Applied Law & Ethics in Health Care

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Dedication

I dedicate the first edition of *Applied Law & Ethics in Health Care* to you, the health care students who have braved all that comes with chasing your dreams, working late into the night, and making sacrifices so you can serve others. I thank you today for becoming tomorrow's guardians of quality health care.

I also dedicate this book to my three sisters, Debbie Esola, Jill Peace, and Erica Pardew, each of whom provided inspiration, encouragement, humor, and perspectives that made writing this textbook so gratifying.

"Go into the world and do well.
But more importantly, go into the world and do good."
— Minor Myers, Jr.

Wendy Mia Pardew
St. Petersburg, Florida
September 2021

Contents

Preface

All health care professionals have a critical need to understand law and ethics as applicable to the health care industry. Maintaining a safe, legal, and ethical health care environment is a shared responsibility of all members of the health care team. To that end, this text is written for a variety of health care professionals, rather than one specific profession. This text can be used in a multidisciplinary health care law and ethics course or by law and ethics courses specific to a health care profession.

The text focuses on legal and ethical topics that apply throughout the health care industry, including the concepts of standard of care, scope of practice, criminal and civil acts, contracts, negligence, health care ethics, and more. This text reflects new health care regulations and technology, and it will prepare future health care professionals for the changing health care environment. The spectrum and depth of topics contained in this text makes it valuable as a resource that would be wise to keep handy long after graduation.

The issues discussed in this text occur in the real world. As a result, actual legal decisions and real-life anecdotes illustrate concepts and enhance understanding. The underlying concept coupled with the cases and anecdotes ensure readers can understand, digest, and apply the material, while also sparking interest and engagement.

Patients' health care needs will continue to expand. And, just as methods of treatment will change, methods of health care delivery and compensation will also change. The law strives to keep pace with the new issues raised due to new maladies, treatments, technology, and regulations. This text serves as an invaluable resource for health care professionals working in the center of this exciting and often challenging time of change.

Organization of the Text

This text is designed to cover the most common legal and ethical issues health care professionals will encounter. Chapters start by exploring the business of health care and the legal system in general (Chapters 1–4) and then move through legal topics students need to know, such as

standard of care, employment laws, criminal and tortious acts, contractual issues, negligence, medical malpractice, and more (Chapters 5–7). The conversation then turns to ethics, presenting the basics of health care ethics, and moving on to discussions of the allocation of scarce resources, medical research, reproductive issues, and end-of-life issues (Chapters 8–12). Each chapter is designed in a similar fashion: first providing student focus through Objectives and Key Terms; then presenting concepts coupled with relevant legal cases and news stories; and ending with a summary and activities for students to apply what they have learned.

Features

The key features in this text are designed to support learning and show real-world context of chapter concepts. The following is a brief description of each feature:

- **Quotes:** Relevant and thought-provoking quotes appear at the start of each chapter and throughout the text.
- **Objectives:** Each chapter begins with a list of objectives to focus attention on what students need to learn.
- **Key Terms:** A list of key terms appears at the start of each chapter, and each key term is presented in boldface and defined in the margin of the text where the term first appears in the chapter.
- **News Stories:** Timely examples of legal and ethical health care dilemmas in the news illustrate chapter concepts and promote engaging discussions.
- **Legal Case Studies:** Summaries of actual legal cases highlight the legal issues and actions most prevalent in health care today.
- **Summary:** A bulleted list of key concepts serves as an at-a-glance study tool.
- **Suggested Activities:** Students can complete a list of additional activities to further engage with the chapter material through research, role play, field trips, and other exercises.
- **Study Questions:** These questions quiz students on their ability to understand and apply key chapter concepts.
- **Case for Discussion:** Real and fictional court cases allow students to practice applying what they have learned.

What's New

Applied Law & Ethics in Health Care, first edition, is an evolution of *Law, Liability, and Ethics for the Medical Office Professionals*, sixth edition, and it is intended for a for a variety of health care professionals.

This edition seeks to make health care law and ethics accessible, interesting, and relevant for students in a range of health care disciplines.

As such, chapters have been reorganized to build on content from preceding chapters to deliver a clearer, deeper picture of legal realities in modern health care, and updated content has been added. New content reflects recent legislation, including the Affordable Care Act (ACA), telemedicine, and euthanasia, among other critical topics. In addition, new legal cases and news stories have been added throughout the text to address some of the most recent dilemmas in medical offices and hospitals throughout the United States. Many key term definitions have been revised for greater clarity. To assist with comprehension, summaries at the end of each chapter are tied to the objectives at the start of each chapter to help students further understand core chapter content at-a-glance. Ethics content has also been expanded in Chapter 8 to provide students with more instruction on ethical decision making and ethical theories.

A chapter-by-chapter summary of major content updates is included below:

Chapter 1—The Big Business of Health Care and You

- New content on certification; scope of practice; vicarious liability; health care delivery systems; surprise billing; HSAs; and technology and medicine, including impact of COVID-19 upon telemedicine and health information on personal electronic devices

Chapter 2—Laws and Regulations You Will Encounter

- Additional content on licensing; scope of practice; medical license revocation or suspension; mandatory reporting; chain of custody, workplace sexual harassment; the Americans with Disabilities Act; Medicare and Medicaid; and unions and health care workers
- Expanded "Controlled Substances Acts" section, including information on the Controlled Substances Schedules, Drug Enforcement Agency, and United States Pharmacopeia (USP)

Chapter 3—From the Constitution to the Courtroom

- Additional content on common law and the phases of a lawsuit

Chapter 4—Criminal Acts and Intentional Torts

- Additional content on classifications of murder; fraud, including false billings, and delegation of duties; and defamation of character
- New content on federal and state anti-kickback statutes, including the Stark law
- Expanded and revised "Abuse" section, including content on child abuse, elder abuse, domestic violence, and sexual assault

- Additional content on reporting illegal activities in the health care setting following proper protocol and completing an incident report related to patient care

Chapter 5—What Makes a Contract

- Additional content about collections, bankruptcy, and termination of delinquent patients

Chapter 6—Medical Malpractice and Other Lawsuits

- New content on expert witnesses and health care providers' duty to their patients
- Additional content on statute of limitations; causation; informed consent; the impact of medical malpractice suits; and defensive medicine

Chapter 7—The Health Record

- Additional content on electronic health records
- New content on HITECH; goals and benefits of data interoperability; source of privacy rights and the Tarasoff case; patient and family access to health records; release of patient information; and chain of custody

Chapter 8—Introduction to Ethics

- New content on definition of ethics; morals; development of values; and professional etiquette
- New section entitled "Ethical Theories", including information about deontology, teleology, utilitarianism, and virtue-based ethics
- New section entitled "Ethical Decision Making", explaining common steps in ethical decision making
- New section entitled "Personal Ethics in the Workplace", differentiating personal and professional ethics

Chapter 9—Laws and Ethics of Patient Confidentiality

- Additional content differentiating patient confidentiality, privacy, and privileged communication
- New content on HIPAA, including the Privacy Rule, the Security Rule, HIPAA compliance, the Enforcement Rule, the Breach Notification Rule, violations and penalties, and filing a HIPAA complaint
- New sections entitled "HIPAA-Authorized PHI Uses and Disclosures" and "Patient-Authorized PHI Uses and Disclosures"

Chapter 10—Professional Ethics and the Living

- New content on the allocation of scare resources; the ethics of transplants; and medical tourism

- Additional content on clinical trials and autonomy versus paternalism in health care

Chapter 11—Reproductive Issues and Early Life

- Updated content on artificial insemination and assisted reproductive technology; genetic testing before birth; embryonic stem cells for research; cloning and gene editing; and medicolegal rights of the fetus and the newborn

Chapter 12—Death and Dying

- Updated content on attitudes toward death; dying and the Uniform Determination of Death Act (UDDA); and the right to die

Instructor Resources

Additional instructor resources for this product are available online. Instructor assets include an Instructor's Manual, Solution and Answer Guide, MindTap Educator's Guide, Transition Guide, PowerPoint® slides, and a test bank powered by Cognero. Sign up or sign in at www.cengage.com to search for and access this product and its online resources.

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The MindTap includes:

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- Concept Checks: Short, low-stakes quizzing designed to assess students' reading comprehension and progression toward mastery of learning objectives
- Case Studies: Scenarios with auto-graded questions
- Writing Assignments: Prompts for students to complete additional research on chapter topics
- Quizzes: Additional multiple-choice questions testing students on learning objective mastery

To learn more, visit www.cengage.com/training/mindtap.

Acknowledgments

Writing the first edition of *Applied Law & Ethics in Health Care* was a team effort, and I was lucky enough to work with the A-team. Several people deserve acknowledgment, praise, and my most sincere thanks: Stephen Smith, for inviting me to take on another rewarding project and for his boundless professionalism and support; Sharon Chambliss, Senior Content Manager, for expertly and enthusiastically guiding me through the copyediting and other final stages of the textbook's production; and, my family and friends for their support and for enduring the many times I had to say, "I can't, I am writing."

Also, I would like to highlight my thanks to Cengage's Learning Designer Kaitlin Schlicht and her exceptional collaboration. This is the second textbook I have worked on with her. Kaitlin has once again patiently, precisely, and perfectly guided me through the substantive writing process. At every stage and with every draft chapter submission, Kaitlin was focused, meticulous, challenging, and engaged in her feedback. Thank you, Kaitlin.

I am indebted to the first edition reviewers listed below whose experience and willingness to contribute helped make this edition one we can all be proud of.

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Chapter 1

The Big Business of Health Care and You

> "Wherever the art of medicine is loved, there is also a love of humanity."
>
> Hippocrates

Objectives

After reading this chapter, you should be able to:

1. Recognize the importance of your role on the front lines of the health care industry.
2. Differentiate among registration, certification, and licensure for health care professionals.
3. Identify proper protocol when a health care professional is asked to perform a task outside of the scope of practice.
4. Summarize what is meant by personal protection and provider protection.
5. Compare standard of care for medical assistants and for different health care professionals.
6. Summarize laws and standards that protect patients.
7. Identify the different types of legal entities.
8. List the main types of managed care organizations.
9. Explain the risks and rewards of telemedicine.

Building Your Legal Vocabulary

Agent
Bylaws
Capitation
Certification
Conglomerate
Directors
Dividends
Fee-for-service
Investment
Joint venture
Legal entity
Licensure

Negligence
Negotiated fee schedules
Notice
Officers
Per capita payment
Reasonable person
Registration
Respondeat superior
Scope of practice
Shares
Standard of care
Stockholders
Utilization review
Vicariously liable

Introduction to the Business of Health Care

Technological advances, mergers of insurance and health care companies, pharmaceutical companies increasingly driven by profit, continued medical malpractice lawsuits, and changes to health care delivery and compensation systems, among others, have all contributed to the health care industry becoming big business. Nationally, the annual health care expenditure grew from $3.0 trillion in 2015 to $3.8 trillion in 2019. From 2019 to 2028, the United States expects to see annual health spending grow at an average rate of 5.4 percent, which would amount to $6.2 trillion by 2028. Centers for Medicaid & Medicare Services. (16 December 2020). Historical. Retrieved from www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.

The business of health care continues to grow increasingly complex. As a health care professional, you will be on the front line of this multi-trillion-dollar industry and how you perform on the front line matters. You will be entrusted with tasks and information that, in the most extreme situation, could mean the difference between life and death. In addition to being familiar with information that will allow you to perform your duties competently and professionally, frontline health care professionals also need to be familiar with the liability and risks that can result in a lawsuit or other undesirable consequences.

The health care industry has many competing interests as providers, nurses, medical office professionals, hospital employees, and others employed in the health care field work to achieve their objectives. Those objectives are most often related to balancing maximum personal financial gain through the health care services provided while delivering quality health care and complying with laws, regulations, and health insurance company protocols. The health insurance companies seek to reduce costs and maximize profits. Employers want to reduce the cost of the health insurance they provide to their employees. The government wants to protect its citizens and manage health care costs. And, patients want the best possible care at the lowest possible price. These competing interests form the framework of the big business of the health care industry.

The industry relies upon competition and regulation to control health care costs. Competition in business has led employers, governments, and health insurance companies to seek control of escalating costs through regulation. Health insurance companies, eager to gain market share, develop new products intended to help manage ever-increasing health care costs. This competitive approach has given rise to managed care organizations (MCOs), which are health care delivery and compensation systems that are different than the traditional pay-for-fee service.

The health care business' framework also includes the legal entities health care businesses use and how health care is delivered and compensated. A solid and well-rounded understanding of these aspects of the health care business will ensure you are the best professional possible while on the front lines.

The Front Line Is You

A patient's first interaction when undergoing care is usually with a frontline health care professional, and this may very well be you. It is the frontline health care professionals who communicate most frequently with patients. What you know and how you conduct yourself can influence patients' experiences and outcomes. The health care industry is a complex maze of laws, regulations, protocols, and interactions that you will want to understand.

To be the best professional you can be, a well-rounded understanding of the health care industry is essential. For your patients, "the best professional" means providing the most professional, efficient, and effective service for them that you can. For your employer, it means representing yourself and your employer in a professional manner, as well as ensuring you do all that you can to prevent complaints, lawsuits, regulatory violations, mistakes, and any other act that creates risk for you, your patient, or your employer.

The Importance of Legal Knowledge

Medical malpractice, licensing and regulations, employment law, federal health care laws, and corporate mergers are just some of the legal issues that arise in the health care industry today. When you understand the nature and scope of these issues, how they arise, and how they affect a business, you can recognize situations that may lead to an unwanted legal action and know what to do when you see such situations brewing.

Today, health care professionals participate in many aspects of the delivery of health care. They are held to a higher **standard of care** than laypersons who do not have your special knowledge and training. Some health care professionals, such as physicians and nurses, are held to the standard of care established by **licensure** and **registration** boards at the national or state level. Professionals who have earned a

standard of care The amount of care that a reasonable person in similar circumstances would exercise.

licensure Completion of basic minimum qualifications required by the state for that profession.

registration Recordation and maintenance of professionals' license-related administrative information.

Table 1-1 Licensure, Registration, and Certification

	Licensure	Registration	Certification
Definition	completion of basic minimum qualifications required by the state for that profession	recordation and maintenance of professionals' license-related administrative information	endorsement by an accredited professional organization that the holder has specific expertise as evidenced by passing an examination
Objective	indicates the license holder has met the requirements needed to work in a specific profession	verifies and records administrative information about licensed professionals	identifies certain areas of specialty or expertise earned by the licensed professional

certification Endorsement by an accredited professional organization that the holder has specific expertise as evidenced by passing an examination.

scope of practice The tasks and services that a qualified health care professional is considered competent and allowed to perform pursuant to their license, or, if no license, their education, and experience.

certification often have a higher level of skill in a specialized area, and have proven their expertise through testing or other processes. Table 1-1 shows the differences between licensure, registration, and certification.

Part of being a health care professional includes fully understanding what **scope of practice** means with regard to what you do. Many categories of health care professionals are not licensed to practice medicine and must carry out their responsibilities without making medical decisions or acting outside of their area of expertise. If you are ever unsure if a task requested of you is within your scope of practice, ask your employer and ensure you get an answer that you fully understand. This is true even if it is a little uncomfortable to do so. You should be provided with the training, support, and supervision to do your job. You should also have the opportunity to voice concerns about what you are asked to do if you are unsure whether it is within your scope of practice.

Personal and Provider Protection

By understanding basic principles of the law as they pertain to health care, you can better protect yourself from litigation, damage to your professional reputation, and loss of personal assets. You will also be in a better position to protect your employer's interests.

Florida's Medicaid Fraud Control Unit and the Miami-Dade Police Department arrested dental hygienist Julio Suarez, who was accused of Medicaid fraud by delivering care outside his scope of practice. Suarez is alleged to have performed procedures on patients that should have been performed by a licensed dentist and then billing Medicaid for the services. In total, Suarez fraudulently caused the Medicaid program to pay more than $8,000. Suarez was charged with one count of Medicaid fraud, a second-degree felony, and one count of grand theft, a third-degree felony. Should he be convicted, Suarez faces up to 15 years in prison and $10,000 in fines.

"It is utterly despicable that a health care professional would knowingly deceive trusting patients about their licenses and credentials in order to practice unlawful dental procedures," said Florida's Attorney General Ashley Moody. "To further use that deception to scam the Medicaid program out of thousands of taxpayer dollars is inexcusable and criminal."

ADANews. (2021, March 24). Inspector General Reports Two Medicaid Fraud-Related Enforcement Actions. *ADANews*. Retrieved from www.ada.org/publications/ada-news/2021/march/inspector-general-reports-two-enforcement-actions-in-march-related-to-medicaid-fraud.

Providers and corporate employers are liable for their own conduct, as well as being **vicariously liable** for their employees' conduct while the employees are working within the scope of their employment. In the employment setting, this theory of liability is known as **respondeat superior**, which is Latin for "let the master answer." It is sometimes difficult to determine whether an employee is acting within the scope of employment. The test is whether the employee's conduct served the interest of the employer or furthered the employer's business.

vicariously liable Legally obligated for the acts of others who are acting as their agent.

respondeat superior Legal theory that holds employer responsible for the behavior of an employee working within the scope of employment.

Across the health care industry, there are a myriad of relationships that can give rise to a vicarious liability claim. For example, dentists have the right to control the professional activities of dental hygienists working for them and the duty to supervise them. As a result, dentists are vicariously liable for the wrongful acts of dental hygienists that work for them. In this hypothetical case, a dental hygienist loses grip of a pointed instrument, which then lands on the patient's eye. The dropped instrument caused permanent visual damage to the patient. The patient could sue the dentist based upon vicarious liability under the doctrine of respondeat superior for the **negligence** of the hygienist.

negligence Failure to act with reasonable and prudent care given the circumstances.

A patient sustained an injury during an Xray of his shoulder at a New Jersey medical center. The plaintiff alleged that the medical center's radiology technician had plaintiff hold weights during the Xray, which was contrary to the directions provided by the plaintiff's physician. Plaintiff's complaint did not name the technician, and, therefore, the lawsuit was focused only on the medical center's vicarious liability.

To assert a medical malpractice claim in New Jersey under the theory of vicarious liability (respondeat superior) against a health care entity and based

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on the negligence of a "licensed professional," the applicable statute requires a sworn statement from an expert with the same type of professional license as the alleged negligent employee.

On appeal, the court ultimately focused on whether the plaintiff met the statute's applicable criteria, which included the submission of a sworn statement from an expert. The appellate court reversed the trial's court's decision and found that no sworn statement was required because the only theory of liability sought was vicarious liability for the technician's wrongful acts, and a radiology technician is not a "licensed professional" for purposes of the statute.

JDSupra. (2021, March 22). Affidavit of Merit May No Longer Be Required for Claims of Vicarious Liability in New Jersey. JDSupra. Retrieved from www.jdsupra.com/legalnews/affidavit-of-merit-may-no-longer-be-7077502/.

As a health care professional, you will want to be aware of your specific scope of practice and the full responsibilities of your employment. Keep in mind that you work in a highly regulated industry. Ignorance of a law or a regulation does not excuse a violation. You are a professional and expected to know the laws and regulations that govern your profession and your job.

As members of society, we are all expected to conduct ourselves in a responsible manner that will not cause harm. This is known legally as holding an individual to a **reasonable person** standard of care. Physicians, nurses, and other health care professionals are all held to a higher standard of care than what is demanded under the reasonable person standard of care because of their specialized training and expertise.

reasonable person A prudent person whose behavior would be considered appropriate under the circumstances.

Locum tenens is used to describe physicians, nurses, and physician assistants who are temporarily performing the duties of another. Providers who are practicing "locum tenens," which is Latin for "to hold the place of," are held to the same standard of care as other providers with the same expertise and certification.

The standard of care takes into consideration the surrounding circumstances, including what a similarly qualified provider would do under the same set of circumstances. An analysis of what a "similarly qualified provider" would do includes factors such as geographic location or physical location. Violations of the standard of care are the basis of medical malpractice lawsuits, certificate or license revocations, and, in some cases, criminal charges.

Besides the agreement never to harm or exploit clients, and to treat them with respect, there is little accord among practitioners in the field about what constitutes proper care. A New York City psychoanalyst's treatment of anxiety is likely to be very different from that of an existentialist's treatment of the same condition in rural Idaho or the local counselor's treatment on an Indian reservation in Arizona. Similarly, a military psychologist or prison social worker are likely to have different sets of loyalties which effect their interventions, disclosures, and other clinical variables. This is why the definition of standard of care is context based. Along these lines the controversial issue of multiple relationships manifests itself or is applied differently in different settings.

Zur, O, Ph.D. (nd). The Standard of Care in Psychotherapy and Counseling. Zur Institute. Retrieved from www.zurinstitute.com/standard-of-care-therapy/.

For many health care professionals, the required standard of care is not well defined. For physicians and nurses, professional guidelines for accepted practices are more clearly defined. When a provider directs a lab technician, for example, to perform certain tasks associated with patient care, (i.e., to act as the provider's **agent**) the delegation of responsibility is based on the premise that the health care professional can perform as well as the person who assigned the task. It also follows that, in those situations, the health care professional may be held to the same standard of care as the provider or nurse for the task performed.

agent One who has authority to act on behalf of another.

Health care professionals are the link between the patient and the provider when arranging office visits, laboratory tests, therapeutic appointments, and hospital admissions. They are crucial in the development of good relations between the patient and the provider. It is important that health care professionals understand the legal issues involved with providing health care and the importance of good patient relations. Positive patient interactions minimize the nonmedical and nonlegal variables involved in malpractice and may prevent a legitimate complaint from developing into a lawsuit.

Patient Protection

Patients trust that they are being treated by qualified health care professionals. State licensure laws protect patients by defining the education and experience required to perform certain procedures before the licensed provider can treat patients. A license indicates that the holder has the basic minimum qualifications required by the state for that occupation.

License requirements also control employers by setting standards for hiring that ultimately protect patients. Licenses are granted by state-run licensing boards, which also have the power to revoke licenses. Although the grounds for revocation may vary slightly from state to state, they always include unprofessional conduct, substance abuse, fraud in connection with examination or application for a license, alcoholism, conviction of a felony, and mental incapacity.

Often health care professionals are closer to the patients and more sensitive to their needs than are providers. The requirements of privacy and respect for the confidential relationship between patient and provider must be met: privacy and confidentiality have ethical and legal bases. Permission to touch and the right to perform certain procedures are interwoven with state medical practice acts.

The Health Insurance Portability and Accountability Act (HIPAA), which is further discussed in Chapters 2 and 9, is a federal law requiring every health plan and provider to maintain "reasonable and appropriate" safeguards to ensure the confidentiality of patient health information.

The Arizona Supreme Court held that the Health Insurance Portability and Accountability Act (HIPAA) can provide guidance as to the standard of care in a negligence claim for wrongful disclosure of medical information. Plaintiff brought suit after his estranged wife picked up a prescription for him and was also given a prescription for erectile dysfunction (ED). The plaintiff's doctor gave him a sample medication for ED, which the plaintiff's pharmacist filled in addition to his usual prescription. The plaintiff decided he did not want to fill the ED prescription and twice asked the pharmacist to cancel it. At the time, the plaintiff sought to reconcile with his estranged wife, and had picked up plaintiff's usual prescription for him. The pharmacy employee also gave her the ED medication. After picking up the prescriptions, plaintiff's now ex-wife ceased all reconciliation efforts and told friends and family members about the prescription.

Initially, the plaintiff complained to the pharmacy, who then apologized and acknowledged that the company had violated HIPAA and its own privacy policy when it disclosed the ED prescription to his ex-wife. Plaintiff then sued, and as part of the case, the court indicated a plaintiff can use HIPAA as evidence of the standard of care for the safeguarding of protected health information in a negligence claim.

This case confirmed that HIPAA standards and rules may be used to establish the standard of care for the use and disclosure of protected health information.

Shepherd v. Costco Wholesale Corp., No. CV-19-0014 (Ariz. Mar. 8, 2021).

In addition to protecting the patient, laws exist that protect the public as a whole. Certain health matters, for example, must be reported by providers in every state, including births and deaths, venereal and other communicable diseases, injuries resulting from violence such as stab and gunshot wounds, child and elder abuse, blindness, immunological proceedings, requests for plastic surgery to change a person's fingerprints, and cases of industrial poisoning, among others.

Patient Bill of Rights Health care facilities and providers have creeds entitled a "Patient Bill of Rights" that establish standards, including ethical standards, for patient care. A Patient Bill of Rights is not always required by law, so the content will change depending on the provider and facility. A Patient Bill of Rights conveys patients' legal and ethical rights and includes acknowledgment of a patient's right to choose treatment, to consent to treatment, and to refuse treatment, among others (Figure 1-1).

The following is a list of rights that may be included in the Patient Bill of Rights:

- To be treated with courtesy and respect in an environment free from discrimination.
- To be treated confidentially, with access to your records limited to those involved in your care or otherwise authorized by you.
- To be informed by your health care provider about your diagnosis, scheduled course of treatment, alternative treatment, risks, and prognosis.
- To use your own financial resources to pay for the care of your choice.
- To refuse medical treatment, even if your provider recommends it.
- To create Advance Directives and have your provider(s) or hospital staff provide care that is consistent with these directives.
- To be informed about the outcomes of care, treatment, and services that have been provided, including unanticipated outcomes.
- To be provided an estimate of charges for medical care, a reasonably clear itemized bill, and, if needed, an explanation of the charges.
- To receive prompt and reasonable responses to questions and requests.
- To know what patient services are available, including whether an interpreter is available.
- To be informed if medical treatment is for experimental research and to give your consent or refusal to participate.

Figure 1-1 Sample Patient Bill of Rights

The Business Structure: Legal Entities

A health care facility can be a solo practitioner operating from a single office, or it may be a group of providers who have agreed to share the costs and sometimes the liability of a group practice with several office locations. It may be a corporation, or a **conglomerate** controlling hospitals or other health care facilities. Each medical practice has an underlying **legal entity** that governs matters such as ownership, profit distribution, liability, taxes, and control, among others. State, county, or city law governs the structure and requirements. Legal entities include sole proprietorships, partnerships, limited liability companies, professional associations, limited liability partnerships (LLPs), and corporations.

conglomerate A corporation diversifying operations by acquiring varied businesses.

legal entity An individual or organization that has legal capacity to contract, incur and pay debts, and sue and be sued.

Any legal entity can choose to operate and hold itself out to the public under a name that is different than its registered name. The alternate name is referred to as a DBA, short for "doing business as." Companies that operate as a DBA (sometimes referred to as a trade name, a fictitious name, or an assumed name) usually have to file state or local registrations that identify the people or legal entity that is responsible for the DBA. The main purpose for these filings is to prevent fraud and let the public know with whom they are doing business.

Sole Proprietorship

A sole proprietorship is a legal entity that requires no state filing to create it. A sole proprietorship is simply one person operating a business for profit. That person has unlimited personal liability for the business. A sole proprietor can have employees, including other providers. The person who chooses this business structure does so for two main reasons. First, individual ownership is the simplest and most basic business structure and appeals to a person who wants to be independent and free from the laws that govern other legal entities. Second, any financial rewards from the practice are for the owner and do not have to be shared with anyone else. However, any losses are also the owner's.

A sole proprietorship should not be confused with a solo practice, which is a type of health care business where the practice includes just one provider. A solo practice can be one of the many legal entities discussed in this chapter. Most solo practitioners choose legal entities other than a sole proprietorship for liability and tax reasons. In fact, all medical practice types such as solo practices, group practices, and employed provider practices may choose their legal entity type.

Partnership

A partnership, sometimes called a "general partnership" (GP), is two or more people who combine their work, money, and talents to achieve a common goal. It is a more complicated form of legal entity than a sole

proprietorship. A partnership is formed when two or more parties agree—in compliance with state and local law—to certain business aspects such as ownership, profit distribution, liability, taxes, and control. Many states require a document or registration that serves as **notice** to the public that the partnership members are doing business together. Unless the terms of the partnership provide otherwise, each partner has a right to participate in managing the business and making decisions.

notice An announcement of pertinent information to those who have a right or obligation to know.

A high degree of mutual trust and confidence must exist between partners. For example, if one partner's personal debts become so large they cannot be satisfied by his or her private assets, creditors may go after that partner's share of the business property, thereby threatening the partnership.

In conducting the affairs of a partnership, all partners are bound by the acts of the others. This affects them as individuals. If, for example, one partner places an order for equipment beyond the financial means of the partnership, the other partners are required to share payment of the bill, possibly by using their personal funds. A notable exception is an LLP. In such cases, personal assets can be protected.

Limited Liability Companies

A limited liability company (LLC) is a legal entity, created by one or more individuals or other legal entities, to further a common goal and to create ground rules for matters such as ownership, profit distribution, liability, taxes, and control. Individuals who have an interest in an LLC are usually referred to as "members." State law, as opposed to federal law, governs LLCs.

Business owners have increasingly used LLCs because they provide protection from being held personally liable and can be advantageous from a tax perspective. LLCs do not always provide the protection from personal liability for the wrongful acts of members or employees, which explains the use of the word "limited." LLCs also require less legal and accounting work to get started. In addition, members can decide among themselves who has authority to perform acts such as hiring or firing employees, contributing capital, and earning profits, among others.

Some states allow for certain professionals, such as providers, lawyers, architects, and accountants, to form professional limited liability companies (PLLCs). A PLLC is very similar to an LLC, but the governing statutes dictate that the limits of liability may only be applied to certain aspects of the business, such as creditors. A PLLC limits the liability protection that certain professionals can expect. In a health care scenario, PLLCs do not allow providers to limit their liability for patient wrongs, such as malpractice.

Corporations

A corporation is a legal entity created by one or more individuals to further a common goal and to make use of corporate tax and legal advantages.

A corporation is formed in accordance with the state laws in which it is registered. State laws usually require that a corporation's name includes a corporate designation such as "Corporation," "Co.," "Corp.," or "Inc."

Much thought is often given to the corporate name. The corporation may use any name, provided it has not been taken by some other legal entity in the state or does not too closely resemble the name of an existing legal entity. Health care providers usually try to choose a name that will instantly indicate to the public the services they provide.

officers Persons holding formal positions of trust in an organization, especially those involved in high levels of management.

directors Those elected and terminated by stockholders to manage a corporation.

stockholders Those who hold an interest in a corporation.

shares Units of stock giving the possessor part ownership in a corporation.

investment Expenditure of resources (money, effort, etc.) intended to secure income or profit.

bylaws Regulations adopted by a corporation or association to govern its internal affairs.

dividends Distributed profits of a corporation.

The life of a corporation does not end upon the death of its **officers**, **directors**, or **stockholders**. Even if all died in a common disaster, **shares** of the corporation would generally be passed on to the officers', directors', or stockholders' heirs. The corporation will not cease to exist until it is dissolved by the requisite legal process. This is true even in a corporation where only one individual holds all of the stock.

One of the most desirable features of a corporation is the protection given to investors. For example, if the corporation loses money and the debts become greater than the assets, the creditors may not collect from the individual owners, known as stockholders. Only the capital of the corporation is available for the payment of debts. It is important to remember that judgments resulting from lawsuits are indeed debts. The most an individual investor may lose is the amount of the original **investment**.

Management responsibility is in the hands of the corporation's board of directors. The number of directors is usually set in the **bylaws** of the corporation, which are adopted at the first stockholders' meeting. Directors answer to the stockholders, who elect and can terminate them. A member of the board of directors is expected to be loyal to the corporation and its shareholders. It is improper for a director to have an interest in any business that competes with the corporation. Officers of a corporation include the president, vice president, treasurer, secretary, and any other officers the board of directors appoints. They are employees of the company and need not be stockholders. Profits of a corporation are distributed to stockholders as **dividends**.

Not-for-profit organizations may also be corporations; there are no shareholders and no dividends. Revenue in excess of expenses is reinvested in the organization.

Similar to a PLLC, a professional corporation (PC) or a professional association (PA) are legal entities that are designed for business endeavors of professionals such as providers, attorneys, architects, and accountants.

Health Care Delivery and Compensation Systems

As cost management in health care rose to crisis levels, alternative delivery and compensation systems have largely replaced traditional health care business practices. In the past, a patient who felt unwell would decide when and whom to visit for health care. The patient would then pay a fee for the provider's service either directly or through an insurance company.

The traditional **fee-for-service** payment system has shown that it encourages increased costs and reduces the quality of care patients receive as compared to other health care delivery systems. Consequently, those with a stake in the matter (health insurance companies, government, employers, patients, and providers) have developed alternative delivery systems that reward cost management, quality care, and efficiency.

fee-for-service Basis of professional billing, either so much per hour or per identified procedure.

Managed care organizations seeking to manage health care costs and improve health care contract with providers and health care facilities to provide health care services for the MCOs insured in accordance with certain requirements. The two longstanding forms of alternative delivery systems are health maintenance organizations (HMOs) and preferred provider organizations (PPOs). Other alternative delivery systems are emerging that bear no resemblance to traditional office-based delivery systems.

Amazon (Nasdaq: AMZN) unveiled major plans to expand its budding home-based care offering, "Amazon Care," across the U.S.... Since then, home-based care stakeholders have been trying to make sense of the news and figure out what it means for them—and the in-home care patients they serve. Their early evaluations are thus far divided, with some excited by Amazon's ability to bring additional attention to home-based care and others concerned about technology overshadowing the human touch.

Amazon launched Amazon Care—an initiative that uses an app to coordinate in-person care and virtual health care services—about 18 months ago. The company initially began testing the platform as part of an exclusive pilot program for employees and their family members in the Seattle area, but eventually expanded it across all of Washington....

While not much is known about Amazon Care as far as health impacts or utilization, Amazon officials have publicly touted the offering's accessibility, convenience and timeliness.

"I would only caution that people who are integral to the building, running and supervising of this platform are those who know health care, preferably with clinicians and patients on the board," Jinjiao Wang, a nurse scientist in New York, shared via social media. "Algorithms should only serve, not dictate, humans." "We're rebuilding the whole delivery system around the human at the center," Nicole Bell, a business development executive with Amazon Care, said in a promotional video posted to the platform's website. "You just open the app and from there, you can do a text chat with a nurse or a virtual care visit with a provider. If we can't meet your needs in that virtual environment, we bring the health care system to you."

Holly, R. 'We're Rebuilding the Whole Delivery System': Why Amazon Is Betting Big on Home-Based Care. (2021, March 22). Home Health Care News. Retrieved from www.homehealthcarenews.com/2021/03/were-rebuilding-the-whole-delivery-system-why-amazon-is-betting-big-on-home-based-care/.

The Affordable Care Act of 2010 resulted in the promotion of another primary MCO, the accountable care organization (ACO), as well as variations of all three. In addition, Medicare and Medicaid have experienced similar changes as the government seeks to contain costs and improve the quality of health care.

The Affordable Care Act

The Patient Protection and Affordable Care Act (PPACA), more commonly referred to as the Affordable Care Act (ACA), was signed into law on March 23, 2010, but many of its provisions did not take effect immediately. As a result, the government, employers, health care industry, and patients had time to prepare for the changes that the ACA required. The ACA is expansive, and it touches on many subjects including:

- use of electronic medical records,
- prohibition of coverage denials based upon preexisting conditions,
- requirement that insurance companies offer all applicants of the same age and locality the same premium without consideration of most preexisting conditions or age,
- imposition of minimum standards for health insurance companies,
- requirement that, with very narrow exceptions, all Americans have some form of health insurance,
- provision of government subsidies for insurance premiums based upon financial considerations,
- introduction of state run health insurance exchanges that allow comparison shopping for health insurance policies,
- revisions to Medicaid eligibility,
- requirement that dependents can remain on their parents' health insurance until their 26th birthday,
- prohibition on canceling policies when policyholders become ill, and
- requirement that new health insurance plans must fully cover certain preventive treatment and medical tests, without charging co-payments or deductibles.

The ultimate goal of the ACA is to encourage health care that increases the quality and affordability of health insurance, lowers the uninsured rate by expanding public and private insurance coverage, and reduces the costs of health care. The ACA seeks to ensure that all have health care, and since its passage, the number of uninsured Americans has decreased significantly.

Managed Care Organizations

Managed care is a term used to describe a method of delivering and compensating health care with a pointed focus on lowering costs and improving quality. An MCO is simply an organization that provides managed

health care. Managed care typically includes a wide spectrum of health care services, including preventative care, diagnosis and treatment of illness, prescriptions, and mental health care. Managed care contracts with physicians, hospitals, clinics, and other health care providers to create provider networks. An in-network provider or health care facility is part of an MCO's network if there is a preexisting agreement between the MCO and the health care provider. The agreement dictates the protocols for patient care and the compensation system. An out-of-network provider is a provider or health care facility that does not have an agreement with the MCO. To discourage the use of out-of-network providers, a patient's reimbursement for services provided by an out-of-network provider is not compensated at the same level as an in-network provider. Managed care focuses on various aspects of health care and can include characteristics such as:

- networks of health care providers or facilities, who have agreed to predetermined protocols and compensation,
- primary care providers (PCPs), who coordinate all of a patient's health care,
- preauthorization for specific treatments,
- limited reimbursement for out-of-network providers,
- claim filing assigned to the provider rather than the patient, and
- tiered coverage of prescription drugs.

There are many different ways that MCO's members contribute to the cost of their health care. A member will typically pay a monthly premium, some or all of which may be paid by a third party, such as an employer or the government. In addition, members may be responsible for satisfying an annual deductible before certain coverages are effective. With a few exceptions, each office or emergency room visit or prescription requires that members contribute in the form of a co-payment. MCOs manage prescription-drug costs by charging members a lower co-payment for drugs that cost the MCO less. See Table 1-2 for an MCO matrix that includes the characteristics of HMOs, POSs, EPOs, and PPOs.

MCOs use PCPs as gatekeepers to control the cost-effectiveness of services offered to members. Gatekeepers control access to specialists. In addition, many MCOs have adopted authorization requirements, meaning that the MCO must approve some procedures before the PCP orders them. The payers are controlling access to health care by denying approval for certain procedures and allowing payment for others. They make decisions that reduce the number of hospital admissions, shorten the time until discharge, control the number of expensive diagnostic procedures, and, in the mental health field, substitute medication for therapeutic counseling treatment. When gatekeepers have an incentive to deny referrals to specialists, limit diagnostic treatments, and shorten hospital stays, the integrity of the patient–provider

Table 1-2 MCO Characteristics Matrix

	Requires PCP	Requires referrals	Requires preauthorization	Pays for out-of-network care	Cost-sharing	Do you have to file claim paperwork?
HMO	Yes	Yes	Not usually required. If required, PCP does it.	No	Low	No
POS	Yes	Yes	Not usually required. If required, PCP likely does it. Out-of-network care may have different rules.	Yes, but requires PCP referral.	Low in-network, high for out-of-network.	Only for out-of-network claims.
EPO	No	No	Yes	No	Low	No
PPO	No	No	Yes	Yes	High, especially for out-of-network care.	Only for out-of-network claims

Source: Verywell

relationship is called into question. When insurance companies make the decision to allow or deny diagnostic testing and hospital admissions, the patient–provider relationship is further eroded, and the well-being of the patient becomes an issue.

MCO's continued search for ways to provide quality care while keeping costs low has also affected the financial well-being of patients. For example, the rise of "surprise billing" resulted in the No Surprises Act, which creates federal rules for out-of-network billing in certain scenarios.

The No Surprises Act contains key protections to hold consumers harmless from the cost of unanticipated out-of-network medical bills. Surprise bills arise in emergencies—when patients typically have little or no say in where they receive care. They also arise in non-emergencies when patients at in-network hospitals or other facilities receive care from ancillary providers (such as anesthesiologists) who are not in-network and whom the patient did not choose.

Surprise bills lead the list of affordability concerns for many families; 2 in 3 adults say they worry about unexpected medical bills, more than the number worried about affording other health care or household expenses. Surprise bills can number in the millions each year. Among privately insured patients, an estimated 1 in 5 emergency claims and 1 in 6 in-network hospitalizations include at least one out-of-network bill. A health plan that generally doesn't cover out-of-network care, such as an HMO, might deny a surprise bill entirely.

> Or plans might pay a portion of the bill, but leave the patient liable for balance billing—the difference between the undiscounted fee charged by the out-of-network provider and the amount reimbursed by the private health plan. Balance billing on surprise medical bills can reach hundreds or even thousands of dollars. Surprise medical bills are not a problem today under public programs—Medicare and Medicaid—that prohibit balance billing.
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> KFF. (2021, February 4). Surprise Medical Bills: New Protections for Consumers Take Effect in 2022. KFF. Retrieved from www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.

An MCO's in-network health care providers are typically compensated by a capitated rate, sometimes also known as "per member per month" (PMPM). The MCO, on behalf of all its members, contracts with various health care providers who make themselves available to provide care in exchange for a set fee per month. The fee represents the number of members in the provider's care. In some cases, providers are employees of the MCO, and they work for a salary. In most cases, providers are part of a larger network maintained by the MCO for the members' benefit.

Health Maintenance Organizations HMOs are comprehensive health care delivery and compensation systems that provide provider and hospital services from participating providers. With the exception of emergencies, HMOs will not cover care provided by out-of-network providers. HMOs require that each member have a PCP who monitors the overall health of the member and provides referrals to specialist in accordance with the HMO's protocols. HMOs typically do not pay for specialist visits that have not been referred by the PCP. HMOs operate on the presumption that maintaining health and preventing illness is less expensive than the cost of treatment for the illness that would otherwise develop.

There are two main HMO provider payment structures: the prepaid group practice (PGP) and the individual practice association (IPA). Prepaid group practices are groups of providers who agree to provide comprehensive health care services for a fixed prospective **per capita payment** to a definite population. The staff model and the group model are two forms of PGPs. Under the staff model, the providers are employees of the HMO, are salaried, and may at the end of the fiscal year receive a portion of any profit. In the group model, the providers are organized as a partnership or corporation in a group practice. The group contracts with the HMO to provide care for HMO members, sometimes called subscribers. The group receives **capitation** payment and a share of the HMO's net income as a group and pays participating providers on a fee-for-service or salary basis.

per capita payment Pay equally according to the number of individuals.

capitation Payment in a lump sum to providers, HMOs, and health care facilities to deliver health care to a segment of the population.

In contrast, IPAs are groups of providers who join together and enter into agreement with other organizations to provide medical services to a defined population. In this structure, the providers practice in their own office on a fee-for-service or capitation basis. Comprehensive health benefits are provided to the designated population for a fixed periodic payment.

HMOs are regulated under the HMO Act of 1973 (42 *United States Code* section 300c-300e-17 [1976 and Supp. III 1979]). Under this Act, member providers must agree to give at least one-third of their time to HMO subscribers. Employers with more than 25 employees must offer an HMO as an alternative choice to conventional health care coverage, if such a choice is available in the area.

In a continued effort to find the best combination of cost savings and quality care, MCO hybrids are routinely introduced. A point-of-service (POS) is a combination of a traditional fee-for-service plan and an HMO. Members are rewarded with lower costs when they choose to use their PCP as a gatekeeper but are not prohibited from choosing out-of-network providers. Members incur higher costs when they receive care from an out-of-network provider.

joint venture A group of persons together performing some specific business undertaking that is limited in duration or scope.

negotiated fee schedules The amount an insurance company or other third-party payer will reimburse for a specific medical procedure.

utilization review A process by which hospitals review patient progress to efficiently allocate scarce medical resources.

Preferred Provider Organizations PPOs are groups of providers and hospitals that contract with employers, health insurance companies, or third-party administrators to provide comprehensive medical services on a fee-for-service basis to subscribers. A PPO may be sponsored by a hospital, a provider, an employer, or an insurer, or it may be a **joint venture** between a hospital and a medical practice. The mechanisms used to control health care costs include **negotiated fee schedules** and **utilization reviews**. A PPO covers the cost of a preferred provider's care, as well as a reduced portion of a nonpreferred provider's care.

The evolution of PPOs with high deductibles prompted the creation of health savings accounts (HSA), which provide tax breaks for money set aside in an HSA for health care–related expenses.

A health savings account, or H.S.A., can help pay for some medical expenses, if you qualify to have one. And they offer three valuable tax breaks: Money is deposited pretax, can grow tax-free and is not taxed when you spend it, as long as the expenses are eligible. . . . There's a catch, though: The accounts are available only to people with health insurance plans that meet specific criteria, such as a high deductible, which is the amount a person pays for nonpreventive medical care before insurance. For 2020 and 2021, the amount is at least $1,400 for an individual or $2,800 for

family coverage. . . . The accounts can pay for a variety of medical and health expenses, including doctor visits, hospital stays, surgery, and vision or dental care. The money can also go toward long-term-care insurance premiums and services. . . . The federal government's pandemic relief program expanded what H.S.A.s can pay for, including nonprescription medicine like pain relief and allergy pills, and menstrual products like tampons and pads. (The I.R.S. has a full list of eligible items.) . . . People often confuse H.S.A.s with other types of health accounts, such as flexible health spending accounts. But unlike F.S.A.s, health savings accounts are portable: If you change jobs or leave the work force, you keep the account. Contribution limits are higher for H.S.A.s, and there is no deadline to spend the cash. Unspent money can be invested for health needs in retirement. . . .

Carrns, A. (2021, March 19). The New York Times. The Triple Tax Break You May Be Missing: A Health Savings Account. Retrieved from www.nytimes.com/2021/03/19/business/health-savings-accounts-tax-break.html.

The PPO has emerged as the most commonly used form of health insurance coverage. Consumers like the freedom to choose their own providers, which is frequently cited as one of HMO's drawbacks. As you might expect, the member costs for a PPO is greater than for an HMO.

An exclusive provider organization (EPO) is a hybrid of a PPO and an HMO, where members can choose from a group of preferred providers. An EPO, however, will not pay any percentage of costs associated with a nonpreferred provider.

Accountable Care Organizations The Affordable Care Act includes guidelines for ACOs and sets the stage for the increased popularity of ACOs. An ACO is a type of MCO that seeks to improve health care and reduce costs by using groups of providers, hospitals, and other health care professionals to coordinate cost-effective, quality health care and to reward positive patient outcomes by sharing cost-savings with providers. It functions similarly to an HMO but without the gatekeeper requirement, and out-of-network providers are covered at a reduced percentage.

Health care providers and health insurance companies are forming ACOs for Medicare patients as well as for patients with private insurance. The ACOs created for Medicare patients include the Medicare Shared Saving Program (MSSP), the Advanced Payment system, the Investment system, the Pioneer system, and the Next Generation system. The variations in the ACO systems differ based upon characteristics such as the way patient outcomes are rewarded, how the providers are compensated, the subset of Medicare patients they serve, or the ACO's level of experience.

Technology and Medicine

Seemingly overnight, technology has worked its way into our health care and some of the risks and rewards are yet to be fully understood. The COVID-19 pandemic sped up the use and acceptance of certain health care technologies. Telemedicine, which was just starting to gain more widespread popularity in 2020, has become a common method of interacting with a provider.

> . . . as Covid snaked its way into the fabric of the world, hospital finances suffered, patients avoided care (in some instances, urgently needed care), and clinician capacity far outweighed demand.
>
> If ever there existed a silver lining to a global pandemic, care technology (like remote patient care) catapulting to the stage was, for the good or the bad, warts and all, a glimmer of hope.
>
> Contemplating the remote care "condition" during the heat of Covid I classified health system and clinical readiness in three rather obtuse categories:
>
> 1. Those who are comfortable with, and deeply embedded in, telehealth care,
> 2. Those who were nibbling around the edges of telehealth with varying levels of implementation (discussions, examination, curiosity), and
> 3. The unprepared (forced to embrace telehealth as the only [short term] means of offering patient visits).
>
> As a refresher, due to Covid, use of telehealth applications increased under the umbrella of a federal Emergency Order which relaxed many regulatory aspects of telehealth and associated remote delivery services. However, once the EO expires, Congress will need to revisit codifying telehealth. That said, it seems the genie is out of the bottle. At this point in Covid's yearlong-plus history, physicians and health systems have learned to either adapt (see #3 above) or thrive (see #1 above) with telehealth.
>
> Gorke, J. (2021, March 19). Deploying Healthcare Technology: How Vulnerable Are You? *Forbes*. Retrieved from www.forbes.com/sites/jeffgorke/2021/03/29/deploying-healthcare-technology-how-vulnerable-are-you/?sh=4be7ca4fd050.

Our personal electronics tell us to eat less or more, to sleep and when, to take our prescriptions, to relax, and to exercise more, among countless other metrics.

Smartphones have endless apps that monitor these health metrics such as heart rate, meditation and mindfulness, medication, general wellness, weight loss, menstrual cycles, sleep, diabetes, blood oxygen

levels, and so much more. Drones are being tested as a method of health care delivery. Thermal cameras are being used to detect elevated temperatures, a common indicator of the COVID-19 virus.

The ever-growing use of electronic records and patient portals to store, report, track, schedule, communicate, and monitor patient health care suggests this practice is here to stay. It also suggests that, as technology in health care grows, so too will the demand for cyber security.

Personal health information has become a lucrative target for illegal actions on the Internet. Health care companies have more liability than just HIPAA violations, and they now need to be stalwart defenders of their technologies' security.

Telemedicine

Telemedicine is a health care delivery system used when the patient is in one location and the treating provider is in another, possibly thousands of miles away.

The COVID-19 pandemic lit a fire under the use of telemedicine, which includes the use of video, as well as the transmission of electronically collected health metrics from the patient to the remote provider. While telemedicine is not new, the recent pandemic brought it front and center stage globally. Medical schools and accrediting organizations are providing classes, best practices, and competencies for those health care provider who will practice virtually. Telemedicine is being used in a wide array of applications and settings, including:

- Psychiatrists, psychologists, licensed social workers, and other mental health care providers often use video and telephone to conduct virtual sessions (driven in large part by the COVID-19 pandemic, which spawned a significant need for mental health care).
- Children's Health Care of Atlanta uses telemedicine for rural pediatric patients, including those who were the victims of sexual assault and who might not otherwise be able to get the specialized health care needed.
- An Arizona neurosurgical practice uses telemedicine so its patients can remember what was said during office visits. Patients have their consultation and follow-up visits videotaped, so the details are available.

In health care's cost-sensitive environment, telemedicine has become prominent, and its applications are many. It offers a way to provide quality care to patients in rural areas or to patients in need of specialized diagnostic evaluation. See Figure 1-2 for a sample timeline of a physician-on-demand videoconference consultation.

There are, however, unanswered legal questions. For example, in which state or county or city is medicine being practiced—where the

9:22 p.m.	Recurrent sinus infection rises to the level where the patient can no longer tolerate the symptoms. She has been too busy all week to schedule an appointment with her primary care provider. It is now late in the evening on a Friday, and she does not want to be sick all weekend. She downloads a smartphone application for a national physician-on-demand service and creates an account. Insurance doesn't currently cover the cost of the visit, which is $40 for each 15 minutes. Her co-pay at her PCP is $25.
9:27 p.m.	Videoconferencing begins. The physician asks about patient's symptoms, history of sinus infections, and current medications. Physician concurs that the signs of a sinus infection are present and that an antibiotic is in order.
9:35 p.m.	Videoconference concludes and the physician electronically sends an antibiotic prescription to the patient's local pharmacy.
9:44 p.m.	Pharmacy calls the patient to report that the prescription is ready for pickup.
10:02 p.m.	Prescription is in the patient's hands, and she takes the first dose that night.
Three days later	Patient receives an email from the physician-on-demand company reminding the patient to follow up with her primary care provider if symptoms have not improved and that her treatment history is available in the smartphone application.

Figure 1-2 Timeline of Physician-on-Demand Videoconference Consultation

patient is or where the provider is located? Does the provider need a license to practice medicine in each state where he or she consults with a patient? Some issues affect the provider engaged in practicing. Others affect the medical profession as a whole.

Nathan Jones (not his real name) is 57 and had recently been hospitalized with the rare autoimmune condition dermatomyositis, which can cause a strange rash, muscle pains, and facial swelling. He'd also experienced difficulty swallowing.

Since going home, Mr. Jones had been diligently taking his medications, but when our telemedicine visit began, I noticed severe swelling around his lips. He also reported a strange phenomenon of his voice changing when lying flat.

Quickly, I instructed him to open his mouth, and I saw that his tongue was swollen. Concerned that his airway was closing, I immediately arranged for an ambulance to transfer him to the hospital. In less than an hour, Mr. Jones was in the care of our medical intensive care unit at Stony Brook University Hospital on Long Island, New York.

> Without telemedicine, I might not have known about my patient's critical condition. Not one "to make fanfare," Mr. Jones says he would never have sought an in-person medical appointment to address these pressing health issues—and his follow-up appointment was not for several weeks, which, in retrospect, would have been too late.
>
> Noel, K. (2021, March 24). What Every Doctor Needs to Know About Telemedicine. AAMC. Retrieved from www.aamc.org/news-insights/what-every-doctor-needs-know-about-telemedicine.

The use of teleradiology is increasing and is in sync with the way businesses now operate globally. Hospitals contract with provider groups in India, for example, to read x-ray, computerized tomography, and magnetic resonance images. Likewise, some radiology groups have established branch locations in places like Hawaii to provide more round-the-clock service to health care providers in other time zones.

Another increasing use of telemedicine is in the field of home health care. More patients are being monitored at home to ensure their well-being. This may require the patient "reporting in" by computer, or it may be a device that sends signals to the medical provider without requiring the patient to do anything.

Companies that deliver provider-on-demand services are popping up to address the needs of patients in rural areas, patients who lack the ability to leave their homes, busy parents or professionals, and patients on vacation. Some of the provider-on-demand services come in the form of a house call by a provider and some provide care by videoconferencing. Employers are adding telemedicine options to its employee benefits.

As experience with telemedicine supports it as a cost-effective health care delivery system, you can expect to see it as a common health care insurance offering. A handful of states already have laws that relate to telemedicine and health insurance coverage.

SUMMARY

- The health care industry is a big business.
- What you do on the front line matters.
- Understanding the laws that apply to health care is important for employees to protect themselves, their employer, and the patient.

- Because medicine is closely regulated by state and federal law, it is necessary for employees to be aware of statutes and regulations that define the procedures they are permitted to perform.
- Health care professionals work in the delivery of health care and are held to a higher standard of care than laypersons without special knowledge and training.
- There are several types of legal entities, all of which are governed by state law.
- The Affordable Care Act made expansive changes to the way the health care industry does business.
- Managed care organizations include HMOs, PPOs, and ACOs, and they all seek to reduce costs and deliver quality health care.
- Technology in health care is booming, and telemedicine has fast become a widely accepted health care delivery system.

SUGGESTED ACTIVITIES

1. Does the area of health care you plan to work in require licensing or registration in the state where you will practice? Does it have certifications that identify those who have expertise in specific areas? Who issues those certifications?
2. Find the website for your state's department of corporations. This is the department that registers businesses. Find a local business' registration material on the department of corporation's website. Can you tell what kind of legal entity it is? Can you tell what year it was created? What else does the business' online registration tell you?
3. If given the choice, what type of health insurance would you prefer: an HMO, PPO, ACO, or something else? Why? What details should you know about your health insurance?
4. Have you or someone you know ever been a telemedicine patient? How was the experience? What do you think would have been different about the visit had it been in person?

STUDY QUESTIONS

1. How can frontline health care professionals help prevent a medical malpractice lawsuit?
2. Identify the major disadvantage of a sole proprietorship or a partnership.
3. How does a corporation differ from a partnership?

4. Summarize the conflicts that exist when an MCO provides bonuses to providers for providing fewer tests.
5. What are the risks associated with technology in health care?

CASES FOR DISCUSSION

1. Brackenridge Hospital admitted Plaintiff to its intensive care unit following a serious car accident. Medical resident Dr. Villafani and attending physician Dr. Harshaw performed a tracheostomy and inserted a breathing tube. Several days later, plaintiff experienced bleeding from the surgical wound. Dr. Villafani examined plaintiff but did not immediately share plaintiff's condition with Dr. Harshaw. Plaintiff went into cardiac and respiratory arrest resulting in permanent and severe brain damage. At the time of plaintiff's treatment, Dr. Villafani was enrolled in a general surgery residency program operated by St. Joseph's Hospital. Central Texas Medical Foundation, an institution participating with St. Joseph's placed Dr. Villafani at Brackenridge Hospital, and had a contractual agreement with St. Joseph's to do so. The Foundation and Brackenridge dictated the details of how and when Dr. Villafani performed his residency responsibilities while at Brackenridge. The contract between St. Joseph's and the Foundation prevented St. Joseph's from having any direct control over Dr. Villafani's work while at Brackenridge. Plaintiff sued several defendants, including St. Joseph's, who was found vicariously liable for plaintiff's injuries under the theory of respondeat superior. On appeal, the court reversed. Who, if anyone, should be held vicariously liable for Dr. Villafani's treatment of plaintiff?
2. Ms. SoderVick was a patient at Parkview Health System's OB/GYN practice and arrived at Parkview's offices for an appointment. A certain Parkview employee was charged that day with updating patient information in the electronic health record system. Parkview had provided the employee with patient privacy issues and HIPAA compliance training. The employee had signed a "Confidentiality Agreement and Acknowledgement Regarding Access to Patient Information," which made clear that the release of patient information could be a violation of HIPAA and Parkview's policies and that an employee could be immediately terminated if the employee released such information. When Ms. SoderVick arrived, she submitted a completed patient information sheet to the employee who recognized Ms. SoderVick's name as someone who had commented on a photo of the employee's husband on his personal social media account. The employee suspected that Ms. SoderVick might be engaged in an extramarital affair with her husband, and she texted

her husband that Ms. SoderVick was a patient. The employee's texts included information, such as the patient's name, her job title, and the reasons for the appointment. The employee falsely texted her husband that Ms. SoderVick was HIV-positive and was promiscuous. Parkview ultimately learned of the employee's texts to her husband about the patient and launched an investigation that included notifying the patient of the disclosure of her protected health information. Ms. SoderVick then sued and asserted the legal theory of respondeat superior. Should Parkview be held liable? Was the employee's conduct incidental to her job duties? Should Parkview be held liable for the employee's acts?

Chapter 2

Laws and Regulations You Will Encounter

> "Law is an ordinance of reason for the common good, promulgated by him who has care of the community."
>
> Thomas Aquinas

Objectives

After reading this chapter, you should be able to:

1. Describe the government's influence on the practice and licensing of medicine.
2. Identify circumstances that require mandatory reporting.
3. Describe controlled substances acts.
4. Summarize basic workplace discrimination and harassment laws.
5. Summarize basic laws impacting employee wages and benefits.
6. Summarize Occupational Safety and Health Act (OSHA) regulations for the health care industry.
7. Describe the purpose and components of job descriptions, procedures manuals, and employee handbooks.
8. Explain the purpose of unions.

Building Your Legal Vocabulary

Bargaining unit
Censure
Collective bargaining
Disparate impact
Disparate treatment
Facially neutral
Inference
Interstate commerce
Mitigating
Negligent per se
Probable cause
Quality assurance
Risk management

Introduction to Health Care Laws, Regulations, and Business Protocols

In addition to the health care business framework details discussed in Chapter 1, the laws and regulations that touch health care and those who work in the industry are also an important part of that framework. As a health care professional, you will want to be aware of various medical practice laws and regulations, the nature of your employment, discrimination, sexual harassment, health care laws and regulations, and, in some situations, union membership and collective bargaining. In addition, it is helpful to remember that you work in a field that is highly regulated by federal and state legislation. Ignorance of a law or a regulation does not excuse a health care professional's violation. You are a professional and expected to know the laws and regulations that govern your profession.

Medical Practice Laws

Medical practice laws control the practice of medicine. State legislatures establish state medical boards with the authority to control health care provider licensing. In all states, individuals who are not physicians are prohibited from practicing medicine, yet not every state defines what "practicing medicine" means. Medical practice acts may include nursing practice acts, or the two may exist independently. State law, if any, governs the licensure of other health care professionals.

Licensure statutes were originally established to prevent unqualified people from practicing medicine. In *Hawker v. New York* (170 U.S. 189 [1898]), the U.S. Supreme Court extended physician licensure decisions to include standards of behavior and ethics, holding that in a physician, "character is as important a qualification as knowledge."

censure A formal statement of disapproval.

Licensing boards not only grant licenses but also renew and revoke licenses. They may fine, reprimand, and **censure**. In so doing, the board must follow due process. Due process requires that a provider be put on notice that there is a pending suspension or revocation, be given an opportunity for a prompt hearing, and be given the rights to confront the accuser, prepare an effective defense, retain counsel, and cross-examine any witnesses.

One ground for the revocation or suspension of a medical license is permitting unlicensed physician to perform procedures or tasks that are outside of the scope of their practice. Physicians should be aware of the risks of assigning medical procedures to nonphysicians, including license suspension or revocation or a medical malpractice lawsuit. As a health care professional, understanding your scope of practice is your responsibility, as is the need to question the assigning provider about tasks assigned to you that you believe may be outside the scope of your practice.

State Board of Registration

State medical licensing laws regulate a state's board of registration. These boards, which are known by many different names depending on the state, are typically overseen by people who have the expertise to understand and enforce the applicable laws. A board learns about provider complaints through anonymous communications, newspaper articles, patients, hospitals, other health care providers, insurance companies, and the provider's employees. The board has the power to perform investigations and make formal conclusions according to its rules. During an investigation, a board may have access to records involving the health care provider's practice—prescriptions, hospital records, reimbursement claims—as long as information that can be used to identify the patient in the record is withheld.

Washington state health officials have restricted the license of a Spokane County osteopathic physician and surgeon after reviewing charges and evidence accusing him of malpractice.

Jason Adam Dreyer is accused by the Washington State Department of Health of performing extensive spine surgeries on patients for financial gain. He currently works for MultiCare in Spokane. . . .

In the statement of charges, the Board of Osteopathic Medicine and Surgery Department says Dr. Dreyer "overstated the Patient's diagnosis of 'dynamic instability' to justify spinal fusion surgeries, overstated treatments performed during spine surgeries, and inadequately charted in Patient's records" at Providence St. Mary's.

Until the charges are resolved, Dr. Dreyer cannot perform spine surgeries.

Nelson, M. (2021, March 16). Spokane Physician Stripped of License After Reports of Excessive Surgeries. KREM2. Retrieved from www.krem.com/article/news/health/spokane-physician-stripped-license-reports-excessive-surgeries/293-14893f1d-7c72-4ddd-b362-61f7672e73bc.

Mandatory Reporting

Under certain circumstances, providers are required to submit reports to governmental agencies. Some of these reports are required by all practicing health care providers, and these include births, deaths, and communicable diseases. Generally, health care providers are required to report injuries and suspicious or "unnatural" deaths to the local coroner or medical examiner. To whom and when the reports are submitted are factors that vary from state to state. In many states, failure to report specific injuries or deaths can result in misdemeanor charges.

Abuse

Providers, nurses, and other health care professionals are required in most states to report the abuse of children, elderly, and patients. The Child Abuse Prevention and Treatment Act requires that states meet certain uniform standards to be eligible for federal assistance in setting up programs to identify, prevent, and treat problems caused by child abuse and neglect. It also protects the reporter of abuse against liability and includes a penalty clause that permits the prosecution of professionals who have knowledge of but do not report abuse.

Being on the front lines of healthcare, nurses have unfortunately needed to report cases of abuse and neglect. As mandated, they are trained to identify signs and symptoms of abuse or neglect and are required by law to report their findings. Failure to do so may result in discipline by the board of nursing, discipline by their employer, and possible legal action taken against them.

If a nurse suspects abuse or neglect, they should first report it to a physician, nurse practitioner, or physician assistant. Notifying a supervisor may also be required, depending on the workplace. If the victim is with a suspected abuser, the exam should take place without that person in the room. Nurses should provide a calm, comforting environment and approach the patient with care and concern. A complete head-to-toe examination should take place, looking for physical signs of abuse. A chaperone or witness should be present if possible as well. Thorough documentation and description of exam findings, as well as patient statements, non-verbal behavior, and behavior/statements of the suspected abuser should also be included.

The nurse should notify law enforcement as soon as possible, while the victim is still in the care area. However, this depends on the victim and type of abuse. Adults who are alert and oriented and capable of their decision-making can choose not to report on their own and opt to leave. Depending on the state, nurses may be required to report suspicious injuries to law enforcement whether or not the patient consents or wishes to press charges.

Depending on the type of abuse, the nurse is required to call Adult Protective Services or Child Protective Services and follow it up with a written report. Contacting additional resources, such as social services, may also be a requirement (depending on the organization). . . .

Nurses should be familiar with their state's mandated reporter laws. Employers are typically clear with outlining requirements for their workers, but nurses have a responsibility to know what to do in case they care for a victim of abuse.

Bucceri Androus, A., RN, BSN. (2021, November 23). What Should a Nurse Do If They Suspect a Patient Is a Victim of Abuse? RegisteredNursing.org. Retrieved from www.registerednursing.org/articles/what-should-nurse-do-suspect-patient-victim-abuse/.

Even if you are not considered a mandatory reporter, remember that you are still an agent of your supervising provider. A suspected case of child or elder abuse should be carefully documented and office policy should be closely followed.

Elder abuse is handled at the state and national level, and virtually every state has some form of elder abuse law. Exactly who is protected and from what the legal protection is provided varies from state to state. Federal acts that seek to protect various forms of elder abuse include The Elder Justice Act of 2009, The Older American Acts, and Elder Abuse Victims Act of 2009. See Chapter 4 for a more detailed discussion of elder abuse.

Elder abuse is a silent problem that robs seniors of their dignity, security, and—in some cases—costs them their lives.

Up to five million older Americans are abused every year, and the annual loss by victims of financial abuse is estimated to be at least $36.5 billion. . . .

How many older Americans are abused?

Approximately one in 10 Americans aged 60+ have experienced some form of elder abuse. Some estimates range as high as five million elders who are abused each year. One study estimated that only one in 24 cases of abuse are reported to authorities.

Who are the abusers of older adults?

Abusers are both women and men. In almost 60% of elder abuse and neglect incidents, the perpetrator is a family member. Two thirds of perpetrators are adult children or spouses.

National Council on Aging. (2021, February 23). Get the Facts on Elder Abuse. National Council on Aging. Retrieved from www.ncoa.org/article/get-the-facts-on-elder-abuse.

Controlled Substances Acts

A controlled substance is a drug or a chemical whose manufacture, storage, distribution, and use are controlled by the government because of its potential for misuse or abuse. Notably, not every drug that is controlled is considered to have the potential to be abused. Controlled substances acts restrict the distribution, classification, sale, handling, storage, prescription, and use of controlled substances. These acts cover

everyone from criminals who are not involved in health care delivery to health care providers, who hold licenses to write prescriptions, to manufacturers of drugs. Because different states have varying prescription and over-the-counter drug regulations, a federal Controlled Substances Act of 1970 (CSA) was implemented. Most states have enacted the Uniform Controlled Substances Act, which is similar to the CSA.

Despite laws and regulations enacted to ensure the legal and proper dispensing and use of controlled substances, the acts are not foolproof. Controlled substances are not always used for their intended purpose, which has given rise to a black market for prescription drugs.

Methods of Obtaining Prescription Drugs

A review of multiple studies demonstrates a variety of ways individuals obtain prescription drugs. The following summarizes the studies' findings.

- 55% free from a friend or relative
- 20% from a prescriber
- 10% purchased from a friend or relative
- 5% stolen from a friend or relative
- 5% purchased from a drug dealer
- 2% from multiple doctors
- 1% from theft from medical practice or pharmacy
- Less 1% from internet

Preuss, C., Kalava, A., King, K. (2021, February 17). Prescription of Controlled Substances: Benefits and Risks. National Center for Biotechnology Information. Retrieved from www.ncbi.nlm.nih.gov/books/NBK537318/.

Opioids are one example of a controlled substance that has acquired a significant black market. Due to its highly addictive properties, opioid addiction has been a significant concern in the United States. According to The United States Department of Health and Human Service - Substance Abuse and Mental Health Services Administration, "[a]mong people aged 12 or older in 2019, 3.7 percent (or 10.1 million people) misused opioids in the past year."

Substance Abuse and Mental Health Services Administration. (2020, September). Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health.

Seven years ago, as the opioid epidemic tightened its hold on Erie, Taylor Miller launched an effort to help recovering addicts like herself.

Miller, then 20, said she wanted to do all she could to get her hometown through the heroin-fueled crisis.

Her advocacy, including a candor that made her message so heartfelt and genuine, has been cut short.

Miller, 27, died Sunday at her family's residence in Fairview. She "lost her battle with mental illness and addiction," her family said in her obituary, published in the Erie Times-News on Thursday.

. . . Miller started a Facebook group, H.O.P.E., for Heroin Overdose Prevention in Erie, that raises the awareness of deaths resulting from heroin overdoses. . . .

Palattella, E. (2021, 15 April). Taylor Miller, Advocate in Erie's Opioid Fight, Dies at 27: 'She Fought So Hard'. GoErie. Retrieved from www.goerie.com/story/news/crime/2021/04/16/taylor-miller-opioid-crisis-heroin-advocate-eries-fight-dies-27-losing-battle/7234867002/.

Controlled Substances' Schedules

Controlled substances are further classified into five schedules, which reflect the drug's accepted medical use and its potential for abuse.

Drug Scheduling

Drugs, substances, and certain chemicals used to make drugs are classified into five (5) distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence. As the drug schedule changes—Schedule II, Schedule III, etc., so does the abuse potential—Schedule V drugs represents the least potential for abuse. A Listing of drugs and their schedule are located at Controlled Substance Act (CSA) Scheduling or CSA Scheduling by Alphabetical Order. These lists describe the basic or parent chemical and do not necessarily describe the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be classified as controlled substances. These lists are intended as general references and are not comprehensive listings of all controlled substances.

Please note that a substance need not be listed as a controlled substance to be treated as a Schedule I substance for criminal prosecution. A controlled substance analogue is a substance which is intended for human consumption

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and is structurally or pharmacologically substantially similar to or is represented as being similar to a Schedule I or Schedule II substance and is not an approved medication in the United States. (See 21 U.S.C. §802(32)(A) for the definition of a controlled substance analogue and 21 U.S.C. §813 for the schedule.)

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are:

heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are:

Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin

Schedule III

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are:

Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone

Schedule IV

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are:

Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol

Schedule V

Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are:

cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.

United Stated Drug Enforcement Administration. (n.d.). Drug Scheduling. United Stated Drug Enforcement Administration. Retrieved from www.dea.gov/drug-information/drug-scheduling.

Prescribing controlled substances is highly regulated. According to the Shands Jacksonville Drug Report, "Federal law states that a prescription for a controlled substance may be issued only by individual practitioners who are authorized to prescribe controlled substances by the DEA in the jurisdiction where they are licensed to practice their profession. The term 'individual practitioner' includes physicians (MD and DO), dentists (DDS), veterinarians (DVM), and podiatrists (DPM). In the state of Florida, mid-level practitioners such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants are not authorized to prescribe controlled substances."

On June 1, 2010, the Electronic Prescribing for Controlled Substances (EPCS) rules took effect to streamline and improve tracking by eliminating paper prescriptions. According to the DEA, "The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, the existing rules. The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances."

Drug Enforcement Agency

In the health care industry, the DEA is primarily charged with enforcing the Controlled Substances Act, including the distribution, classification, sale, handling, storage, prescription, and use of controlled substances.

> The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.
>
> DEA. (n.d.). Who We Are /About. DEA. Retrieved from www.dea.gov/divisions/about.

United States Pharmacopeia (USP)

The United States Pharmacopeia (USP) is a collection of drug information and standards published by the United States Pharmacopeial Convention. The USP defines standards for prescription drugs, over-the-counter drugs, drugs intended for humans as well as animals, dietary supplements, and some food ingredients. If a specific drug or drug ingredient has a USP quality standard, it is noted via a "USP-NF" marking. And, if that marking is present, the drug or drug ingredient must match the USP standards.

The USP standards are a reference guide for regulating entities, who use them as a benchmark to ensure the products meet the standards. Drug manufacturers also use the USP to ensure its products meet regulatory requirements. Both prescription and over-the-counter drugs must meet the applicable USP standards.

Employment Law

The federal law described in this Employment Law section seeks to ensure employees can work in an environment that is free from discrimination and harassment.

Equal Opportunity Employment

While everyone cannot reach the highest rung on the corporate ladder, the Civil Rights Act of 1964 tells us that the opportunity to do so cannot be denied employees on the basis of race, color, religion, sex, or national origin.

Title VII of the act prohibits employment discrimination and applies to all employers of 15 or more employees whose business involves **interstate commerce**, to labor unions of 15 or more members, to employment agencies, as well as to state, local, and federal employees. The Equal Employment Opportunity Commission (EEOC) administers and enforces Title VII. Illegal discrimination may be shown by either **disparate treatment** or **disparate impact**.

interstate commerce The movement of goods and services, or services that rely on the movement of goods, which cross state borders within the United States.

disparate treatment A marked difference between the way two things are handled.

disparate impact Disproportionate result that seemingly fair practices or policies have upon a protected group.

inference A process of reasoning by which a fact is deduced as a logical consequence of other facts.

Disparate Treatment

The most obvious form of discrimination occurs when an employer treats similarly situated employees differently because of their race, sex, religion, or national origin. Because of the difficulty in proving a disparate treatment situation, courts allow plaintiffs to prove disparate treatment indirectly. **Inferences** may be drawn from the acts of the employers. If an employer has been shown to discriminate in the past, the inference will be stronger that the present act involves discrimination.

Plaintiffs prove their disparate treatment cases by proving the required elements: (1) the plaintiff must be a member of one of the groups protected by Title VII, (2) the plaintiff must be capable of doing the job, and (3) he or she must have been discriminated against.

Disparate Impact Some employment policies are **facially neutral**, in that they appear to treat all employees equally, but have a "disparate" or "adverse" impact on a particular protected group. For example, a minimum height requirement may discriminate against women, or a maximum weight requirement may discriminate against men.

facially neutral On the surface the matter appears to be impartial.

An employer, faced with the charge of disparate impact, may counter that the policy is justified by business necessity and is related to job performance. In the following case, an employer's business necessity defense was upheld by the court.

Gregory Backus, RN, requested placement as a full-time registered nurse in the labor and delivery section. The hospital refused the request on the basis that it did not employ male RNs on the obstetrics and gynecology units and gave as a reason their concern for female patients' privacy and personal dignity. Backus filed a sex discrimination complaint with the EEOC, alleging that the hospital's refusal to transfer him to the labor and delivery section was discriminatory based on sex.

Testimony in the hospital's defense relied on its policy of recognizing and respecting the privacy rights of its patients. Hospital policy required that catheterizations be performed by individuals of the same sex as the patient. The hospital's policy of restricting nursing positions in labor and delivery came from the fact that obstetrical patients continually have genitals exposed and that there are few duties that a nurse performs that are not sensitive or intimate in nature.

The court decided against Backus and found merit in the hospital's argument that the majority of women patients would object to intimate contact with a member of the opposite sex in the labor and delivery room. The court commented that "in addition to offending patients, a male nurse would necessitate the presence of a female nurse to protect the hospital from charges of molestation. . . . The court refused to consider a male nurse analogous to a male doctor because the doctor, and not the nurse, had been chosen by the patient."

Backus v. Baptist Medical Center, 510 F. Supp. 1191 (1980)

Filing with the EEOC Most EEOC actions begin with the filing of a Charge of Discrimination by an individual who believes they have been discriminated against. A Charge of Discrimination must be filed within 180 days following the incident, unless the facts warrant an exception that extends the period to 300 days. After a Charge of Discrimination is filed, the EEOC will conduct an investigation.

probable cause Having more evidence for than against.

If the EEOC finds **probable cause** and that Title VII may have been violated, attempts are made to mediate the matter. If the parties are not able to reach agreement, the EEOC issues a Right to Sue Letter to the complaining party, who is free to pursue the matter in a court of law.

Interviewing

Discrimination law has made many changes in the employment interview situation necessary. Employers are not allowed to ask interview questions involving race, religion, age, or whether the interviewee is pregnant. Interview questions must have a legally permissible and non-discriminatory purpose. Sometimes, the mere phrasing of a question can render the question discriminatory. See Table 2-1 for "Interview Questions to Avoid and What to Ask Instead."

Table 2-1 Interview Questions to Avoid and What to Ask Instead

Instead of This	Ask This
How many children do you have?	What days and hours are you able to work?
How old are your children? Or: What arrangements do you have for child care?	Do you have nonwork–related responsibilities what will interfere with specific requirements for the job?
What is your religion? Or: Will you need personal time for particular religious holidays?	Are there specific times that you cannot work?
Do you own a car?	Do you have a reliable method of transportation to get to work?
What is your national origin? Or: Where did you live while growing up?	Are you legally eligible to be employed in the United States?
What is your maiden name?	Have you ever been employed under a different name?
Do you have any disabilities?	Can you perform the duties of the job for which you are applying?
Are or have your wages ever been garnished?	Credit references can be used if in compliance with the Fair Credit Reporting Act of 1970 and the Consumer Credit Reporting Reform Act of 1996.
Do you own your own home?	How long have you resided at your current address? What was your previous address? How long did you live there?
When did you graduate from high school or college?	Do you have a university or college degree, a high school diploma, or equivalent? (Ask only if relevant to job performance.)

Source: Jeanine D'Alusio, J. (2020, February 5). Hiring in Healthcare: Interview Questions to Avoid and What to Ask Instead. Relias. Retrieved from www.relias.com/blog/hiring-in-healthcare-interview-questions-to-avoid-what-to-ask.

It is surprising that a simple interview question can leave your organization vulnerable to risk, but it is true. In fact, an Associated Press and CNBC poll conducted by The Associated Press-NORC Center for Public Affairs Research found that:

- 35% of job seekers have been asked whether they were married (which is against federal law)
- 21% of job seekers have been asked about their medical history or a disability (which can open employers to discrimination lawsuits)
- Overall, 51% of job seekers said they were asked at least one inappropriate or personal question.

Jeanine D'Alusio, J. (2020, February 5). Hiring in Healthcare: Interview Questions to Avoid and What to Ask Instead. Relias. Retrieved from www.relias.com/blog/hiring-in-healthcare-interview-questions-to-avoid-what-to-ask.

Preemployment Testing

Employers are allowed to test potential employees as part of the hiring process, but such tests must be carefully constructed, usually by experts, to ensure that they only measure the skills and abilities necessary to do the job. In *Griggs v. Duke Power Company*, a landmark case in discrimination law, the U.S. Supreme Court established a strict standard, called the business necessity test, for business practices that have an adverse impact on various minority groups. Some forms of testing were determined to be a subtle means of discrimination:

Duke Power Company, a large power-generating corporation in the Carolinas, for years limited blacks to the labor department, the lowest-paying area of the company, and refused to approve requests for transfers to other departments. When Title VII was passed, the company instituted a policy which stated that employees who wanted transfers from the labor department had to present a high school diploma or pass a high school aptitude test. Black employees sued, contending that the company was trying to lock them into their jobs as laborers by imposing unnecessary transfer requirements that they would be unable to meet because of unequal educational opportunities.

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