperwork and payment for health claims. Self-insured employers have the ability to recognize pharmacists as providers; however, like private third-party payers there is no obligation to include or exclude pharmacists within their provider network.

### Self-Pay Patients

Cash paying patients always reserve the right to pay cash for services. Pharmacists may bill dependent on the market demand of patients willing to pay pharmacists cash for their services.

Payer Types	Can a pharmacist bill directly?
Medicaid / State Programs	Only if an individual state passes legislature.
Medicare	Part B – No. Pharmacists are not recognized as providers.
	Part D - Yes, Medication therapy management is a required element can be provided by pharmacists or other qualified providers.
Commercial Third Party Payers	Only if the commercial payer includes pharmacists in their network
Self-Insured Employers	Only if the Self-Insured Employer includes the pharmacists in their network
Cash Paying Patients	Yes, if the patient is willing to pay

**Table 7-1.** Payer types<sup>24</sup>

## BILLING FOR CLINICAL PHARMACY SERVICES IN AN AMBULATORY SETTING

If a healthcare professional is not included in the provider network of a third-party payer, they will receive no reimbursement for their services from that payer; however, there are ways in which they can generate revenue by indirectly billing for services. Each health care professional carries their own unique National Provider Identifier (NPI) number. An NPI number identifies specific healthcare professionals or healthcare entities (e.g. hospitals, nursing homes, etc.) on HIPAA standard transactions such as bills.<sup>7</sup> Although pharmacists are not eligible to bill Medicare Part B under their own NPI number, they can collaborate with a physician or other recognized provider to bill indirectly under the collaborating provider's NPI number. To bill under another healthcare professional's NPI number using any of the billing methods outlined below, a collaborative practice agreement is often written and signed by all parties. A collaborative practice agreement is a signed document granting authority to a pharmacist (or other healthcare professional) to bill for services under a supervising practitioner's NPI number.<sup>3</sup> A collaborative practice agreement includes specific practice protocols which the pharmacist must follow.

### "Incident To" Billing Methods for Pharmacists

Indirect or "incident to" billing is the framework under which a non-physician practitioner may bill under a supervising physician's NPI number, given certain criteria are met. CMS defines "incident to" as those services that are furnished "incident to" physician professional services in the physician's office, separate office suite, in an institution, or a patient's home.<sup>8</sup> In the outpatient setting, health care professionals utilize Current Procedural Terminology (CPT) codes to identify services rendered and International Classification of Diseases-10 (ICD-10) codes to detail the indication for those services. The indirect billing method is utilized by ambulatory care pharmacists and other mid-level practitioners who work in conjunction with a physician to see patients and bill for services. There are several conditions which CMS requires in order for a non-physician provider (NPP) to be eligible to bill for services "incident to" ([Table 7-2](#)).<sup>8</sup>

<b>Establish with Physician</b>	<p>Physician or Medicare Part B-approved provider must perform an evaluation or service for the same problem that is being evaluated by the pharmacist's service</p> <p>Physician must establish a plan of care which includes future incidental services.</p>
<b>Active Involvement</b>	Physician or Medicare Part B-approved provider must be actively involved in the patient's course of treatment and provide subsequent services at a frequency that reflects their active involvement
<b>Common Services</b>	Services rendered must be of a type that are commonly furnished in the physician's office or clinic.
<b>Services Order</b>	The physician or Medicare Part B-approved provider must have provided authorization for the service and authorization must be documented in the medical record.
<b>Employee Relationship</b>	The pharmacist providing the service must be an employee, leased, or contracted to the physician or Medicare Part B-approved provider.
<b>Scope Of Practice</b>	All services rendered must be within the scope of practice for that specific healthcare professional and medically appropriate to be given in the provider's office.
<b>Direct Supervision</b>	<p>A physician or Medicare Part B-approved provider must be on the premises, but not necessarily in the same room, when services are being performed.</p> <p>Direct Physician Supervision also requires the physician must be clinically appropriate to supervise any situation or emergency that may arise.</p>

**Table 7-2.** "Incident to" rules<sup>2</sup>

"Incident to" Billing in an Institutional Ambulatory Setting

Hospital based "incident to" billing refers to physician outpatient clinics that are financially



tied to a hospital. To determine if a physician clinic is financially tied to a hospital, check to see if they have similar tax identification numbers or ask the billing department for that clinic or hospital. When a patient is seen by a Medicare Part B recognized provider, they may bill two fees: a professional fee for the services they perform and a facility fee for the hospital to cover facility expenses. Because pharmacists are not recognized providers under Medicare Part B, pharmacists can only bill via a facility fee and cannot bill a professional fee. The disadvantage of facility fee billing is the extra financial burden on the patient. For example, if a patient sees the physician and pharmacist in the same day, they will receive two bills: a bill for the professional fee for the physician and their facility bill, and a separate facility fee bill that includes the services provided by the pharmacist.<sup>2</sup>

#### "Incident to" Billing in a Non-Institutional Ambulatory Setting

Physician clinic based "incident to" billing refers to a physician outpatient clinic that is not financially tied to a hospital. The physician, or physician group, owns the entity in its entirety and the clinic practices under their own business tax identification number. Unlike hospital based "incident to" physician billing which can bill a facility fee, physician based clinics cannot bill a facility fee and only have the option to bill professional fees. Again, because pharmacists are not recognized providers under Medicare Part B, they must indirectly bill "incident to" physician for their professional fees. The same CMS "incident to" rules apply (**Table 7-2**). When billing "incident to" in physician based clinics, pharmacists may be reimbursed at 100% of the physician rate, or 85% of the physician rate if a non-physician provider (NPP) is serving as the supervising provider.<sup>9</sup>

#### Billing Levels

Billing for services in both hospital and physician based clinics are executed via five CPT codes 99211-99215. CPT code 99211, or level 1 billing, is the lowest level of billing and yields the lowest reimbursement. CPT code 99215, or level 5 billing, is the highest level of billing and yields the highest reimbursement amount. When billing at the lowest level, 99211, there are no documentation requirements; however, when documenting a patient visit to support a higher level of billing, there are three main areas required: number of body systems reviewed, number of disease states assessed, and the level of complexity of decision making.<sup>10</sup> The level of billing is then determined by the complexity of the visit based on the components included in the note documentation (**Table 7-3**). For most regional carriers of CMS, pharmacists are limited to the lowest billing level, 99211, when billing "incident to" because they are not recognized Medicare Part B providers.<sup>2</sup> For non-Medicare "incident to" billing, state Medicaid programs and commercial third party payers may allow pharmacists to bill at

higher levels as long as documentation supports the higher level of billing.<sup>2</sup>

<b>Patient History</b>	Patient history is comprised of several components such as family history, social history, history of present illness, chief complaint, and review of systems. Review of systems analyzes each organ system (genitourinary, respiratory, etc) pertinent to the patient's chief complaint. The more systems reviewed, the more complex the visit and the higher the billing level able to be billed.
<b>Physical Exam</b>	The physical exam is a required component of the visit. Physical exam can range from a multi-system physical exam, to a single-organ exam. CPT code 99211 may be billed without a physical exam. The more elements involved in the physical exam, the higher the billing level able to be billed.
<b>Medical Decision Making</b>	Medical decision making complexity is based on the three main components of the number of diagnostic options, amount of complexity, and the risk of decision making. A points system is utilized to categorize the level of medical decision making and the appropriate corresponding billing level.

**Table 7-3.** Billing components<sup>2</sup>

## MEDICATION THERAPY MANAGEMENT

Medication Therapy Management (MTM) is a medical service provided to optimize drug therapy and improve therapeutic outcomes. Medication therapy management services are patient-centered services, rather than product-centered services.<sup>11</sup> In 2003, The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) created Medicare Part D but also required insurers to cover MTM services for their beneficiaries.<sup>12</sup> The MMA identifies three MTM parts: education to improve patient's medication understanding, programs to increase medication adherence, and detection and prevention of adverse drug reactions.<sup>13</sup> MMA does not require that MTM services be provided by a pharmacist, but as drug experts, pharmacists can play a vital role in improving patient's health care quality and reducing exacerbations.<sup>13</sup> MTM services can be billed via CPT codes which are chosen based on the visit length of time (**Table 7-4**). These CPT codes are not recognized by Medicare Part B, because MTM is not a covered service under Part B, only Part D; therefore, these CPT codes cannot be utilized in the physician clinic setting as Medicare Part B is the entity that covers

services provided in the physician office (hospital-based or physician-based). These CPT codes; however, can be utilized via contracts with prescription drug benefits plans under Part D in a licensed dispensing pharmacy setting. MTM services can still be provided by a pharmacist or other practitioner in the institutional or non-institutional outpatient settings; however, billing codes utilized are those that are covered by Medicare Part B and pharmacist billing methods are similar to other pharmacy services in these settings, as outlined previously.

<b>CPT Code 99605</b>	Billed for a new patient visit for the initial 15 minutes of face-to-face MTM.
<b>CPT Code 99606</b>	Billed for an established patient for the initial 15 minutes of face-to-face MTM.
<b>CPT Code 99607</b>	Billed for each additional 15 minutes of MTM. This code can only be used after billing either 99605, or 99606.

**Table 7-4.** MTM CPT Codes<sup>25</sup>

## TRANSITIONAL CARE MANAGEMENT

Transitional care management (TCM) refers to services offered during a period where a patient is transitioning from an inpatient to an outpatient setting. This transition represents a vulnerable time for the patient who is now required to manage changes in diagnosis, medications, and/or lifestyle habits.<sup>14</sup> These rapid and sometimes drastic changes can increase the patient's risk of exacerbation and hospital readmission if not properly managed.<sup>14</sup> The Centers for Medicare and Medicaid puts a strong emphasis on quality of healthcare, and in October 2012 introduced the Hospital Readmissions Reduction Program. Through this program hospital reimbursement rates are reduced if patients are readmitted to the hospital within 30 days.<sup>15</sup> In addition, effective January 1, 2013, Medicare created a new method for reimbursement of transition-related activities. These CPT codes for TCM services may be used to bill physician and qualified non-physician providers care management following patient discharge. Qualified non-physician providers who may provide TCM services include: certified nurse-midwives, clinical nurse specialists, nurse practitioners, and physician assistants.<sup>14</sup> TCM appointments aim to reduce hospital

readmissions by minimizing patient risk of new or changed medication regimens and ensuring proper education of lifestyle habits and self-management of chronic disease. The TCM CPT codes provide higher rates of reimbursement and combine face-to-face and non-face-to-face TCM components into one billing code (**Table 7-5**). The required components for TCM billing are outlined in **Table 7-6**. Additional components, not required, may include: caregiver education, managing medications, obtaining and reviewing discharge information, reviewing pending diagnostic tests and treatments, communicating with other health care providers, establishing referrals, arranging community resources, and assisting with follow up with other providers or services.<sup>16-18</sup>

Visit Type	Timing (Calendar days)	CPT Code	Complexity	Claim Deadline
TCM	Within 7 days of discharge	99496	High	30 days from discharge
TCM	Within 14 days of discharge	99495	Moderate	30 days from discharge

**Table 7-5.** Billing Codes for Transitional Care Management (TCM) Billing<sup>16-18</sup>

<b>Interactive Contact</b>	Interactive contact must be made with the patient via e-mail, telephone call or face-to-face appointment within 2 days of the date of care transition.
<b>Non-Face-To-Face Services</b>	<p>The practitioner must provide non-face-to-face services to the beneficiary. These services may be conducted by licensed clinical staff under the physician or NPP's direction.</p> <p>If the physician or NPP determines that non-face-to-face services are not indicated, then they are not a required element.</p>
<b>Face-To-Face Visit</b>	<p>A moderately complex patient must have a face-to-face visit within 14 days of the date of transition of care.</p> <p>A highly complex patient must have a face-to-face visit within 7 days of the date of transition of care.</p> <p>Medication reconciliation and management must be furnished before or on the date of the face-to-face visit.</p>

**Table 7-6.** Required components for transitional care management billing<sup>19</sup>

While pharmacists are not included in the list of qualified non-physician providers able to bill for TCM services, these codes present an opportunity for pharmacist's services to be reimbursed as a part of a multidisciplinary team. The billing claim itself must be submitted under a Medicare recognized provider and can only be billed once per beneficiary during the TCM period (30 days post-discharge); however, the high reimbursement rates reflect the need for involvement of multiple providers. As medication experts, the required medication reconciliation component offers pharmacists a unique niche to become a more incorporated part of the TCM team.

## **ANNUAL WELLNESS VISITS**

Annual Wellness Visits (AWV) aim to provide a personalized prevention plan to reduce patient risk of morbidity or mortality. The components of a Medicare AWV include: a health risk assessment, establishing current providers, family history, past medical history, risk factors for depression or other mood disorders, and functional ability.<sup>19</sup> AWVs also include a general checkup of height, weight, body mass index, blood pressure and any other

measurements deemed necessary based on the medical diagnoses the patient has received.<sup>19</sup> The health risk assessment component of an AWW addresses demographic data, self-assessment of health status, psychosocial risks, behavioral risks, activities of daily living (dressing, bathing, and walking etc.), and instrumental activities of daily living (shopping, housekeeping, and managing finances etc.) at a minimum.<sup>19</sup> Unlike TCM services, Medicare Part B will reimburse for AWWs performed by a pharmacist. Additional providers recognized by Medicare to provide AWW include: physicians, qualified non-physician practitioners (physician assistant, nurse practitioner, or certified clinical nurse specialist), or medical professionals (health educators, registered dietitians, nutrition professionals, or other licensed practitioner) under the direct supervision of a physician. Pharmacists fall under the category of other licensed practitioner; therefore, require direct supervision (as defined in “incident to” rules) by a physician.<sup>19</sup>

Billing for Medicare AWWs can be multifaceted, because there are time frames and requirements to consider when billing. Optimally, AWW would be conducted on an annual basis for each patient. The initial AWW is billed with one code (G0438) and subsequent AWWs are billed with a separate code (G0439). An Initial Preventive Physician Examination (IPPE) is a “Welcome to Medicare” physical and can only be performed by a physician or NPP. Medicare will cover the initial AWW if it is 1) at least 12 months following an IPPE or 2) for beneficiaries who are no longer within 12 months of their Medicare coverage effective date. Subsequent AWWs cannot be billed within 12 months of the initial AWW. Medicare will pay for one initial AWW per lifetime and one subsequent AWW per year thereafter.<sup>19</sup>

CPT Code	Type of Visit
G0402	Initial Preventive Physician Examination (IPPE) or “Welcome to Medicare” physical
G0438	Initial Annual Wellness Visit
G0439	Subsequent Annual Wellness Visit

**Table 7-7.** Medicare annual wellness visit billing codes

## CHRONIC CARE MANAGEMENT

Chronic conditions such as diabetes and heart failure are devastating life-long diseases, and

primary care services help to contribute to better health and quality of life for patients living with chronic disease. Effective January 2015, Medicare began paying for Chronic Care Management (CCM), recognizing the value primary care brings to health care.<sup>20</sup> CCM aims to utilize non-face-to-face interactions to decrease the risk of hospital readmission and prevent exacerbations by educating patients on their conditions, their medications, and providing access to care. Eligible CCM patients must have two or more chronic conditions which place the patient at significant risk of death, acute hospitalization, or functional decline.<sup>21</sup> CCM chronic conditions include, but are not limited to, diabetes, heart failure, Alzheimer's disease, asthma, cancer, COPD, depression, and osteoporosis.<sup>21</sup> CCM has several required elements such as recording patient demographics, a written, patient-centered, care plan to be documented and given to the patient, providing 24/7 access to care, and managed care services.<sup>21</sup> CMS requires the billing practitioner to conduct a comprehensive evaluation & management visit, AWW, or IPPE visit prior to billing for CCM services.<sup>21</sup> Additionally, healthcare providers are required to inform patients of their CCM eligibility and obtain a written consent form before furnishing services.<sup>21</sup> The practitioner must also explain to the patient how to revoke CCM services and that only one practitioner may bill for CCM services per month.<sup>21</sup> A CCM visit provides payment for at least 20 minutes of a health care professionals' time per month of non-face-to-face care.

Billing for CCM is conducted on a per month basis and codes may only be submitted once per month per patient. This prevents multiple physician offices from conducting CCM visits on the same patient in the same month. CCM billing is not eligible to be billed in the same period as TCM services, hospice supervision services, or certain end-stage renal disease services.<sup>17</sup> Pharmacists may provide CCM services and bill "incident to" the billing physician or non-physician practitioner and/or contribute to 20 minute/month time allotment, as long as they comply with all "incident to" physician billing requirements. CMS provided an exception under Medicare's "incident to" rules to allow clinical staff (including pharmacists) to provide services under general supervision of a physician or non-physician provider. Therefore, not requiring the physician to be on the premises providing direct supervision. CCM visits are billed using CPT code 99490. Although patient copayments or coinsurance applies to CCM visits; CCM provides a valuable service which may prevent patient costs for more expensive face-to-face visits in the future.

Transitional care management, annual wellness visits, and chronic care management appointments are three unique services that are only eligible for reimbursement by Medicare Part B, unlike "incident to" services, which may be reimbursed by Medicaid, commercial third party payers, and self-insured employers.

## **DIABETES SELF-MANAGEMENT TRAINING**

Diabetes Self-Management Training (DSMT) is a service provided to patients with a new diabetes diagnosis or patients struggling to control their diabetes. Pharmacists must be a member of a recognized DSMT program by the American Association of Diabetes Educators, the American Diabetes Association, or Indian Health Services division of diabetes treatment and prevention in order to provide DSMT services.<sup>22</sup> Because pharmacists are not a recognized Medicare provider, pharmacists may not bill for DSMT services; however, because pharmacies are a recognized Medicare entity, a pharmacist can bill under the pharmacy if it is a certified DSMT facility.

DSMT services may also be billed in either a physician based or hospital based clinic. In order for a pharmacist to bill for DSMT services the pharmacist must have a written physician's order for DSMT services for the patients involved. During the first initial year, up to 10 hours of DSMT services can be billed per patient in 30 minute increments in either individual or group training.<sup>21</sup> After the first year, up to 2 hours of DSMT services can be billed per patient in 30 minute increments in either individual or group training.<sup>22</sup> Subsequent years begin 12 months after the first DSMT visit. Individual visits are billed under CPT billing code G0108, group visits of 2-20 people are billed under CPT billing code G0109.<sup>22</sup> Individual visits provide a higher reimbursement rate per person than group visits.<sup>22</sup>

## **CLINICAL LABORATORY IMPROVEMENT ASSESSMENTS – WAIVED LABORATORY**

The Clinical Laboratory Improvement Amendments (CLIA) is the way CMS regulates laboratory testing performed on humans.<sup>23</sup> CLIA ensures laboratories are performing tests correctly and providing accurate test results. CLIA covers blood tests such as electrolyte and cholesterol levels, in addition to home drug tests, pregnancy tests, and any other tests requiring bodily fluids. In order for a pharmacy to do point-of-care testing such as diabetes or cholesterol screening, they must apply for a CLIA certificate of waiver. The entity must use application form CMS-116 and pay a \$150.00 application fee. If approved, the entity will receive a CMS Part B Provider Identification Number (PIN). Pharmacists submit claims to CMS by using the entities PIN on the CMS 1500 form and the proper CPT codes. Pharmacists are allowed to bill because the claim is for the laboratory services only, and not for cognitive services. There are numerous CPT billing codes for the variety of CLIA-waived laboratory assessments available. The pharmacy can bill CMS for the tests performed by their pharmacist, and the pharmacy will receive reimbursement.



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# SECTION 3

## QUALITY

The manufacturing and aviation industries have long used quality improvement initiatives to remain competitive and manage public perception.<sup>1</sup> Because cost has been the primary focus of healthcare reform, resources allocated for improvement were focused on medical and medication error reduction. The focus on accountable care and patient-centered care has renewed and expanded the focus on healthcare quality. Outcomes, value, and patient satisfaction are emphasized and impact reimbursement to healthcare providers.

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# CHAPTER 8

## QUALITY MEASURES AND IMPROVEMENT

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Through the movement from fee-for-service to managed care (see **Chapter 6**), payers began to pay for performance rather than for quantity. This included paying for improving health outcomes while containing costs. The movement to accountable care has created a similar initiative called value-based care. New value-based structures mean that healthcare entities must commit to delivery on many quality measures, which determine reimbursement. Therefore, there is a new financial incentive to focus on quality to control costs.

The Institute of Medicine (IOM) defines quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”<sup>1</sup> The 2001 Quality Chasm Report by IOM provided 6 dimensions of quality: Effective, safe, timely, patient-centered, equitable and efficient.<sup>2</sup>

The first three dimensions, effective, safe, and timely, are the traditional items associated with quality healthcare interventions. Effective refers to basing decisions on evidence and scientific knowledge which is discussed in **Chapter 10**. Safe refers to avoiding injury from care that is intended to help patients. Timely focuses on improving access and communication between healthcare providers to reduce delays in treatment.

The other three dimensions, patient-centered, equitable, and efficient, are specific targets of health care reform. Patient centered care refers to services that are respectful and responsive to individual patient preferences, needs and values and allowing those to guide treatment decisions. Equitable care does not vary in quality because of personal characteristics including ethnicity and socioeconomic status. Equitable and patient centered care personalizes care to the patient not to the preference of the provider. Efficient care avoids waste to limit the additional cost and intrusion to patients but also to the system as a whole. Limiting unnecessary use protects funds and availability for other patients who need to access care. The challenge is to use evidence to determine what is necessary and unnecessary.

### QUALITY IMPROVEMENT

Quality improvement (QI) is a formal method of analyzing and correcting errors. Quality

improvement is its own career path where individuals understand the different tools available and how to apply them to their setting. Terminology associated with measuring quality includes quality assurance, quality control and quality assessments. Quality assurance is planning and ensuring compliance with set standards and requirements. It may be thought of as the “office” component to quality reviewing reports, writing policies and procedures and reviews of processes. Quality control is the specific process for measuring products or services against the specific standard. This may include sample testing to look for defects, customer service audits, etc. It may also be thought of as a data collection aspect of quality to identify the current state of quality. Quality assessments are usually the specific standard or increment that is being evaluated. These specific measures may be a stand alone clinical outcome or a tool that collects multiple measures. Organizations that implement quality improvement initiatives may use the term Total Quality Management (TQM) which incorporate all of these items.<sup>3-5</sup>

Agreement on a need to improve quality is easier than actually assessing quality and making improvement, this is especially challenging since patients, providers, administrators and payers may view quality differently.<sup>6,7</sup> Several organizations referred to as quality improvement organizations (QIOs) utilize health quality experts, clinicians, and consumers to work together to establish quality measures and set standards.<sup>7</sup> Some QIOs work directly with the Centers for Medicare and Medicaid Services (CMS). There is also a federal agency that promotes evidence-based quality, the Agency for Healthcare Research and Quality (AHRQ). These organizations develop quality measures, patient perspectives, and detailed outcomes measures. The Pharmacy Quality Alliance develops and recommends specific pharmacy based performance measures. These may be used to impact reimbursement in value based payment models.

As mentioned above, quality tools and process exist to collect quality information within an organization and local, state and federal organizations exist to set standards and specific measures of quality. The results of this effort may be reported and utilized in one of three ways: accreditation purposes, report cards, and consumer ratings.<sup>7</sup>

Accreditation refers to acknowledgement by an authoritative group providing a certification of competency or credibility to an individual, institution or other healthcare entity. The accreditation, used by payers, consumers, or employers, confirms certain standards. For example, the Joint Commission is the standard accrediting body for hospitals, long-term care facilities, and other medical practices.<sup>5,7</sup>

Report cards provide details on the results of specific quality measures often referred to as

key indicators. The National Committee for Quality Assurance (NCQA) provides report cards for physicians and health care insurance plans. One example of data provided by NCQA is the Health Care Effectiveness Data and Information Set (HEDIS). This data set is used by a majority of health insurance plans to measure performance. Other examples of organizations that report on quality initiatives include the Pharmacy Quality Alliance (PQA) and Medicare Health Outcomes Survey (HOS).<sup>5,7</sup>

Many organizations now provide patients an opportunity to provide direct feedback via online or phone based surveys. The data may be published or used internally for quality improvement. A cycle of surveys followed by improvements and resurveys is often referred to as continuous quality improvement (CQI) or total quality management (TQM). CQI or TQM may utilize critical pathway processes to develop specific procedures to improve care and improve efficiency in a specific location. They define key steps that are necessary quality checks. For example, a patient is admitted to the hospital for a severe skin infection. A critical pathway may include ordering from a list of specific antibiotics, timing of cultures, timing of wound care, etc.<sup>7</sup>

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# CHAPTER 9

## INTRODUCTION TO STATISTICS AND RESEARCH DESIGN

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There will be interactions that pharmacists have with other providers that will require the pharmacist to be able to definitively and confidently support their position or perspective with evidence, or published medical literature. Along with the ability to utilize drug information databases and effectively searching medical literature, pharmacists must also be able to understand and discuss research and research findings. Collectively these skills enable the pharmacist to practice evidence-based medicine.

Not all research is the same. Understanding the different types of research will help the pharmacist when advocating for the patient. Generally, the type of research that pharmacists will use will be clinical research, or research that is examining questions related to clinical practice, outcomes, or both.<sup>1</sup> This is different from laboratory research, or basic research, which may be experimental or exploratory in nature. Basic research is conducted in a controlled laboratory setting and does not involve human subjects. Clinical research focuses on applications to patient care and uses a systematic process to answer clinical questions.<sup>2</sup> The goal of clinical research is to draw inference from the study sample to a larger population. A population would include every person with the specific disease or illness being studied and it's not realistic or feasible to include everyone in a study, so instead a sample is used. A sample is a group of subjects in the study that represent the population.

Generally clinical research will either directly involve human subjects by having humans participate in the study or use data from human subjects. In the latter, the data already exists, but humans aren't actively enrolled in the study. Instead human subjects' data is used in the research. To highlight this difference, Fuller and colleagues implemented a chronic obstructive pulmonary disease (COPD) clinic in a community pharmacy setting and designed a study to determine if pharmacists can accurately perform spirometry screenings.<sup>3</sup> Some rationale behind the study was that if pharmacists could accurately perform the screening, then they could improve their education of the patient about COPD risk factors and potentially increase patient participating in smoking cessation programs. A total of 175 patients were enrolled and completed a spirometry session.<sup>3</sup> In contrast, Chen and colleagues conducted a study to determine the effectiveness of a pharmacist-managed telephone

tobacco cessation clinic in a Veterans Affairs (VA) health system.<sup>4</sup> This study looked at data from patients who had participated in the clinic, and the data was obtained through the health system's electronic medical records. Both of these studies are examples of clinical research that aimed to answer a clinical question about smoking/tobacco cessation. A difference was that the study by Fuller actively included patients whereas the study by Chen looked at patient data, but didn't actually enroll a single human.

## RESEARCH DESIGN

The way a study is designed is based on the question the study sets out to answer. Some questions can't be answered with certain study designs. Pharmacists will use information from studies during their interactions with other providers, and a good starting place in using the information is to determine what research question was being asked. The research question is developed by researchers by starting with a broad idea or problem, and this might be something observed in everyday practice. This larger idea or problem is then narrowed down into a smaller and specific question. Sometimes several specific research questions might come from one larger idea, and this would result in multiple studies. Once the researchers have finalized their research question, they will rephrase the question and write it into the study as the study objective. As pharmacists read over a study's objective, they can consider what the original question might have been and if the study was designed appropriately to answer the question.

The studies by Fuller and Chen offer a look at different study designs and studies with different perspectives. There are two perspectives a study might take. A prospective study progresses forward in time and a retrospective study looks at data or information or events from the past. Fuller and colleagues started at one point in time and progressively enrolled patients and followed those patients into the future. Chen and colleagues looked back in time at a specific time period and collected data that was obtained during that time period. There are strengths and limitations of each perspective. Retrospective studies might be easier to conduct and cost less, but are limited by confounding factors. Prospective studies provide the research with more control, which will be discussed later in the chapter, but are potentially limited by the cost or time they take. Another limitation of prospective studies is patient enrollment, especially for studies looking at less commonly encountered conditions. It's important for pharmacists to understand these differences when discussing clinical research with providers.

Other aspects of research design will be discussed throughout this chapter. Aspects such as control types refer to what type of control, if any, is used in the study. Some studies may not

include a control group, whereas other designs might include a placebo, historical, crossover (where the subject serves as their own control), or active (e.g. standard of care) control.<sup>5</sup> Studies should be designed to increase both internal and external validity. Validity relates to how well a test is measuring what is intended to be measured.<sup>6</sup> Internal validity, then, is how well the study was designed to minimize errors within the study. Systematic and random error can impact internal validity.<sup>2</sup> Systematic errors include bias and confounding and random errors include chance.<sup>2</sup> Chance is what it sounds like and is the likelihood that a finding is due to random error. Statistical tests are used to quantify or determine the level of chance.<sup>2,5</sup> Bias occurs when there is a systemic error in subject selection or the measurement/collection of observations that leads to a false conclusion of association.<sup>2</sup> Confounding is commonly heard when thinking about variables. For example, a study might be looking to determine if a variable is a risk factor for an outcome variable. Confounding variables are those that are associated with the predictor variable, but are also themselves predictors of the outcome independent of the variable being studied. But, the confounding variable is not part of the relationship between the study variable and outcome of interest.<sup>7</sup> Pharmacists evaluate internal validity of studies by reading through the methods and analyses and determine if they were appropriate to answer the research question. Evaluation of the results, to determine if they are accurate based on the methods, and reading through the conclusions to make sure conclusions are supported by the data are additional ways for pharmacists to assess internal validity.

External validity is slightly different and refers to how the study is applied to a wider population. External validity can be thought of as related to generalizability.<sup>2</sup> The ability to apply the findings from the study and make inference to a wider population is generalizability and this is an area that is sometimes difficult to navigate in interactions with practitioners. Issues of how easily findings from a study can be applied to a cohort within a certain practice arise commonly and these are instances where pharmacists can be pivotal in these conversations. Ultimately, however, if there were errors leading to a decrease of internal validity, then there will be decreased external validity. Without internal validity, there can be no external validity. Some methods to improve both internal and external validity include reducing confounding variables, improve subject selection, blinding, using a control group, and using objective data and validated measurement techniques.

## Design Types

In addition to the study perspective, there are different types of study design types that could be used to answer the research question. Broad types include observational and

interventional studies, which are commonly referred to as clinical trials. As the name indicates, there is no intervention in an observational study, rather events or patients are observed either prospectively or retrospectively. Descriptive studies describe findings from observational studies. Although statistics are commonly used to describe the findings, there won't be any statistical comparisons of patient groups. Analytical studies make use of statistical tests or analysis to determine presence of any association among variables and to make inference. There are several different designs within observational studies. A cohort study, makes observations of a group over time. These can be retrospective or prospective and can be descriptive or analytical. Cohort studies can evaluate independent variables (or risk factors) for development of diseases or conditions. This design is related to exposure. The Framingham Heart Study is a well-known and classic example of a prospective cohort study. Investigators prospectively followed over 5000 residents of Framingham, Massachusetts in order to get a better understanding of risk factors for cardiovascular disease.<sup>8</sup> Nearly 70 years and hundreds of subsequent studies later, information obtained from the original Framingham cohort has shaped the way practitioners approach patient care. A recent publication by Bolesta and Kong describes a retrospective and analytical cohort study to determine the impact of the 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (also known as statins) on post-operative atrial fibrillation.<sup>9</sup>

Case-control studies are different from cohort studies in that there will be 2 distinct groups of subjects, but the design first finds cases of subjects with the outcome of interest (the condition or disease) and compares those subjects with a control group of subjects to determine exposure to an independent variable (risk factor). These are retrospective and the design starts with the disease or condition of interest. For example, a 2013 study by Barletta and colleagues is a case-control study aimed at determining any associations between proton-pump inhibitor usage and *Clostridium difficile* infection (CDI).<sup>10</sup> With this design the investigators first identified patients who had a hospital-acquired CDI. This made up the case group. The investigators then identified patients within the same time period who did not have CDI and used those patients to form the control group.

Cross-sectional studies collect data or make observations at a single point in time. Surveys are a common type of cross-sectional studies. Surveys will be distributed and the collected responses will reflect data from the respondent at a single time point. These study designs can be efficient and relatively cheap to conduct. The designs can be used for different target recipients (ie. patients or practitioners), but they are limited by the observations being at one point in time. Significant consideration must be made to the development of the survey questions and the types of response scales used in order to get the most accurate and unbiased

information from the target sample. The biggest limitation is participation, in that subjects may not participate. Survey response rate is important to consider when reviewing these types of studies. Owenby and colleagues distributed surveys to VA pharmacy clinical coordinators to characterize pharmacy services within VA emergency departments.<sup>11</sup> In contrast, Li and colleagues surveyed patients with recent medical visits to assess factors related to their search of online health information.<sup>12</sup> Both of these examples are cross-sectional studies, but with different target recipients.

Clinical trials are interventional studies that are designed to evaluate the efficacy and/or safety of an intervention. Parallel designs, where subjects receive only the study intervention or the control throughout the study, are common. Crossover designs, where subjects serve as their own controls may also be used. Randomized controlled trials (RCTs) are the gold standard of clinical trials because of the degree of experimental control utilized in the study. These are also going to be the most expensive to conduct. To pay for RCTs, researchers may seek federal or organizational grants to pay for the study. In other situations, and pharmaceutical or medical device company may pay to conduct the study.

To better understand RCTs, it's important to understand all of the aspects that go into one. Randomization is one key component of RCTs, and this is done at the beginning of the study to make the study groups similar. The goal of randomization is to make any observed differences in the study group due solely to chance. The group differences ultimately are balanced through randomization. One way to think of randomization is to think of flipping a coin. If a study has 2 study groups (also sometimes referred to as arms), a treatment and control, then a researcher might flip a coin to randomize assignment. Subjects with heads on the coin flip could be assigned to the treatment group and those with tails on the coin flip could be assigned to the control group. There are many more sophisticated randomization methods, but at the core randomization is intended to assure that subjects have an equal chance of being assigned to each study group, and baseline confounding variables are eliminated. Blinding is a technique used to hide group assignments. The intent is to reduce or eliminate information bias from the participant or observer/researcher. Blinding can be single or double. Single is where only one side is blinded (subject or researcher) and double is where both subject and researcher are unaware of the group assignment. It can be difficult to blind some interventions. For example, it might be difficult in a study comparing liquid clindamycin and amoxicillin because liquid clindamycin is well known for having a bad taste and amoxicillin is more palatable.

Understanding RCT and being able to discuss RCT findings with practitioners also requires

knowledge of the analysis technique utilized in the study. There are two general types, intention to treat (ITT) and per protocol (PP). Either may be used and the methods section of the article should state which was utilized. With the ITT analysis, outcomes are compared based on subjects' assignments and no data is eliminated. If subjects drop out of the study or are lost to follow-up their data is still included, but the outcome is characterized as no outcomes. This provides a conservative estimate of efficacy difference between groups, but a more liberal estimate of toxicity differences. Per protocol is different in that it compares outcomes based on subjects who followed the study protocol and eliminates data of subjects who did not complete study. This provides higher degree of efficacy difference between groups for efficacy outcomes, but lower degree of difference for toxicity outcomes. For example, a study comparing drug A and drug B is evaluating which drug has better treatment success. If 20 patients are included in each study group, outcomes will be compared. Let's say for drug A, 15 subjects have success, 4 have failure, and 1 drops out. For drug B, 15 subjects have success, 1 has failure, and 4 drop out. Success rates for drug A and drug B would be equal with the ITT technique (ie. both at 75%), but would be 79% (15 of 19 completing protocol) vs. 94% (15 of 16 completing protocol), respectively, with the PP technique. The opposite would be true if a toxicity were an outcome of interest. There are studies that will perform analyses based on both the ITT and per protocol to evaluate if there were different findings based on analysis strategy.

There are different types of RCT. **Table 9-1** highlights some differences between superiority, equivalence, and non-inferiority designs.<sup>13</sup> When interacting with practitioners about equivalence or non-inferiority studies, it should be noted that a fundamental concept in these studies is that they are based off of a superiority RCT that has been previously conducted. It would be important, then, to read through the original superiority RCT before discussing the merits of the non-inferiority or equivalence study. A couple of terms will continually be noted for both equivalence and non-inferiority studies. The delta ( $\Delta$ ) notes the least relevant difference and should be considered a marker of clinical significance or importance. This will be established by researchers and should generally be based on existing literature. The non-inferiority margin is the pre-determined maximum difference between "intervention" and "control", and is another term for delta. The delta and non-inferiority margin will be utilized for interpreting study results.

## STATISTICAL ANALYSIS

Even the term statistical analysis has a tendency to bring out a variety of uncomfortable responses from practitioners, but a common response is one of confusion and hesitancy.

Type	Method	Goal
Superiority	Compares investigational treatment to control (ie. placebo, standard of care)	Show that investigational treatment is superior to control or standard treatment
Equivalence		Show that the treatments differ by an amount that is NOT clinically important (ie. difference between $-\Delta$ and $+\Delta$ )
Non-inferiority		Show that investigational treatment is NOT clinically inferior to control (ie. can be worse, but no worse than $-\Delta$ )

**Table 9-1.** Randomized controlled trial types<sup>a</sup>

a = Table modified from reference #47,  $\Delta$  = delta

Many practitioners find statistics intimidating, almost like a foreign language. Regardless of the response, the reality is that a basic understanding of how to apply statistical analysis techniques is needed if pharmacists are to have meaningful interactions with practitioners and optimize patient care. The majority of pharmacists working in patient care roles won't be doing statistical analysis, just like they won't be doing research. As was highlighted previously, a good understanding of research design and all of the elements that go into doing research will allow pharmacists to be smarter consumers leading to more effective interactions with other practitioners and more optimal patient advocacy. This is the case for statistical analysis as well.

The statistical analysis section of a published study may seem like a good area to pass over quickly. Perhaps some authors may not even spend much time writing this section. Spending some time evaluating the statistical analysis section of a published study may allow the reader to discover that researchers used inappropriate statistical methods or potentially manipulate the findings. Understanding statistics can help a reader connect the dots in a published study. That stated, statistical analysis is another piece of the overall research design. It is connected with the research design, and ultimately the research question. For example, the goal of clinical research is to draw inference from a study sample to a larger population, but the validity of that inference is dependent upon the appropriate design being married with the

appropriate statistical analysis. If one of the two is not appropriate, then the study's validity may be called into question. If the validity is questionable, then the study findings may not be appropriate to utilize to drive patient care decisions. All of this is complicated. Knowing where to start and the process to use to apply knowledge of statistical analysis to patient care situations is crucial in overcoming the intimidating barrier that can sometimes arise from statistics.

## Data Types and Scales

The type of statistics that are used depends on the type of data that is collected, and there are different types of data and data scales for discussion. Remember that some practitioners will use the term variables or parameters or even outcomes, but all of these terms are also terms for data, and data can be considered either categorical or continuous. Categorical are qualitative and can be placed into categories or buckets. Examples of categorical data include hair color or grade level. Continuous data are quantitative and can take any range of possibilities. Examples of continuous data include age, weight, or blood pressure. Data are further considered on scales, and for the purposes of the medical literature there are 4 data scales (**Table 9-2**).

Scale	Characteristic	Statistics	Example
Categorical or Discrete			
Nominal	Unordered categories	Counts, frequencies, percentages	Gender, diagnosis
Ordinal	Ordered categories	Above + medians	Likert scales, pain scales
Continuous			
Interval	Arbitrary zero	Above + means, standard deviations	Temperature (C, F)
Ratio	Absolute zero		Weight, age

**Table 9-2.** Data scales

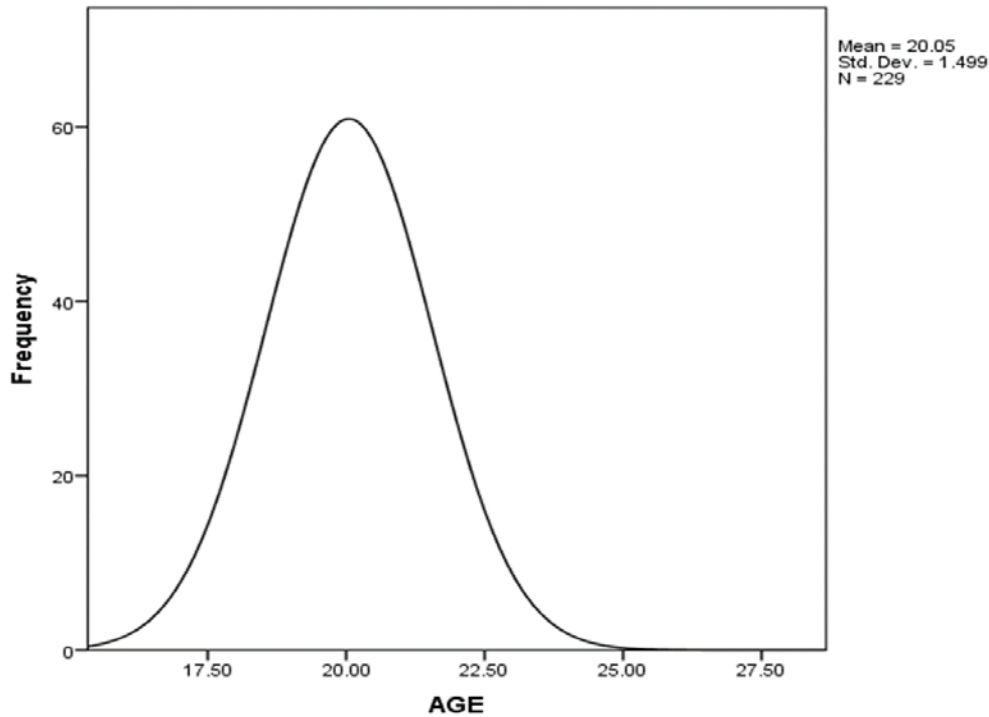
The nominal data scale is the most basic data scale. Data falling onto this scale can be classified into two or more categories that are mutually exclusive from one another and are exhaustive. The categories are unordered and have no relation to each other. Dichotomous data are data that can be placed into one of two categories like alive or dead, pregnant or non-



pregnant. Dichotomous data is a specific type of nominal data. The ordinal scale includes ordered categories with some rank and relation to another. Data derived from surveys using Likert-scale questions (ie. strongly agree, agree, disagree, strongly disagree) or measurement scales such as pain rating scales are examples of ordinal data. While ordinal data may be reported as a number (ie. pain score of 7 or Likert score of 4) the number corresponds to a category, and there is no consistent degree of difference between each category (ie. 3 is not 3 times greater than 1). Continuous variables can take on an infinite number of possibilities. With continuous data there is both an order to the values and a consistent degree of difference between each value. Continuous data can be placed on either the interval or ratio scale with the difference being that ratio data has real zero (ie. heart rate) compared to an arbitrary zero (ie. temperature on fahrenheit scale) of for interval data.<sup>14</sup> Any continuous data could be turned into either nominal or ordinal categorical data, but the opposite is not true. Categorical cannot be converted to continuous data.<sup>14</sup>

## Descriptive Statistics

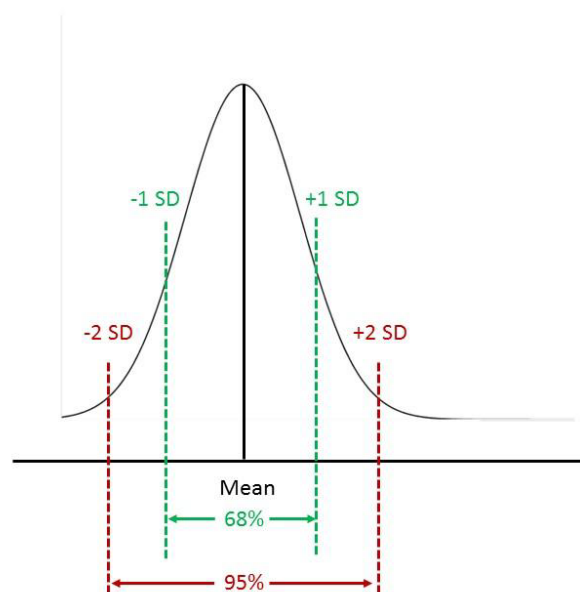
Statistics should be considered as two broad categories, descriptive and inferential. As the name implies, descriptive statistics describes study observations. These are very useful to research consumers because descriptive statistics allow the reader an understanding of the subjects that were included in the study. Data within these data scales can take on a number of possible values, making it important to understand data distribution. The binomial and Poisson distributions are examples of distributions of categorical data.<sup>15</sup> The normal distribution is a distribution of continuous data. With this, data are equally distributed around the mean and the values of the mean, median, and mode are all equal. The next paragraph describes mean, median, and mode. The curve of a normal distribution takes on a bell appearance, and it's often referred to as a bell-shaped curve. **Figure 10-1** illustrates a normal distribution curve of age that came from a dataset containing 229 patient observations and in addition to the shape of the curve, the distribution can provide a lot of useful information to providers. Some examples of these will follow.



**Figure 9-1.** Normal distribution curve

Measures of central tendency and measures of variability are types of descriptive statistics. Measures of central tendency include mean, median, and mode and describe the main observations of the dataset while measures of variability are used to describe the amount of uncertainty in the dataset. The mean is the average of the values in the dataset and can be calculated for continuous data. The mean is highly affected by outliers making it suboptimal to describe data that aren't normally distributed. Because there is inconsistent degree of difference between ordinal categories, the mean is not useful to describe ordinal data. The median is the middle measurement (ie. 50<sup>th</sup> percentile) in a dataset and can be used for ordinal data or continuous data that aren't normally distributed. There are an equal number of values above and below the median making it resistant to the influence of outlying variables. The mode is the value occurring most often in a dataset. The standard deviation (SD) is a measure of variability commonly used with the mean because it represents deviation from the dataset's mean. The SD is the square root of variance which is derived from sum of squares. The mean of a dataset is subtracted from each data observation, and all of those deviations are added together to make the sum of squares. Neither the variance nor sum of squares are used commonly in the medical literature, but the SD is and knowing its origins helps make sense of what information the SD provides practitioners. Because the mean is used in the calculation

of the SD, this variability measure is most appropriate for normal or near normally distributed data. Using the SD, a reader can apply the empirical rule for additional information about the dataset. The empirical rule states that for normally distributed data, 68% of observations will fall between 1 SD of the mean, 95% of observations will fall between 2 SD, and 99% of observations will fall between 3 SD. **Figure 9-2** provides an illustration. Applying this rule to the mean and SD within **Figure 10-1** and learn that 68% of the patients had ages of 18.5 – 21.5 years, 95% were 17.1 – 23 years, and 99% were 15.5 – 24.5 years. This type of application of descriptive statistics is particularly useful as a provider and when discussing with other providers because it allows for some generalization. Using data from a study where 95% of the patients were 17.1 – 23 years old wouldn't be useful or appropriate for providers who predominantly care for elderly patients.



**Figure 9-2.** Normal distribution curve with 68, 95 rule

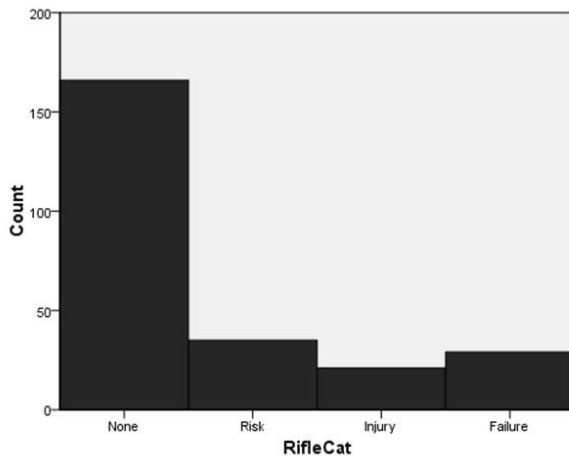
The standard error of the mean (SEM) may be commonly confused with or used in place of SD. However, the SEM quantifies certainty in the estimate of the true population mean where the SD is providing an estimate of variability around a sample mean. The two are not interchangeable, but the SEM will always be smaller leading some researchers to report it because of the feeling that less variability is better. A reader can always determine the SD from the SEM by taking the SD divided by the square root of the number of observations:

$$(SEM = SD \div \sqrt{n}).$$

Using the data from **Figure 10-1**, the SEM would be calculated as:

$$1.499 \div \sqrt{229} = 0.098$$

which is obviously smaller than the reported SD of 1.499. This equation can be used to determine the SD when the SEM is inappropriately reported. Standard errors are used in the calculation of confidence intervals (CI) which estimate a range of values that is likely to contain a population value a certain percentage of time. These are commonly reported in the literature as 95% confidence intervals. Confidence intervals will be further explained later in the chapter. The interquartile range (IQR) represents data between the 25<sup>th</sup> and 75<sup>th</sup> percentiles and contains the middle 50% of observations. This measure of variability is commonly reported as 2 numbers with the highest representing the 75<sup>th</sup> percentile and lowest representing the 25<sup>th</sup> percentile. The IQR is particularly useful for non-normally distributed continuous data, along with the median, or for ordinal data. Other types of descriptive statistics include frequencies and percentages or visual data displays such as histograms, scatter plots, and box plots (**Figures 9-3 - 9-5**).



**Figure 9-3.** Histogram

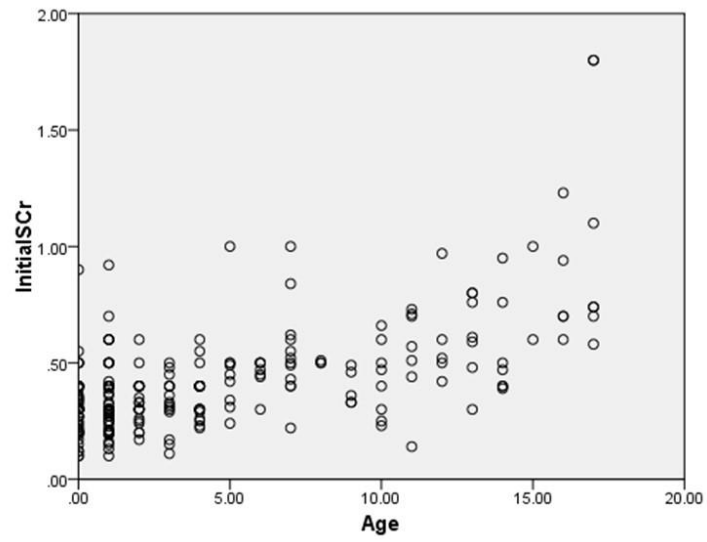


Figure 9-4. Scatterplot

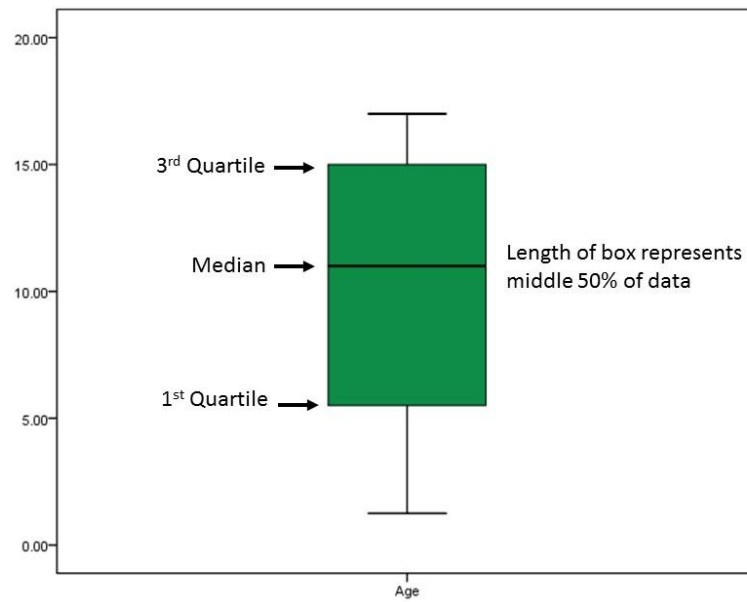


Figure 9-5. Box plot

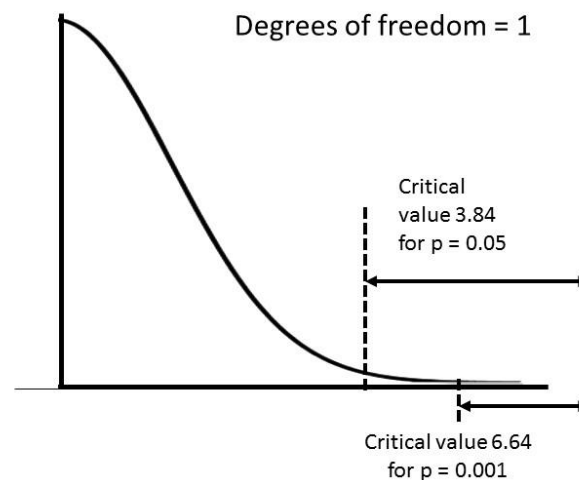
## Inferential Statistics, Hypothesis Testing, and Decision Errors

Inferential statistics are used to make a generalization about a population from the results of a study and practitioners will use study finding to make decisions on how to manage the patients in their care. The foundation of inferential statistics is with hypothesis testing, and statistical tests are used in hypothesis testing. Not all studies will be testing hypotheses, so not every study will include inferential statistics, but all studies that are reporting findings will include some element of descriptive statistics. With hypothesis testing, statistical tests are used to test the null hypothesis ( $H_0$ ) which states that there is no difference between predictor and outcome variables. In other words, if a study were comparing two interventions (Intervention A and Intervention B) the  $H_0$  would state that Intervention A = Intervention B. The alternate hypothesis ( $H_1$ ) would then state that Intervention A  $\neq$  Intervention B. The  $H_1$  cannot be directly tested, so it is accepted by default in instances where the  $H_0$  is rejected. The  $H_0$  is rejected based on the results of a statistical test. In general, for studies which pharmacists will be reading and using, hypothesis testing is two-sided. In other words, the researcher is interested in a difference in either direction. It might be important if Intervention A is better than or worse than Intervention B. Occasionally, inferential statistics will be used for one-sided hypothesis testing. In a one-sided hypothesis, a direction of difference is stated and tested. For example, the  $H_0$  might be written as Intervention A  $\geq$  Intervention B with the  $H_1$  written as Intervention A  $<$  Intervention B.

For statistical testing, researchers determine which statistical test should be used because there are different tests for different types of data or the number of groups being compared. Once the researchers decide on the statistical test, the level of significance (also referred to as alpha or  $\alpha$ ) is selected. This is generally set at 0.05 and it essentially means there is a 5% probability of incorrectly rejecting the null hypothesis (ie. making a Type 1 error). Once the alpha is set, a critical value will be determined based on what statistical test will be used. The critical value corresponds to the pre-set  $\alpha$ . A common place where statistical testing becomes confusing for providers is what it all means. The p-value is the probability of making an observation as extreme or more extreme than the observed if the  $H_0$  were true.<sup>17</sup> The statistical test is then done and the test statistic is compared to the critical value and a p-value is calculated. P-values less than the preset alpha are considered to be statistically significant, the  $H_0$  is rejected, and by default the  $H_1$  is accepted.

A recent study by Hammond and colleagues sought to compare the incidence of acute kidney injury (AKI) in patients who were receiving vancomycin plus either piperacillin/tazobactam or cefepime.<sup>18</sup> In this example, the  $H_0$  would be AKI with PT = AKI with cefepime. This study

had two groups (PT vs. cefepime) and the primary variable being compared was AKI which was a nominal variable. Patients either had AKI or didn't making this a categorical and nominal variable. Because the researchers were comparing a nominal variable between two groups, the chi-square test was most appropriate. More on this test will follow. The researchers state that the pre-determined  $\alpha = 0.05$ , which meant that the corresponding critical value of the chi-square test = 3.84. In general, textbooks of statistical analysis will include supplementary tables containing critical values for statistical tests, so this information is easy to obtain. With a critical value of 3.84, any test statistic greater than 3.84 would correspond to a p-value of  $< 0.05$  (**Figure 9-6**). Hammond and colleagues reported that there was no difference in AKI between the PT (32.7%) and cefepime (28.8%) patients and that the p-value = 0.761. The actual test statistic was not reported, and it typically is not in medical literature, but a reader can assume from the reported p-value of 0.761 that the test statistic resulting from the chi-square test was less than the critical value of 3.84. With this example, because the test value was less than the critical value, the researchers could not show a difference in AKI between the drug regimens and would ultimately conclude that there is no AKI difference between patients receiving PT and those receiving cefepime.



**Figure 9-6.** Chi-square critical value and p-value

With inferential statistics, there is always a chance of error and the two types of error that can be encountered are Type 1 (false-positive) and Type 2 (false-negative). These errors are due to chance variability or bias and the likelihood of encountering them may decrease with increasing sample sizes. With a type 1 error the researcher rejects an  $H_0$  that is actually true.<sup>19</sup> The probability of making a type 1 error is signified by pre-set alpha ( $\alpha$ ) and the p-value that is determined from the test provides a more precise probability of making a type 1 error. A type 2 error occurs when a researcher fails to reject an  $H_0$  that is actually not true.<sup>18</sup> Beta ( $\beta$ ) is the probability of making a type 2 error and this typically ranges from 0.1 – 0.2. There are several ways to think about decision errors so that they make more sense. One way to consider is related to that of a jury decision.<sup>20</sup> An innocent person did not commit a crime and a guilty person did commit a crime. If a jury convicts the criminal and acquits the innocent, then the correct decision was made. But, if the jury convicts the innocent person, a type 1 error has been made because the jury has concluded that there is an association when in reality there is not. Likewise, if a jury acquits the criminal they have made a type 2 error by concluding that there is no association when there actually is one.<sup>20</sup> The popular belief of those who followed or were familiar with the O.J. Simpson murder trial was that Simpson did commit the murders although the jury acquitted him (ie. making a type 2 error).<sup>21</sup> Contrast that with the case of Mark Schand who spent 27 years in prison after a jury wrongfully convicted him of committing murder (ie. making a type 1 error).<sup>22</sup> In medicine, type 1 errors may result in drugs or treatment being introduced to market or practice when they are truly no different than standard treatments. Concerning are the potential downfalls of the new treatments which likely are more expensive than standard care, but also may have more side effects.

Power is a term that is used quite a bit by practitioners who might say that a particular study was underpowered or that a study had adequate power. Power is the probability of correctly rejecting the  $H_0$ . This might also be considered as the probability to detect a difference when the difference exists. The equation for power is:

$$Power = 1 - \beta$$

and it's dependent upon several things. The predefined  $\alpha$ , sample size, estimated size of difference between outcomes (ie. the difference that researchers are trying to detect), outcome variability, and the statistical test can all influence power. Sample size and power are connected in that while sample size can influence power, power is also considered when determine the required sample size. Hammond and colleagues determined that 122 patients were needed to detect an approximate 20% difference in AKI between PT and cefepime.<sup>18</sup>



Researchers established the  $\alpha$  at 0.05 and  $\beta$  at 0.2 for a power of 80%. The sample size was based on AKI estimates of 36.5% in the PT groups vs. 15% in the cefepime group. While beyond the scope of this text, there are resources that would allow the reader to compute the actual power of this particular study.

With inferential statistics, there is always a degree of uncertainty and p-values will tell one aspect of the story, which is about statistical significance. But, the p-values themselves don't provide information about the clinical impact or size of any difference, if present. Confidence intervals are useful to determine the size of the potential difference because confidence intervals give a range of possible estimates including the observed value. All values within the CI are statistically possible. For examples, authors report no difference in mean  $\pm$  SD vancomycin dosing (mg/kg/day) in pediatric patients with ( $47.5 \pm 14.6$ ) and without AKI [ $41.2 \pm 16.6$ ) with a p-value = 0.102.<sup>23</sup> This finding is not statistically significant, so the researchers fail to reject the  $H_0$  that the dose in those with AKI = dose in those without AKI. But, is this finding clinically meaningful? Some practitioners might say yes, leading to the suggestion that dose is an important consideration with AKI, while other practitioners may disagree. The actual difference between the doses was -6.3 mg/kg/day, but if the 95% CI of the difference would have been included, it would have been -13.8 to 1.25. Remembering that the CI is the range of values that could contain the true population value, one could interpret this 95% CI by saying there is a 95% certainty that the true dosing difference lies between -13.8 and 1.25 mg/kg/day. This perspective provides more clinical importance to the finding. Some practitioners might agree that a dosing difference of nearly -14 mg/kg/day is clinically important for this drug, but they may also to say that a difference of 1.25 mg/kg/day is not important at all. It should be noted that within this 95% CI is 0, meaning that the true dosing difference could be also zero. This is how CIs can also be used to test hypotheses. If the  $H_0$  is that the dose in those with AKI = dose in those without AKI, or there is 0 difference in dose, then the 95% CI tells a reader that the  $H_0$  should not be rejected because 0 is contained within the CI. A more simplified approach to determining statistical significance from reading a 95% CI is this. If estimating a difference between continuous (ie. means) or categorical variables (ie. percentage or proportions), CIs containing zero (0) are NOT statistically significant (ie. the p-value > 0.05), and the  $H_0$  should not be rejected. If estimating an odds ratio (OR), relative risk (RR), or hazard ratio, CIs containing one (1) are NOT statistically significant, (ie. p-value > 0.05), and the  $H_0$  should not be rejected.

### Common Statistical Tests

Statistical tests are widely reported in both pharmacy and medical literature.<sup>24,25</sup> Common

statistical tests can be divided into parametric and non-parametric categories. Assumptions for parametric tests are that the data is continuous with a normal or near-normal distribution, data is randomly obtained, the observations are independent of one another, and the variances between groups are equal. Parametric tests include t-tests and analysis of variance (ANOVA) and are considered more powerful than non-parametric tests. The t-test compares means between no more than 2 groups. These will be used to test an  $H_0$  that a mean in one group is the same as the mean dose in another group, similar to the previous example of mean vancomycin dose and AKI. There are different types of t-tests. A one-sample compares the mean in a study group to that of a known population. Independent samples t-tests (also called Student t-tests) compare means of two unrelated groups (ie. Group 1 vs. Group 2), where paired t-tests compare the means of dependent observations (ie. measurement 1 vs. measurement 2 in one group). A paired t-test would be commonly used in a before-after type of study design. Analysis of variance compares means of 3 or more groups. The ANOVA is more powerful than a t-test when there are 3 or more groups because the alpha is held constant. There are a different types of ANOVA: one-way (ie. mean in Group 1 vs. Group 2 vs. Group 3), two-way (ie. comparing two factors in Group 1 vs. Group 2 vs. Group 3), and repeated measures (ie. one group but comparing the mean of Measurement 1 vs. Measurement 2 vs. Measurement 3). With ANOVA, the test result will correspond to a p-value that tells the researcher or reader if a significant difference exists, but the test doesn't signify where the difference exists. If an ANOVA yields a significant p-value, researchers must perform further tests, called post-hoc tests, to determine precisely where the difference lies. Pearson correlation is a parametric procedure used to examine the direction and strength of relationship between 2 normally distributed continuous variables. The Pearson correlation coefficient ( $r$ ) ranges from -1 to +1 with values closer to 1 representing a stronger relationship between the variables. Positive numbers indicate direct or positive relationships with negative numbers representing inverse or negative relationships. In general  $r$  values of  $< 0.3$  are considered weak,  $0.3 - 0.5$  are moderate, and  $> 0.5$  are considered strong relationships.<sup>26</sup> The coefficient of determination ( $r^2$ ) is the percentage of variance in the dependent variable that is explained by the other.<sup>26</sup> Lee and colleagues evaluated the relationship of serum creatinine concentrations on antifactor Xa concentrations and found an  $r = -0.262$ .<sup>27</sup> This can be interpreted as a weak negative relationship. The  $r^2$  value = 0.0688 which means that 7% of the variance in antifactor Xa concentrations can be explained by serum creatinine concentrations.

Non-parametric tests are used when the assumptions of parametric tests are violated. Several analogies can be made to parametric tests. The Wilcoxon rank sum and Mann-Whitney U are analogous to the independent samples t-tests and are used for two independent samples of

non-normally distributed continuous data or ordinal data. The Wilcoxon signed rank test is analogous to the paired samples t-test and would be used for data types above from related samples. The Kruskal-Wallis test can be considered analogous to ANOVA, and would be used for non-normally distributed continuous data or ordinal data from 3 or more groups. For nominal data, Chi-square analysis can be used to compare proportions between 2 or more independent groups. An assumption of the Chi-square analysis is that of sufficiently large expected frequencies, so when this is violated (eg. when any cell has less than 5 expected frequencies) the Fisher exact test is more appropriate. The McNemar test can be used to compare proportions in paired samples. Lastly, Spearman correlation is analogous to Pearson correlation and is used for continuous variables that aren't normally distributed or for nominal and ordinal data. Range of values from the Spearman rho ( $r_s$ ), which is the output from a Spearman correlation, are negative 1 to positive 1 and interpretation is similar as Pearson. **Table 9-3** describes common statistical tests and their appropriate uses.

Regression determines how one variable predicts another variable, but it shouldn't be considered as establishing a cause-effect relationship. Simple regression is a relationship between a single dependent and independent variable; multiple regression is a single dependent with multiple independent variables. There are 2 types of regression. Linear regression is used when dependent variable is continuous and normally distributed, and the independent variable is continuous (simple regression) or either continuous or categorical (multiple regression). The output from linear regression is the coefficient of determination ( $r^2$ ) which explains how clearly the model describes the relationship and beta ( $\beta$ ) which describes the change in the dependent variable caused by a 1-unit change in the independent variable. Logistic regression differs in that the dependent variable is categorical while the independent variables could be continuous or categorical. The result of logistic regression is an odds ratio that can be interpreted as previous described.

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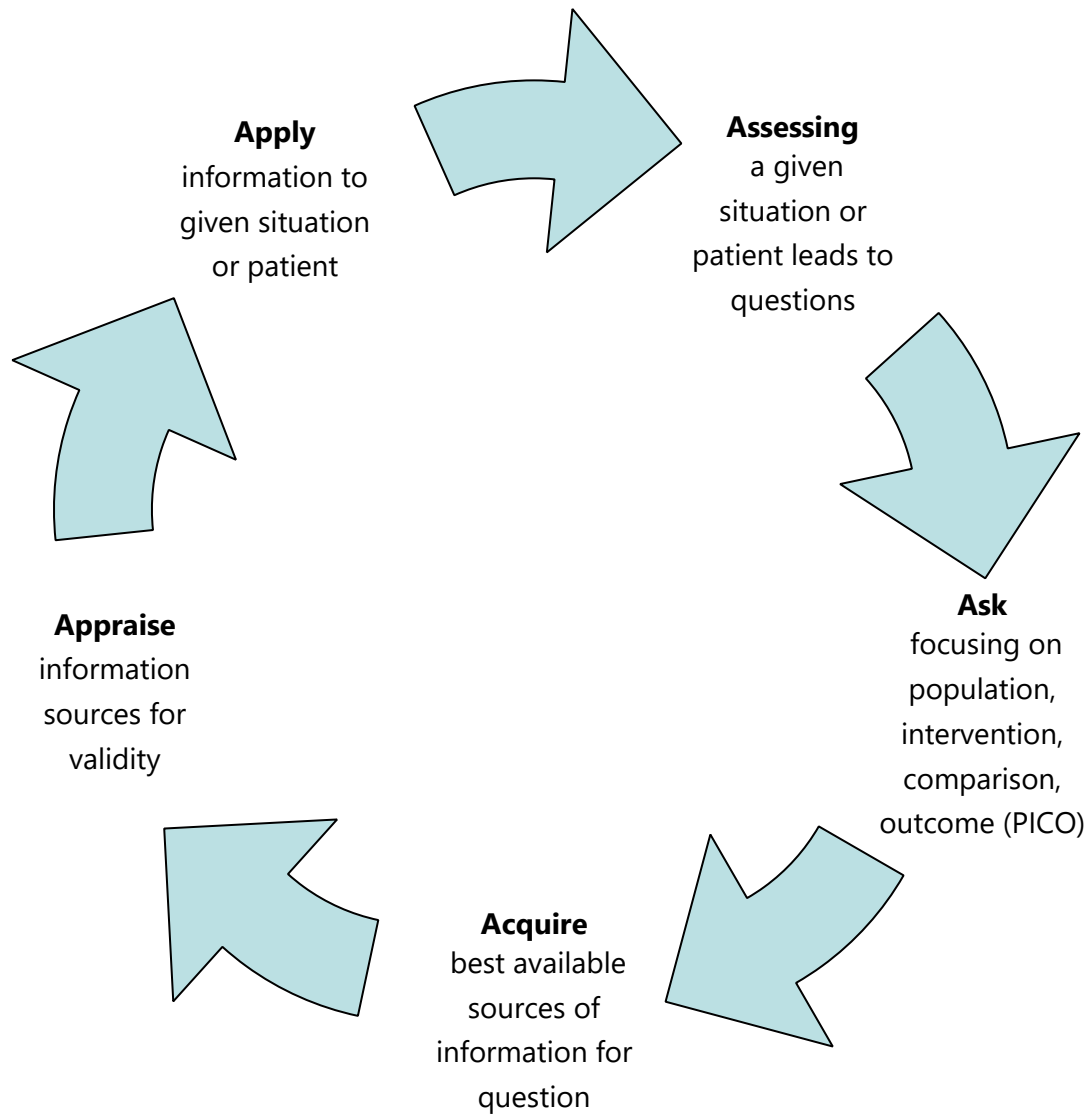
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# CHAPTER 10

## EVIDENCE-BASED MEDICINE

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Evidence-based medicine (EBM) has been defined as the “conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”.<sup>1</sup> In recent history, the EBM movement has been credited to a group of clinicians working on new approaches to teaching medical professionals over 25 years ago.<sup>2</sup> While medical professionals have always relied on clinical experience when making decisions, the original impetus of EBM was to intentionally incorporate appraisal of the best available evidence to resolve practice issues. However, clinical expertise should not be ignored as it is integral to balancing the patient’s clinical circumstances, relevant research evidence, and the patient’s preferences or values when making decisions.<sup>3-4</sup> Clinicians are now expected to not only consult the best available evidence, but also be able to make their own independent appraisal and application of the evidence.<sup>5</sup> A process or step-wise EBM approach commonly cited in literature is described below and depicted in **Figure 10-1**, which can be used for resolving patient issues or practice challenges.



**Figure 10-1.** Evidence-based medicine cycle

## ASSESS

The EBM process starts with an assessment of a patient or practice situation. Assessment is a skill that many first acquire in the classroom or in training programs, and then further develop with experience. Assessing an individual patient or practice situation will likely lead to issues that need to be resolved and resultant questions that need to be answered. These questions that arise are often referred to as knowledge gaps. It is possible that many

knowledge gaps may arise in a single encounter or situation necessitating a prioritization approach to addressing and resolving them. Knowledge gaps will vary among practitioners based on their level of clinical experience and familiarity with the current best available evidence.<sup>5</sup> Before proceeding, it is important to have a good idea of the clinical status and circumstances of the patient and their preferences or values with respect to their health goals.<sup>6-8</sup> Without this crucial step, clinicians may not achieve optimal outcomes for their patients. During this phase, clinicians may need to research background questions, to answer any resounding knowledge gaps, before they pursue specific questions. If a practitioner is unfamiliar with a given disease, intervention, or outcome, it is important to understand these elements before pursuing specific patient questions involving these variables. For example, before answering the question, “does tranexamic acid increase the risk of venous thromboembolism (VTE) in patients with atrial fibrillation who are undergoing knee replacement?” one may need to review background information on how tranexamic acid works, common risk factors for VTE in general, and VTE complication rates in the orthopedic setting. Common sources of information clinicians use to answer background questions are tertiary sources such as review articles or textbooks.

## **ASK**

The next step is to frame the knowledge gap into a structured question. Structured questions are one way of finding answers using keywords that will hopefully best address the situation.<sup>5</sup> Many databases used to search for literature utilize structured search terms that can accommodate this strategy.

Patient specific questions usually require the practitioner to refer back to original studies or primary literature. On occasion, pre-appraised sources of information such as guidelines or systematic reviews may have addressed the specific question, but more commonly clinicians have to extrapolate information from studies with similar but not identical characteristics of their clinical situation.<sup>3,5,9</sup> While different types of specific questions may arise in the course of clinical work (e.g. diagnosis, prognosis, therapy, prevention), a suggested general acronym practitioners can remember when structuring questions is PICO. PICO stands for population, intervention, comparator, and outcome.<sup>3</sup> In order to be efficient at evaluating a body of literature that is expanding at exponential rates, asking a focused question using a structured template such as PICO, can assist in yielding relevant studies. In the example used previously, the population would be patients with atrial fibrillation who are undergoing knee replacement, the intervention would be tranexamic acid, the comparison is inferred to be not using tranexamic acid, and the outcome is venous thromboembolism. Occasionally, our questions may not yield any literature hits and then we need to expand some element of our



PICO framework. In this case, one might expand the population to patients undergoing joint replacement and leave out atrial fibrillation under the auspices that this still may help answer whether tranexamic acid increases risk of VTE, irrespective of atrial fibrillation.

## ACQUIRE

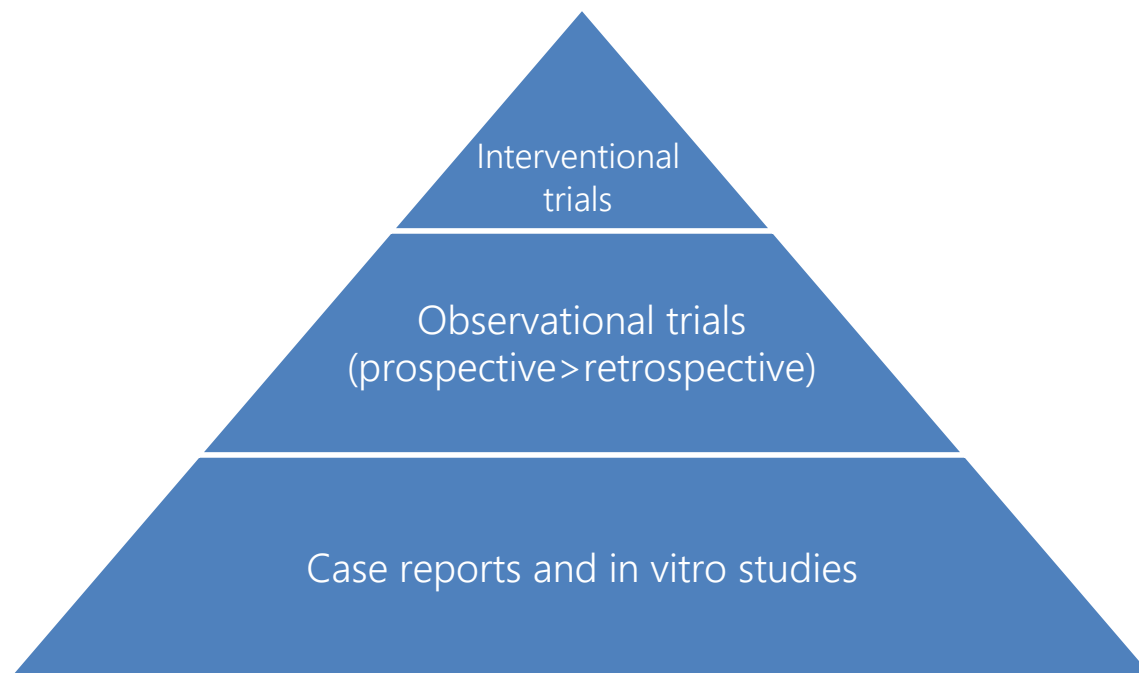
While possessing the requisite skills to assess patients and discern what questions need to be addressed, the process of acquiring information takes time that many practitioners do not have.<sup>3,5,8,10</sup> One popular approach is to consider the usefulness of information as an equation, with relevance and validity in the numerator and work in the denominator.<sup>11-12</sup> The relevance of an information source refers to whether the outcome described is of value to your patient, whether the interventions or practices described are feasible, and if the interventions would lead to a change in practice. The validity refers to the trustworthiness of a given article, and the work refers to the time, money, and effort it takes to obtain an answer to a clinical question. While relying on authority or experience may require little work on the clinician's part, this equation reminds the clinician that information which is not relevant or valid is useless, no matter how much effort is required. This approach also encourages clinicians to focus on finding relevant evidence first and then apply principles for assessing validity rather than vice versa.

Acquiring evidence can be an intimidating task because information appears to be increasing at exponential rates.<sup>10</sup> It is difficult to stay up to date with medical information so one must find ways to efficiently make use of the available evidence. While many types of information are available to practitioners today, this doesn't mean all resources are useful. Knowing types of resources and how they differ from each other, their strengths and weaknesses, and how to use them is an important attribute for efficient practice.<sup>12</sup> Studies on information seeking behavior in literature note that this step is often not pursued when questions arise in practice and when it is pursued, clinicians spend little time on this before either quitting the search or going with what they were able to find.<sup>5</sup>

Strategies to ensure one is getting the best available evidence commonly vary from asking colleagues for their expert opinion, reviewing clinical practice guidelines, searching for systematic reviews and/or meta-analyses on existing literature, to searching databases such as PubMed for original research studies.<sup>13</sup> While practice guidelines or systematic reviews may appear useful since they have already appraised the validity of information sources, the clinician needs to be aware these can rapidly be out of date, based on the number of trials that get published every day. Likewise, relying on experts or clinical experience to answer questions may be perceived as an efficient way to acquire evidence, but a danger with this

approach is that it assumes that practitioners are up to date with current literature and that he or she is not biased by their own personal experiences. Similar to this, using general search engines on the web can be misleading in that they provide 'hits' but they may not provide information specific to your inquiry.

A traditional model in EBM is the hierarchical approach of categorizing types of resources as seen in **Figure 10-2**.<sup>3</sup> This approach implies there are some resources with more validity and relevance than others. Study designs are ranked based upon the likelihood of providing causality estimates. Randomized controlled trials are commonly listed at the top of these models since the design allows the researcher control over various factors. Opinions are commonly listed at the bottom of the pyramid because there is not a readily available way of testing this information for validity.



**Figure 10-2.** Hierarchy of study designs

Another way sources of evidence are described is based on efficiency (i.e. time required for practitioner to find answer) as seen in **Figure 10-3**.<sup>2,5</sup> In this case, resources that are pre-appraised for validity (e.g. practice guidelines, systematic reviews) are noted on the EBM pyramid as being more useful while original studies that are not pre-appraised (i.e. reader has

to do this) as less useful. However, these models do not adequately address every type of question or resource that could arise so practitioners ultimately need to be familiar with multiple types of resources and how to appraise them.



**Figure 10-3.** Hierarchy of resources based on efficiency

## APPRAISE

After acquisition of evidence, the clinician must be able to appraise the information for validity, or trustworthiness. Depending on the type of original question asked (e.g. diagnostic, prognostic, therapy, etiology), some primary sources of literature are better suited than others. While some sources of information have been pre-appraised (e.g. guidelines, systematic reviews), it is important to determine the process of validation and be able to confirm or agree with the information independently.<sup>14-17</sup> Otherwise this is analogous to relying on authority or experts again. While prospective controlled studies by design are more

suited to answering questions of causality, this does not automatically mean observational study designs are weaker as all studies can have methodologic flaws impacting their validity.<sup>17</sup> Several tools are available for evaluating research evidence for validity. The EQUATOR network ([www.equator-network.org](http://www.equator-network.org)) provides reporting guidelines for a variety of study designs in order to enhance the quality and transparency of the published article. The Centre for Evidence Based Medicine ([www.cebm.net/critical-appraisal](http://www.cebm.net/critical-appraisal)) at the University of Oxford provides appraisal tools to help clinicians determine reliability, importance, and applicability of articles. While these tools can offer a checklist approach to evaluating studies, it is important to remember that the appraisal process is just to determine whether given results are plausible, not whether they should be used in your patient or practice setting. A common criticism of EBM is that it implies there is a stepwise appraisal approach (i.e. cookbook approach) to treating every practice issue. This objection is related to the loss of perception of autonomy in decision making and is an untoward application of EBM with respect to standardizing care and insisting on one way of doing things. However, this is not the intent of EBM and it actually acknowledges the role of experience and intuition and the fact there are differences in skill, is what explains variations in results at times.<sup>1-4</sup>

## **APPLY**

After the evidence has been acquired and appraised, it must be applied back to the individual issue, be it a patient or practice situation. This process of application should not be based solely on the conclusions of studies written by study investigators or the opinions of experts. A danger with relying on those with vested interest in a given intervention, could be misappropriating what is of value both to patients and clinicians. For example, drug and medical device companies could set research agendas to define what are relevant disease characteristics, what test and treatments to compare (thus of value) and what outcomes will be valuable.<sup>3</sup> Additionally, with a lot of drug therapies available that have marginal, if any, differences in outcome, it is important to be able to answer what is the best course of action for this patient, in these circumstances, and at this time in their illness or condition?<sup>8,18</sup> External evidence can inform but not replace individual expertise. This is what ultimately is drawn upon to balance research evidence plus clinical status, and decides what applies to whom and if it should be used in a decision. There may be tradeoffs that affect a given decision and some recommendations may be stronger or weaker based upon these factors such as cost, risks, and benefits. An online resource that can be used to develop recommendations based on these factors is <http://www.gradeworkinggroup.org>.<sup>16</sup> While costs are often not necessarily the focus of EBM, certainly effective care is important, and ineffective care would be seen as waste from a cost standpoint. Effectiveness depends on not only whether

something can work but also on the accuracy of diagnosing a condition, compliance with protocols, patient adherence, and coverage. Just because something can work doesn't mean it will be used in the right people, at the right time, if patients will take it right, or whether people can afford it.<sup>18</sup> Often, an overlooked area in the EBM process is an ideal way to present information to patients so that they can make an informed decision. Keeping in mind that the original reason to apply EBM is resolve patient issues or questions, the way this information is communicated to patients plays a large role in achieving optimal outcomes.

## **ASSESS**

We end where we started. That is, after applying the research evidence to the clinical situation and taking into account the patient preferences and values, we should seek out whether issues have resolved or whether new issues have presented. This is why this process is sometimes referred to as a cycle.

## **SUMMARY**

Evidence is essential, but not sufficient, for practitioners wanting to use EBM. The best available evidence, clinical context, and patient preferences integrated with clinical experience are what make up the hallmark of decision making.<sup>7</sup> Without clinical experience, practice is at risk of becoming dictated by checklists on appraisal of evidence, which may be inapplicable to or inappropriate for an individual patient. Without the best evidence, practice is at risk of becoming rapidly out of date, to the detriment of patients.<sup>1</sup> It is this individual expertise that can effectively integrate experience and evidence within context, decides whether external evidence should be applied at all, and if so, how it should be integrated.<sup>1</sup>

Efficient EBM practice requires formulating focused questions (PICO), matching questions to most appropriate resources, assessing confidence in estimates, and understanding how to apply results to clinical decision making. In addition, given the acknowledgment of time constraints, we need to ensure that management strategies are consistent with patient values and preferences.

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# CHAPTER 11

## RISK EVALUATION AND MITIGATION STRATEGIES (REMS)

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The Center for Drug Evaluation and Research (CDER) and the Center for Biologic Evaluation and Research (CBER) are the departments within the Food and Drug Administration (FDA) responsible for evaluating drugs (or biologics in the case of CBER) to make sure they are not only effective but safe for human use. Every prescription and over-the-counter medication is evaluated by CDER or CBER prior to market.<sup>1</sup> There are drugs that, although they have substantial therapeutic benefits, carry significant risks. To ensure that the benefits outweigh the risks, the FDA may require manufacturers to go beyond product labeling and implement special restricted access programs.

Risk management programs have been around since the early 1990s. One of the first medications to have prescribing and dispensing restrictions is clozapine (Clozaril®).<sup>2</sup> This antipsychotic significantly increases a patient's risk for agranulocytosis, so patients must obtain weekly blood counts to receive the drug. Physicians must monitor and submit lab results to the manufacturer's restricted access program in order to receive prescribing authority. The amount of clozapine dispensed is limited to the number of days until the next lab draw. Patients, physicians, and pharmacies must be registered with clozapine's "no blood, no drug" program to ensure compliance.<sup>2</sup>

Historically, such risk management programs were called Risk Minimization Action Plans (RiskMAPs). The Prescription Drug User Fee Act (PDUFA III) of 2002 allowed the FDA to suggest RiskMAP programs for drugs that might not otherwise be allowed on the market because of significant safety concerns. RiskMAPs were tools "...designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits."<sup>3</sup> Examples of these tools include targeted education, reminder systems, and performance-linked access systems (eg. clozapine's "no blood, no drug" program). Although effective, there were limitations to the program. RiskMAPs were voluntary and the FDA could only recommend a risk minimization program. They had no authority to require a manufacturer to comply, nor could they require postmarketing studies, labeling changes, or other safety communications. The FDA Amendments Act of 2007 expanded the FDA's authority regarding drug safety. A section of the legislation now allows the FDA to require



postmarketing studies and to mandate Risk Evaluation and Mitigation Strategies (REMS) for drugs that have the potential to cause serious patient harm.<sup>2,4</sup>

## **WHAT ARE REMS?**

REMS are strategies designed to mitigate a known or potentially serious risk associated with a drug or biologic product.<sup>5</sup> When determining whether or not a REMS is needed, the FDA takes into consideration the number of patients who would potentially use the drug, the seriousness of the disease or condition it's intended to treat, the duration of treatment, and of course, the expected benefit compared to the severity of its adverse effects.<sup>4</sup> The FDA can base its decision on results from clinical trials, adverse drug event reports, or post-marketing studies.

REMS can be implemented at any stage of the product lifecycle. It can be included as part of a license application for a new drug or new indication, or the FDA can require the implementation of a REMS for drugs already on the market if new safety information becomes available.<sup>6</sup> This is why post-market surveillance is so important. The number of people who participate in pre-market, Phase 3 clinical trials can be small compared to the larger population who ultimately uses the drug. Therefore, continually assessing the efficacy and safety of drugs post-market is necessary to identify any potential safety concerns not known at the time of a drug's approval process.

The FDA can mandate a REMS for drugs they feel need additional safety measures beyond that of standard professional labeling. These safety measures are unique to each drug or therapeutic class. Therefore, no two REMS are exactly alike. The following are potential elements of a REMS:<sup>6</sup>

- Medication guide
- Communication plan
- Elements to assure safe use (ETASU)
- Implementation system

Once a REMS is approved, it is enforceable. The FDA has the authority to hold the manufacturer accountable for not complying. If the manufacturer fails to implement a REMS, they can be fined. The FDA can also restrict its use by preventing the sale of the drug and/or consider it misbranded.<sup>4</sup>

## **REMS REQUIREMENTS**

A REMS can contain any one element or a combination of elements listed above. The specific

components of a REMS can vary based on several factors, including the severity of the drug's potential adverse effects and the population likely to use it.<sup>6</sup>

## Medication Guides

A medication guide is a handout written in patient-friendly language by the manufacturer highlighting important safety or efficacy information about a drug product. These are not the same as Consumer Medication Information sheet (CMI) which provide general information about all aspects of a prescription drug. Unlike CMIs, which are written by organizations or the private sector without review by the FDA, medication guides are written specifically for a drug product by its drug manufacturer. Since each medication guide is approved by the FDA, they are not interchangeable. Substitution of one manufacturer's medication guide for another is discouraged, even though the content for a generic drug may be similar to that of its brand name equivalent.

Medication guides may be related to safety, addressing potentially serious risks patients should be aware of prior to taking the drug or they can be about efficacy, where patient adherence to directions for use is important to a drug's effectiveness. The FDA determines whether or not a medication guide is required. Although close to 300 drug products have medication guides, only a small portion are part of a REMS. Typically, medication guides that are part of a REMS include an Element to Assure Safe Use (ETASU), which often have more stringent requirements.

If required, medication guides must be dispensed with every new prescription and with each refill. They do not, however, have to be given to patients in an inpatient setting (eg. hospital, nursing home) since the medication is being administered by a healthcare professional. The only exception is if the patient requests one or if the medication guide is part of a REMS that requires distribution to inpatients. In other settings where medications are dispensed to a healthcare professional for administration to a patient, medication guides are only required when the patient is receiving the medication for the first time or if the medication guide has been updated with new information. Examples of such settings include dialysis centers, physician offices, chemotherapy infusion clinics, home health care, etc.<sup>7</sup>

Setting	Patient or Patient's Agent Requests Medication Guide	Medication Guide Provided Each Time Drug Dispensed	Medication Guide Provided at Time of First Dispensing	Medication Guide Provided when Medication Guide Materially Changed	Drug is Subject to an ETASU REMS that includes Specific Requirements for Providing and Reviewing a Medication Guide
<b>Inpatient</b>	Must provide medication guide	FDA intends to exercise enforcement discretion; Medication guide need not be provided	FDA intends to exercise enforcement discretion; Medication guide need not be provided	FDA intends to exercise enforcement discretion; Medication guide need not be provided	Must provide medication guide as specified in REMS
<b>Outpatient when drug dispensed to healthcare professional for administration to patient</b> (e.g., clinic, infusion center, emergency department, outpatient surgery)	Must provide medication guide	FDA intends to exercise enforcement discretion; Medication guide need not be provided	Must provide medication guide	Must provide medication guide	Must provide medication guide as specified in REMS
<b>Outpatient when drug dispensed directly to caregiver</b> (e.g., retail pharmacy, hospital ambulatory pharmacy, patient samples)	Must provide medication guide	Must provide medication guide	Must provide medication guide	Must provide medication guide	Must provide medication guide as specified in REMS

**Table 11-1.** Medication guide enforcement discretion policy<sup>7</sup>

## Communication Plan

While a medication guide educates patients, a communication plan is a REMS element that informs healthcare professionals about the safe and effective use of a drug product. Manufacturers use communication plans to inform health care providers about the risks of a drug. They are also used to educate them about REMS elements, such as the use of periodic laboratory tests for medical monitoring, and encourage implementation. Communication plans typically involve sending “Dear Healthcare Professional” letters. These are sent directly to the health care provider, disseminated through professional organizations, or distributed to specific practice settings. Communication Plans may also include training materials or presentations. Health care providers are then supposed to use the information to promote appropriate use of the drug and reinforce patient compliance.

The antidiabetic agent liraglutide (Saxenda®) is an example of a medication with a Communication Plan.<sup>5</sup> This REMS is required so that healthcare professionals are aware of liraglutide’s increased risk of thyroid carcinoma and acute pancreatitis.<sup>8</sup> The manufacturer’s Communication Plan for this drug includes a Dear Healthcare Professional letter, web-based information, and dissemination of a letter to professional organizations.

## Elements to Assure Safe Use

The most complicated and extensive component of a REMS is the Element to Assure Safe Use (ETASU). As defined by the FDA, they are “strictly controlled systems or requirements put into place to enforce the appropriate use of a drug.”<sup>6</sup> Drugs with ETASUs can be considered potentially harmful if not used appropriately. Therefore, this REMS element allows patients to have access to drugs known to have serious risk that would otherwise not be available.

Every ETASU is different. Medications with an ETASU may require that prescribers have specific training, experience, or be certified before being able to prescribe that drug.<sup>9</sup> Other ETASUs may require special laboratory monitoring and/or enrollment of patients in a drug registry. Still other ETASU may only allow the medication to be dispensed by a specialty pharmacy or dispensed to patients in certain healthcare settings, such as a hospital.

One example of a medication with an ETASU is Aveed® (testosterone undecanoate).<sup>5</sup> This injectable product is used to treat adult males with low testosterone levels. The REMS requires that it be administered by a trained healthcare professional in a doctor’s office, clinic, or hospital with on-site access to equipment because of its significant safety risks. Aveed® has the potential to cause anaphylaxis as well as pulmonary oil microembolism (POME), which is a serious lung condition that occurs when tiny droplets of castor oil contained in Aveed®

travel to the lungs.<sup>10</sup> Since anyone can experience these adverse reactions with any treatment, the ETASU requires that patients stay in the healthcare setting at least 30 minutes after receiving the injection for observation. Additionally, the REMS requires that both the prescriber and healthcare setting complete the REMS certification with an assessment of knowledge before being able to prescribe or administer the drug. The education program includes training on the proper administration of Aveed®, information on patient counseling, and understanding of how to manage POME and anaphylaxis.<sup>11</sup> Patients must also be aware of the potential side effects and agree to receive the drug, despite its significant risks.

### Implementation System

All ETASU include an Implementation Plan. This REMS element tells the FDA how the manufacturer plans to monitor patients, practitioners, and healthcare settings to ensure they are being compliant with the ETASU. It is also a way for the manufacturer to evaluate their REMS program and make improvements, if necessary.

For example, the Implementation System for Aveed® spells out exactly how the manufacturer will “...maintain, monitor, and evaluate” the REMS to ensure it’s meeting the program’s goals. It includes items such as maintaining a database of all certified healthcare providers, maintaining an informational call center and website, as well as completing an audit of certified healthcare settings. It also includes a timetable for when the manufacturer will submit assessments of the REMS to the FDA.<sup>12</sup>

### Timetable for Submission of Assessments

Assessments are also technically considered a REMS element. They are used to evaluate the effectiveness of a particular REMS. For example, healthcare professionals can be surveyed regarding their understanding of the safe use of a drug. Prescriber compliance with REMS certifications is another assessment tool. Data can also be collected on patient use of a particular drug. Depending on the results, REMS can be modified if the assessment shows changes are needed. REMS can even be eliminated if it has been shown that the REMS was successful at meeting its goals.<sup>6</sup>

### SHARED SYSTEM REMS

As of July 2017, there are 70 approved REMS.<sup>5</sup> With so many REMS and each one unique to a particular drug’s manufacturer, it has been very cumbersome for healthcare professionals to comply, especially for drugs with an ETASU. It is time consuming for a physician to make sure he/she has completed the required training before writing a prescription or for a pharmacist

to verify a patient's labs in a registry before dispensing a medication, for example. To minimize the workload and burden on healthcare systems, the FDA has been moving towards the development of standardized REMS. For some identical or closely related drugs (ie. drugs within the same therapeutic class), the FDA has mandated drug companies to develop a single, shared system REMS. One such example is isotretinoin's iPLEDGE program.<sup>13</sup>

Isotretinoin is a drug used for the treatment of severe acne. Studies have shown a 15-20 week course of therapy to be effective at improving nodular acne. However, isotretinoin is teratogenic and serious birth defects, spontaneous abortion, and premature births have been reported.<sup>14</sup> Therefore, the REMS for isotretinoin informs prescribers, pharmacists, and patients about the drug's serious safety risks and safe-use conditions with the goal of preventing fetal exposure to isotretinoin. In the past, every manufacturer of isotretinoin, brand and generic, had their own REMS each with different ETASU. This made prescribing and dispensing isotretinoin extremely challenging and frustrating. To consolidate and simplify the process, the FDA requested that all the manufacturers of isotretinoin products work together to create one standardized REMS. This single, shared system REMS, called iPLEDGE, includes a medication guide, ETASU, and implementation plan.<sup>14</sup>

Prescribers, pharmacies, patients, and wholesalers must all be registered with the iPLEDGE program.<sup>14</sup> It is a computer-based program that tracks and verifies the critical elements of the program. Prior to receiving the medication, females must commit to 2 simultaneous forms of birth control. They must also complete Patient Monthly Comprehension Questions and a pregnancy test before each prescription.<sup>15</sup> Physicians then enter the results of the pregnancy test and the patient's forms of contraception into iPLEDGE. The pharmacist must obtain verification from iPLEDGE before given authorization to dispense isotretinoin to the patient. Since patients are required to meet these same criteria every month, refills are not allowed and only a 30 day supply can be dispensed.<sup>15</sup>

## **REMS FOR OPIOID PRODUCTS**

There are several other single, shared system REMS including a number of class-wide programs for opioid agents. Not only were these designed to streamline the REMS process, but the opioid REMS are part of a larger, federal initiative aimed at reducing prescription drug abuse, misuse, and overdose. Extended-release and long-acting (ER/LA) opioid products were identified as a subset of opioids at high risk of abuse and misuse, while simultaneously having a high volume of use. The misuse and abuse of this potent class of drugs led to a significant health crisis of addiction, overdose, and death. According to the CDC, 40 people die every day from prescription painkiller abuse. As a result, a class-wide REMS was

introduced for all ER/LA opioid products and their generic equivalents.<sup>16</sup>

The purpose of the ER/LA Opioid Analgesics REMS is to reduce risks while maintaining patient access.<sup>17</sup> This potent class of drugs is intended to manage chronic pain and serious medical conditions, so it's important that these products continue to be available for patients with these conditions. Unfortunately, they often lead to improper use and then abuse. One in 20 individuals age 12 and older admit to taking prescription opioids for non-medical use.<sup>18</sup> It is thought that prescribers are contributing to this abuse and misuse epidemic, as the number of painkillers prescribed over the past 15 years has quadrupled.<sup>19</sup> As a result, prescriber education and patient awareness are the main components of the ER/LA Opioid REMS.

Currently, prescribers are not required to complete the training associated with ER/LA Opioid REMS; however, it is "strongly encouraged".<sup>20</sup> In addition to educating prescribers on proper pain management and patient selection, the REMS education program includes patient counseling tips. Patients should be aware of opioids' addiction potential, informed on the proper disposal of expired or unused medications, and the need to lock them away when not being used.<sup>21</sup>

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# CHAPTER 12

## HOUSEHOLD DISPOSAL OF PRESCRIPTION DRUGS

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The amount of unused, unwanted, and expired medications is a growing problem that is significantly impacting our healthcare system. Not only is it costly, but the health and safety of patients and our environment is being affected. One recent study found that approximately 2 out of 3 prescription medications per household were unused.<sup>1</sup> The most common reason cited by study participants was discontinuing use because of improvement in their medical condition and/or symptoms. Other reasons included side effects, expiration, felt it wasn't helping, felt they no longer needed to take it, or forgot to take it. Noncompliance is a major contributing factor to the volume of unused/unwanted medications and it is costing the United States about \$100 billion per year in extra medical costs.<sup>2</sup> According to a 2010 bulletin published by the World Health Organization, only about half of the population takes their medications correctly. Additionally, more than half of prescriptions are prescribed, dispensed, or sold inappropriately, further contributing to household possession of excess medications.<sup>3</sup>

Medications left unused in the home pose potential safety concerns. For example, if an elderly patient has multiple medication bottles in their medicine cabinet they are at a greater risk for inadvertently taking the wrong drug or duplicating therapy.<sup>4,5</sup> Accidental ingestion is also a concern.<sup>5</sup> There have been over 30 reports received by the FDA of accidental exposure to fentanyl patches, a potent opioid analgesic. Most of these involved small children less than 2 years old that resulted in hospitalization or death.<sup>6</sup> Drug overdose is another safety concern; it's the leading cause of death by injury according to the CDC.<sup>7</sup> Having excess medications laying around the home also leads to diversion.<sup>5</sup> When a national survey asked nonmedical users of opioids where they obtained their drugs, more than 50% said a family member or friend gave it to them, over 10% bought them from family or friends, and about 5% just took them.<sup>4</sup> Therefore, properly disposing of unused, expired, and unwanted medications is important to help minimize the risk of accidental exposure, intentional misuse, or diversion.

Studies have found that consumers don't always know how to dispose of medications properly, nor do they remember receiving education on proper storage and disposal.<sup>1,8</sup> The majority either throw them away in the trash or use the toilet or sink for disposal.<sup>7</sup> Such

practices have been questioned in terms of their safety and appropriateness.<sup>9</sup> Disposing of medications via sink or toilet has a negative impact on rivers, streams, and supplies of drinking water. A US Geological Survey that studied water in Minnesota found organic contaminants in 90% of the samples tested, most of which were prescription and nonprescription medications.<sup>10</sup> Although not at therapeutic levels, active therapeutic ingredients in water could be dangerous not only to humans but to wildlife as well.<sup>11</sup> Disposing of unwanted medications in the trash has its own set of concerns. Throwing away prescription bottles with personal, patient information on the label can lead to identity theft. It can also be a source of accidental exposure by children and animals or contribute to drug diversion.

Various organizations have developed programs or guidelines on the proper disposal of medications, including the Office of National Drug Control Policy in conjunction with the Food and Drug Administration (FDA). These federal guidelines suggest:<sup>12</sup>

- taking advantage of pharmaceutical take-back programs in the community
- using appropriate safeguards when throwing away medications in the trash
- flushing drugs down the toilet or drain ONLY if advised by the FDA and/or instructed by printed material accompanying the medication

## **COLLECTION PROGRAMS**

Drug take-back programs are the preferred method for disposing medications.<sup>4,5,12</sup> These programs allow consumers to bring their unwanted and expired medications to a central location for proper disposal. Collection events are designed to ensure that unused, expired, or unwanted medications are collected anonymously and destroyed in a way that is safe, legal, and environmentally sound.

There are various types of take-back programs available, ranging from small, one-day events to on-going collection sites. City, county, and state sponsored take-back programs are available. One such event is the National Prescription Take-Back Event hosted by the Drug Enforcement Administration (DEA) twice a year, once in the spring and again in the fall.<sup>13</sup> These events have been extremely successful. In April of 2017, the DEA, along with more than 4,000 state and local law enforcement partners, held its 13<sup>th</sup> Take-Back event which collected over 900,000 pounds of unwanted medications across 50 states.<sup>14</sup> The DEA's take-back events began in 2010 with the passing of the Secure and Responsible Drug Disposal Act which was intended to help address the growing prescription drug abuse epidemic. According to a

recent National Survey on Drug Use and Health, 6.5 million Americans abuse prescription drugs.<sup>15</sup> As mentioned previously, the majority of abused drugs are obtained from family and friends. Therefore, it's extremely important to get rid of unwanted, unused medications. In the past, however, only law enforcement officials were allowed to take-back and inventory controlled substances at collection events. This act gave the DEA authority to expand ways in which the general public can dispose of medications, including controlled substance prescriptions, safely and conveniently.

In October of 2014, the DEA's revisions to the Controlled Substance Act were implemented. The Disposal of Controlled Substances Rule now allows authorized collectors to accept unwanted, unused, or expired prescription medications, including controlled substances, by providing collection receptacles and/or mail-back programs.<sup>16</sup> Medications can only be placed in the receptacles or mailed by *ultimate users* which is defined as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household."<sup>17</sup> Pharmacy staff are not allowed to do it on their behalf. So who is considered an authorized collector? Facilities, such as retail pharmacies, hospitals and clinics with on-site pharmacies, narcotic treatment programs, long-term care facilities with pharmacies, manufacturers and distributors can volunteer to become an authorized collector simply by modifying their DEA registration. Many law enforcement or police stations are authorized collection sites as well.

Facilities that choose to have collection receptacles must follow certain requirements. Receptacles must:<sup>16</sup>

- have tamper-evident, waterproof, tear-resistant inner liners
- be securely fastened to a permanent structure so that it cannot be removed
- be placed in a location that is not only be accessible to the public but where employees are present

Pharmacies that choose to offer mail-back programs can sell or provide at no cost prepaid, pre-addressed mail-back packages. Packages must:<sup>16</sup>

- be nondescript, water- and spill-proof, tamper-evident, tear-resistant, and sealable
- include a unique identifier that can be tracked
- sent to authorized collectors that destroy medications on-site

Information about take-back programs in your area can be obtained by contacting local waste management agencies. Online resources, such as Dispose My Meds, DEA's Office of Diversion Control, US Environmental Protection Agency, and Recycle Indiana – Unwanted

Medicine, are also helpful for locating pharmacies and authorized collection sites with options for safe disposal of unwanted, unused, and expired medications.

## **HOUSEHOLD DISPOSAL**

In the event that a take-back program or authorized collector is not available, most medications can be disposed of in the household trash. Several agencies, including the FDA, DEA, and EPA recommend the following steps for properly disposing of unwanted, expired, and unused medications:<sup>5,18</sup>

1. Take drugs out of their original containers.
2. Mix the medications with a substance that is unpalatable and undesirable, such as dirt, kitty litter, or used coffee grounds.
3. Place the mixture into a disposable container, such as a sealable bag.
4. Throw the sealed container away in the household trash.
5. Remove, cover with permanent marker, or scratch out all personal information on the prescription label of the empty pill bottles and medicine packages to make it unreadable before placing them in the trash.

## **FLUSHING**

Not all medications should be thrown away in the trash if a take-back event or collection receptacle is not available. The FDA recommends disposing of certain medications by flushing them down the toilet or sink. There is a small list of medications that are considered life-threatening if taken by someone other than the person for whom it's intended.<sup>17,18</sup> These drugs are mostly high-potency opioid analgesics and other controlled substances that are not only dangerous if accidentally ingested by a child or pet, but are more likely to be associated with drug diversion and misuse. Examples include fentanyl, morphine, and oxycodone. The most complete and up-to-date list of medications recommended for disposal by flushing can be found on the FDA's webpage on Disposal of Unused Medication.<sup>18</sup>

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# VALUE

In the perspective of access, cost and quality, value is the balance of quality with cost. In other words, value equals quality divided by cost. Access is assumed to remain constant for this determination because without continued access there can be no value. Value can be increased either by increasing the quality or decreasing the cost. In order to determine value we must be able to measure quality.

As discussed in Section 3, health outcomes are one way to measure quality for healthcare providers. Patient satisfaction, time off work and quality of life may be different ways patients measure quality. Since quality can change by perspective, value changes as well. For example, a treatment for cancer may continue to decrease the size of a tumor but the quality of life provided during that treatment may not be worth it to the patient. In the first part of this example, value as measured by the oncologist is determined by the decrease in tumor size divided by the cost of the medication and any health care provider fees. In the second part of this example, value to the patient is quality of life is divided by the cost of the medication and any health care provider fees. There may come a point at which the patient feels the value assessed by the health care provider, decreased size of tumor, is less than the value to them in terms of quality of life.

Different pharmacoeconomic evaluation methods are used to measure quality and value for patients and health care providers. Through provisions of the Affordable Care Act, the Centers for Medicare and Medicaid Services (CMS) developed a payment option for acute care hospitals that bill CMS for services provided to Medicare patients. This is called hospital value-based purchasing.<sup>1-3</sup>

Value-based purchasing rewards hospitals based on the quality of care they provide to patients, how closely recommended guidelines are followed and the extent patients are satisfied with their hospital experiences.<sup>1</sup> Previously hospitals were paid by Original Medicare on a fee for service basis as explained in Section 1, Chapter 1. This means they were paid for the quantity of services they provided (paid for each service provided). The movement away from quantity and towards value pays hospitals on the quality of the care they provide and the value they provide to patients. There are many criteria in which quality and value are measured which is beyond the scope of this chapter. Hospitals can choose to participate in these new payment models. If they do each hospital receives a score on these



different measures. The results are compared to other hospitals and provided publically. Data on hospitals participating in this model is provided on the CMS website.<sup>4</sup> The score is also used for each hospital by comparing yearly performance to a baseline score for that specific hospital. This allows hospitals to demonstrate improvement.

The incentive for participating in the value-based program is initially financial. At the start of this initiative CMS reduced the payments to hospitals for the care they provided to Medicare patients. The score is then used to redistribute the money back to those hospitals with the highest score. Therefore, the hospitals that do well receive more payment for services than those who do not score well. An added benefit for those hospitals that don't just score well but who make a noticeable improvement from a patient perspective is that those patients may refer other patients to that facility. Increasing the revenue for that hospital. Since different patients and communities may view improvement differently, health systems may need to consider the communities they serve. Physician practices have a similar program to the acute care hospital value-based purchasing program. This program, currently referred to as the Quality Payment Program (QPP), provides incentives for physicians and clinics to be rewarded for quality and value to patients.<sup>5</sup>

While healthcare providers have always been focused on caring for individual patients, value based changes have the potential to change how care is delivered to all the patient served in a specific office or hospital. One example of value is electronic prescribing. Electronic prescribing allows pharmacists to receive prescriptions quicker and often more legibly than before. This improves health outcomes. Patients receive value because the prescription can be sent to the pharmacy before the patient leaves the clinic and the prescription is more likely to be ready when they get to the pharmacy. Despite the work involved in purchasing and learning new computer software, the subsequent value associated with this change has changed how pharmacy services are provided. Looking back at our earlier example, if all practitioners changed how they viewed value for cancer therapies it might change how we approach cancer therapy especially in end of life decisions. Therefore, value based changes made by multiple offices or hospitals can lead to changes for an entire population of people.

## **POPULATION HEALTH**

The education of healthcare providers is focused on preparing providers to serve the needs of individual patients. However, sometimes the needs of one patient may be applied to multiple patients within an institution or practice. If this need impacts the community as a whole, a public health concern might arise. This is especially important if the condition impacts others either because it can be easily transmitted to others or it uses significant financial

resources. The connection between public health and healthcare delivery is hundreds of years old.<sup>6</sup> Initially, focused on communicable diseases, public health means so much more today and is sometimes referred to as population health. However, population health usually relates to large efforts by an institution such as a health systems or health care payer whereas public health is more general. As mentioned above, as quality and value are improved for patients, facilities, and communities, the impact continue to expand to new populations. These initiatives and innovations can impact a single state or in the case of the value-based program the entire United States population.

While the value-based program is one example of a population-based initiative, many different population-based local, state, and federal initiatives are taking place. The use of healthcare information technology is one source of information for population health initiatives. This includes patient care electronic medical records, insurance based electronic claims transmissions, and pharmaceutical and device company data collection. The analysis and use of these large databases of information are often referred to as data analytics. For example, data collected primarily from health insurance claims allows payers for health care to determine how best to spend their money.

Expanding the view of healthcare beyond the patient-provider relationship, expands our discussion of value. Payers must consider value for the health care they purchase. Medicare was the payer in the value-based program mentioned earlier but state Medicaid programs and private insurance companies are also interested in establishing payment based on value. As more payers seek value, healthcare providers will need to continue to justify value in their daily operations. This perspective can be applied to pharmacy practice as well.

Brian is a 55 year old patient with multiple sclerosis. Because of his condition, he requires a high cost injectable medication that has side effects. Brian gets this medication from specialty pharmacy X. His medication is paid for by insurance company Y. The medication is made by pharmaceutical manufacturer Z. Because of the high cost of the medication, the value of paying for this medication has to be determined by insurance company Y. If the medication keeps Brian, and others like him, from incurring other medical expenses, there is likely a value for insurance company Y to pay for Brian's medication, as long as the cost does not outweigh the benefit. The insurance company however does have to consider that the more medications it covers, even if they all add value to their patients. This means it will add cost to the plan which will likely result in increased premiums or co-insurance rates for all patients being served by that insurance company. All the patients served by that insurance company would be the "population" served by their insurance company.

Pharmaceutical manufacturer Z has to be able to demonstrate that value, determined by the payer, to justify the price they place on their medication. This could change the strategy of pharmaceutical manufacturer Z; not only do they need to show that their medication is effective but they need to show that the medication produces appropriate value. Assuming that manufacturer Z is able to demonstrate value to insurance company Y, then the patient will be able to order the medication from the specialty pharmacy X.

When Brian begins treatment and obtains the medication from the specialty pharmacy, specialty pharmacy X must demonstrate that they are providing Brian the medication in a timely manner, without interruption, and that they are supporting Brian through his treatment, such as answering questions and addressing side effects. The reason that the specialty pharmacy needs to demonstrate this is because the payer and the manufacturer have a role in determining which specialty pharmacy will supply the medication to the patient. If the specialty pharmacy wants to maintain that business, they need to demonstrate their value to the payer and manufacturer.

If the patient is not adherent or successful on the medication due to preventable causes, such as delay in receiving treatment or misjudging a potential side effect, the money that has already been spent on that medication was wasted. This wasted money reduces the amount of money available to be spent on other patients in the population of that insurance company. In the case of wasted dollars, money for no value.

## **ADVOCACY, PUBLIC POLICY, POPULATION HEALTH AND VALUE**

Every day that pharmacists care for patients, they advocate for their success. This may include discussing a medication change with the prescriber based on a new study, negotiating coverage with the insurance carrier based on patient experience, or providing advice on proper medication disposal. The development of policies for a practice site may include establishing guidelines for antibiotic use or setting prescribing guidelines for a new formulary agent. When, these policies extend beyond individual advocacy they serve as advocacy of the site population. When multiple advocates seek for higher level population changes, such in the form of laws or regulations, this is referred to as public policy.

Public policy development involves the creation of laws and regulations as well as identifying the necessary budgets and resources necessary to make them a reality.<sup>7</sup> For example, **Section 1: Chapter 3** discusses the growth in ambulatory care, the need for provider status and the importance of billing for services. Different legislation and regulation is needed at the federal and state level to support provider status to allow pharmacist to be recognized as health care

providers who can bill for their services. Without the approval of federal funds to support payment to pharmacists, which is based on the demonstrated value of pharmacists, the proposed legislation would not be implemented.

The process of public policy development can be divided into three phases: 1) formulation, which involves deciding what to focus on, 2) implementation, which involves executing the policies, and 3) modification, which involves reviewing current policies and identifying areas for improvement.<sup>8</sup> At each stage different special interest groups may demonstrate a voice. For healthcare policy, these may include employers, payers, providers, consumers, etc.

Public policy efforts initiated by volunteers or members of an association that are advocating for themselves is often called grassroots efforts. Public policy efforts initiated by paid individuals is called lobbying and these “lobbyists” register with the government entity they serve. For example, state and national pharmacy associations are involved in many kinds of advocacy and policy development. The participation of their members is considered grassroots but they may also hire paid lobbyists to assist with the cause.

The target of public policy may be legislators or one of many government agencies that make decisions on health policy. Locally, this may include the state department of health, board of pharmacy, department of insurance, etc. At the federal level, regulatory agencies include the Department of Health and Human Services (DHHS), Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), etc. In addition to government agencies, several non-government (private) groups are influential in setting health care policy. These include the Institute of Medicine (IOM), The Joint Commission (JTC) and the American Medical Association (AMA).<sup>7</sup>

Policy decisions are often supported by data collected by individuals who do health services research. These researchers examine the influence that pharmacists and other health care providers have on patients and the health care system. This is a robust field in the current environment of frequent health care reform.<sup>8</sup>

## **CONCLUSION**

The authors of this text expect that many changes will continue to happen with healthcare reform in the United States over the next several years. While the authors cannot predict these changes, the fundamentals of health care reform presented in this book are likely to remain: the focus on access, cost, and quality. And specifically, the renewed focus of value will continue to evolve the health of patients and populations.

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