

CHAPTER 4

REGULATORY ISSUES, THE LAW, AND PRACTICE MANAGEMENT

Risk comes from not knowing what you're doing.

—Warren Buffett

LEARNING OBJECTIVES

- Appreciate the number of regulations affecting the medical practice.
- Understand the nature of contracting.
- Describe contracting prohibitions for medical practice contracts.
- Articulate legal requirements for a valid contract.
- Understand the seriousness of Stark law.

INTRODUCTION

Healthcare is one of the most heavily regulated industries in the United States. The need for such extensive regulation is understandable when one considers the impact of healthcare and the medical practice on society (Field 2008). In recent years, calls for additional regulation have increased in the wake of criticism that the US healthcare system and physician practices may place patients at undue risk due to the imbalance of the agency relationship that exists between a physician and his or her patients (Makary 2012).

The medical practice makes decisions and guides patients on matters of great consequence. In addition, providers, unlike almost any other types of professionals, can influence the behaviors and actions of consumers. Most patients have limited knowledge of healthcare, and as a result, they rely on the physician or another provider to serve as their agent in seeking solutions to their healthcare needs (Gafri and Whelan 1998). Some observers argue that the provider–patient relationship constitutes an agency relationship under the law; at the least, the practitioner has an absolute obligation to act in the best interest of the patient (ACP 2016; this resource is a valuable reference that all practice managers and leaders should be familiar with and have available for use in the practice).

This unmatched position of trust also places the healthcare provider in a position to potentially abuse the relationship because he or she has such immense power over the patient.

One issue that emerged as a consequence of the traditional fee-for-service or volume-based care is physician-induced demand (PID). PID is an economic concept whereby the service provider is in a position to create demand for these services for the provider's own benefit. Because medical services have, until recently, been reimbursed entirely on a volume basis such that the more service that is provided, the more the practice is paid, physicians have had an incentive to deliver more services than may be needed (Johnson 2014). Through policy and education, and aided by the growth of reimbursement models based on value rather than volume, practices must defend against self-serving behavior in the practice.

The number of rules and laws regulating healthcare is enormous. The Affordable Care Act (ACA) alone contains more than 11,000 pages of regulations (O'Donnell and Akinnibi 2013). Being aware of, let alone understanding, all the rules and regulations pertaining to healthcare delivery is almost impossible for any practice manager. One way for managers to stay current with new and changing rules and regulations is to regularly check sources such as the following:

- ◆ The *Federal Register*, at www.federalregister.gov
- ◆ The US Department of Health & Human Services “Laws & Regulations” web page, www.hhs.gov/regulations
- ◆ The Centers for Medicare & Medicaid Services (CMS) “Regulations & Guidance” web page, www.cms.gov/regulations-and-guidance/regulations-and-guidance.html
- ◆ The websites of, briefings by, and seminars offered by professional organizations, such as the American College of Healthcare Executives (www.ache.org), Medical Group Management Association (www.mgma.com), Healthcare Information and Management Systems Society (www.himss.org), Healthcare Financial Management Association (www.hfma.org), and American Group Psychotherapy Association (www.agpa.org)

- ◆ CMS's Center for Consumer Information & Insurance Oversight website, www.cms.gov/ccio/resources/regulations-and-guidance/

Another recommendation is to have a working relationship with a law firm that specializes in healthcare matters; when in doubt about regulations, seek its opinion. Newsletters published by health law firms can also be helpful in keeping the manager current on new and changing regulations. The American Health Lawyers Association (2017) may be a useful resource in selecting a law firm for the practice.

JURISDICTION

The jurisdiction refers to the governmental unit empowered to make regulations and to enforce those regulations. Medical practices are governed under the laws of local, state, and federal jurisdictions. On occasion, international law may also be relevant.

Legal issues in the practice management realm generally fall into two categories:

- ◆ General applications of the law, which include most areas of state and federal law that apply to all businesses and all employment situations
- ◆ Specific applications of the law, which apply to the medical practice and the healthcare environment

LAWS REGULATING THE ORGANIZATION AND GOVERNANCE OF CORPORATIONS

BUSINESS LICENSES

Most cities and municipalities require all businesses, including medical practices, to be licensed. Practice leaders should check with the local city clerk's office for regulations regarding the requirements for business licenses and proceed in accordance with these local requirements.

LICENSING OF MEDICAL PROFESSIONALS AND THE NATIONAL PROVIDER DATA BANK

The licensing of medical professionals is performed at the state level. With that activity falling to the states, national licensing functions are naturally limited. However, a national database, known as the National Provider Data Bank (NPDB), tracks the significant negative occurrences of medical professionals. Prior to the development of the database, practitioners who had serious issues related to their practices could avoid detection by moving to

another state. The NPDB, which now contains more than 1.26 million reports, allows any prospective employer or any hospital considering privileging a practitioner to determine if that practitioner has any serious violations in his or her background, regardless of the state of origin.

The database requires that the following events be reported (HHS 2016a):

- ◆ Adverse actions—negative actions taken against providers related to licensing, privileges, and certifications. Licensing bodies, hospitals, and certification authorities are required by federal law to report these events to the NPDB.
- ◆ Medical malpractice payments—payments made on behalf of a provider by his or her insurance company for a written claim or judgment against the provider.
- ◆ Criminal convictions—all criminal convictions handed down by federal or state courts.

Practices must be aware of the NPDB status of its current and prospective providers. These data are available at the NPDB website, www.npdb.hrsa.gov. In addition to making inquiries at the time the practice is vetting new members, practice leaders should query the NPDB annually to check the status of each current provider.

CORPORATE ORGANIZATIONAL DOCUMENTS

Practices can organize in a number of legal forms, as discussed in chapter 1. A provider may choose to practice outside of any legal entity, which is known as a sole proprietorship. Other forms, as shown in exhibit 4.1, require the creation of a legal organization. The exhibit compares the different legal forms of practices on the basis of their prominent features.

Each state has laws in place governing the establishment of corporations and partnerships. In cases other than a simple proprietorship, most states require the medical practice to file organizational documents with the state and to register as a business. These documents include the corporate or partnership name, the business purpose in the case of corporations, the registered agent, and the person responsible for tax and other important notifications regarding the entity. Corporations are also required to indicate the person filing the incorporation documents, including information about the number and type of shares that will be issued. Additionally, many states require the names and addresses of the directors and officers and the legal address of the company.

In most cases, practices wishing to form corporations or partnerships should seek the advice of competent legal counsel and other advisers to be sure that the practice is properly documented and registered.

EXHIBIT 4.1

Corporate and Partnership Entities and Their Taxation

Issue	C-Corp	S-Corp	Partnership	LLC
Tax treatment	The corporation and the shareholders are taxed on distributions (double taxation)	Expenses and revenues flow through to shareholders	Expenses and revenues flow through to partners	Expenses and revenues flow through to partners
Limit on ownership	No limit on number of shareholders or classes of stock	Limited to no more than 75 shareholders, only one class of stock, and must be a domestic corporation	Can be a partnership of individuals or other entities such as corporations or trusts	Must have at least one owner, but no limitation on the number of owners
Designation of owners	Shareholder	Shareholder	Partner	Manager sometimes referred to as member
Governance	Directors and officers	Directors and officers	Partners	Members or managers
Governing documents	Articles of incorporation, bylaws, and agreements between the shareholders	Articles of incorporation, bylaws, and agreements between the shareholders	Partnership agreements	Articles of organization, operating agreement
Authority to bind entity to contracts	Officers and directors	Officers and directors	Partners	Members or managers
Liability of owners for obligations of the organization	No personal liability, but individuals can be held liable for their own actions	No personal liability, but individuals can be held liable for their own actions	Partners are jointly and severally liable for obligations. This means each partner is liable for all obligations	Members and managers are not liable for obligations of the organization. Individuals can be held liable for their own actions

Finally, following the corporate document requirements regarding meetings, elections of officers, shareholder meetings, voting, and other corporate organizational duties is important. Corporations that fail to do so risk the removal of their corporate status, which results in the loss of all corporate benefits.

SPECIAL ORGANIZATIONAL FORMS FOR PROFESSIONALS

Chapter 2 discusses some of the many ways medical practices are organized and structured. Although the laws vary from state to state, a number of special categories for medical practice corporate forms are common. They are as follows:

- ◆ Professional corporations (PCs)
- ◆ Professional associations (PAs)
- ◆ Professional limited liability corporations (PLLCs)

These organizations have characteristics that differentiate them from other incorporated entities. These characteristics include the following:

- ◆ The owners must be providers and be licensed by the state.
- ◆ In many states, the tax year for PCs, PAs, and PLLCs must be based on the calendar year. This requirement helps prevent tax avoidance through shifting income between the owners and the company, as most PCs operate as a vehicle for providing income to the owners.
- ◆ Taxation is different, as professional corporations are taxed at a flat 35 percent level and distributions are taxed again at the individual level.
- ◆ Industry-specific rules may apply to the organization regarding its name or how it is otherwise designated. This requirement varies significantly by state; for example, practices that operate in California are prohibited from using a fictitious person's name as part of the organization's name (Medical Board of California 2013).
- ◆ The owners are required to be the primary producers of the services offered. This regulation is a departure from most corporate structures. The potential hazard in situations whereby the governed are also the governors is that rules and performance standards are less rigorous. The practice manager must continually help the providers understand that the organization provides the structure and framework to fulfill the goals of the physicians.

- ◆ Special approvals may be required by state medical governing boards of the secretary of state.

Because rules of incorporation for professionals vary by state, practice leaders should familiarize themselves with the laws of the state in which they intend to incorporate.

CONTRACT LAW

Contract law is an important aspect of practice administration and requires special expertise. Depending on the organizational structure of the practice, contracts exist between the physicians and the practice, other providers, outside payers, vendors, and other entities. Examples of entities that contract with medical practices include the following:

- ◆ Government payers
- ◆ Commercial payers (insurance companies)
- ◆ Other healthcare organizations, as when a practice member becomes a hospital's medical director
- ◆ Medical supply companies
- ◆ Equipment leasing companies
- ◆ Real property lessees
- ◆ Lending institutions, in the form of promissory notes
- ◆ Staff, in the form of employment agreements

Some aspects of standardized contracts may seem routine, but the practice manager should be cautious about the execution of any contract without expert legal advice.

FEDERAL AND STATE TAXATION

Medical practices are subject to all local, state, and federal rules and regulations on taxation, including property, sales, employment, and income taxes. These taxes vary greatly by state, and special circumstances may apply in any particular jurisdiction, so medical practice managers must understand all the relevant tax issues that pertain to the practice in its location. Complications may arise if the practice operates in more than one jurisdiction, such as practice locations in more than one state, which is increasingly common today.

PCs, PAs, and PLLCs often are taxed differently in many states and are taxed at the highest individual tax rate. This is one reason medical practices often do not retain

Retained earnings

Profits not distributed to shareholders as dividends; the accumulation of a practice's profits less any dividends paid out. Retained earnings are not spendable cash.

Equity

The owners' share of a business.

Stock

A certificate (may be electronic or another type of record) that indicates ownership of a portion of a corporation; a share of stock.

Accountant

A person who is trained to prepare and maintain financial records.

earnings. In other corporations, **retained earnings** add to owner **equity**, which can ultimately be taxed at a favorable capital gains rate (Harkavy 1953). (In many corporations, retained earnings increase the equity and, therefore, the value of the **stock** of the corporation. When the stock is held for the required period and then sold, that gain can be treated under a favorable capital gain status.) In special corporations such as PCs, these retained earnings may be treated as ordinary income and, again, taxed at the highest individual tax rate.

Practices, especially small ones, often contract with **accountants** and other tax professionals to assist with the many requirements of the tax system and the intricacies of the corporate forms that practices may employ (Anderson 2016).

ANTITRUST LAWS

Recently, antitrust laws have not been as significant an issue for most medical practices as in the past; however, like other businesses, medical practices are subject to antitrust laws. Antitrust laws are intended to prevent the concentration of market power, which could create monopolies that become harmful to individuals and the public at large. Some relevant federal laws governing antitrust are as follows (Legal Information Institute 2016):

- ◆ The Sherman Act regulates the artificial raising of prices by prohibiting the restriction of supply and other monopolistic practices.
- ◆ The Clayton Act clarifies and provides additional specifications to the Sherman Act regarding remedies, exceptions, and enforcement strategies.
- ◆ The Robertson-Patman Act prohibits the establishment of minimum prices as a protection for small business.
- ◆ The Federal Trade Commission (FTC) Act outlaws unfair trade practices and unfair methods of competition, such as deceptive advertising. The FTC is allowed to investigate and apply financial remedies to violations of the law.
- ◆ The Hart-Scott-Rodino Act requires large corporations to file a report with the FTC prior to a merger so that the commission can determine if the merger would violate antitrust laws.

In addition, state antitrust statutes may influence the merger and acquisition activity of medical practices.

Although this area of the law has been relatively quiet in recent years for medical practices, the US Department of Justice in 2016 brought an antitrust action against the Carolinas HealthCare System for anticompetitive activities related to its numerous medical practices (DOJ 2016). This recent case demonstrates the importance of practice managers

maintaining familiarity with antitrust laws. For in-depth information and full guidance on antitrust issues related to medical practices, see FTC (2017).

LABOR LAWS

Generally speaking, all labor laws apply to the medical practice, as they do to any employer. Therefore, practice managers must be aware of all of the applicable local, state, and federal laws that apply to employment practices. For example, laws vary in their application on the basis of the number of people employed, highlighting the importance of understanding the nature of each law and how it may apply to the particular organization.

Labor laws deal with fair employment practices, wage and hour rules, and nondiscrimination in hiring and employment. The US Department of Labor (2016b) maintains a helpful website that provides a great deal of information about individual states' employment laws as well as federal regulations.

The Americans with Disabilities Act of 1990 provides definitions and rules regarding the employment of people with disabilities and helps define what constitutes a disability. As with other federal laws regarding employment, this act is enforced by the US Equal Employment Opportunity Commission (EEOC 1990).

The Occupational Safety and Health Administration (OSHA 2016) enforces regulations related to workforce health and safety and investigates potential safety violations and outbreaks of workplace illnesses.

The Family Medical Leave Act and its amendments offer protection for employees requesting a leave of absence to deal with health-related issues. The legislation provides for the following (DOL 2016a):

Twelve workweeks of leave in a 12-month period for:

- the birth of a child and to care for the newborn child within one year of birth;
- the placement with the employee of a child for adoption or foster care and to care for the newly placed child within one year of placement;
- to care for the employee's spouse, child, or parent who has a serious health condition;
- a serious health condition that makes the employee unable to perform the essential functions of his or her job;
- any qualifying exigency arising out of the fact that the employee's spouse, son, daughter, or parent is a covered military member on "covered active duty;" or
- twenty-six workweeks of leave during a single 12-month period to care for a covered service member with a serious injury or illness if the eligible employee is the service member's spouse, son, daughter, parent, or next of kin (military caregiver leave).

These policies are intended to protect workers from being terminated because of an extended leave due to the conditions described above, and they help the organization preserve the employer–employee relationship.

The private inurement doctrine is part of the *Internal Revenue Code* and prohibits private parties from receiving undeserved benefits from a charitable organization as defined under section 501(c)3 of the code. This issue may be relevant for physician practices or for physicians in employment or contractual relationships with not-for-profit organizations, such as hospitals, because it imposes certain compensation restrictions. In general, any compensation received from a charitable organization must be set at market rate. This doctrine often comes into play when practices are acquired by hospital systems or other organizations that are tax-exempt under section 501(c)3 (IRS 2016).

Other laws that have major implications for medical practices include the following:

- ◆ Health Insurance Portability and Accountability Act (HIPAA), discussed later in the chapter
- ◆ ACA
- ◆ Genetic Information Nondiscrimination Act
- ◆ Health Information Technology for Economic and Clinical Health Act, discussed in chapter 3

FEDERAL LAWS GOVERNING MEDICARE FRAUD AND ABUSE

Fraud and abuse has resulted in billions of wasted dollars each year and is a significant problem for Medicare and Medicaid. Fraudulent billing may amount to 3 percent to 10 percent of the total healthcare spending in the United States, representing \$98 billion in 2011 (Goldman 2012). Significant efforts are ongoing to deter fraud and abuse, which in some cases have created difficulties for providers. Many well-intended, law-abiding practitioners have been caught up in the web of regulation due to misinterpretations of these complex rules. Regulations related to fraud and abuse require great attention and focus in the medical practice environment (GAO 2012).

FALSE CLAIMS ACT

The False Claims Act is part of the US Criminal Code. Passed in 1863, the law provides for assignment of liability, including triple damages and penalties, to anyone who knowingly submits or causes the submission of a false claim to the US government. The act was

a result of false claims for payment submitted to the government during the Civil War (Showalter 2017).

This law has found new meaning for the medical practice in modern times because it is used to prosecute fraudulent claims for medical services to Medicare and Medicaid. It contains an old legal device known as *qui tam*, a Latin phrase meaning “he who brings a case on behalf of our Lord the king, as well as for himself” (DOJ 2017). The *qui tam* provision allows whistleblowers to bring cases on behalf of the federal government against providers they believe have engaged in fraudulent billing activities to Medicare or Medicaid. The federal government has encouraged whistleblower activity by providing large bounties in cases where money is recovered from the provider.

ANTI-KICKBACK STATUTE AND PHYSICIAN SELF-REFERRAL LAW

The anti-kickback statute (AKS) and Stark law have similar aims in protecting assets of the Medicare and Medicaid program. Exhibit 4.2 illustrates the comparison between the two sets of laws. Note that the AKS applies to all federal programs and those doing business with the government, whereas the Stark law applies specifically to the Medicare and Medicaid programs.

The Stark law, named for Rep. Fortney Hillman “Pete” Stark Jr., D-CA, who sponsored the initial legislation, is set forth in section 1877 of the Social Security Act. Also known as the physician self-referral law, Stark deserves special consideration by practice leaders because it has an enormous impact on the medical practice. It is intended to prohibit self-referral of designated services (listed in exhibit 4.3) offered by the provider, a family member of the provider, or an entity controlled by the provider or family member. The prohibition stems from PID, as providers create a conflict of interest and the potential for abuse when they refer patients to services in which the providers have an economic interest.

The Stark law is complicated and requires careful attention from practice leaders. It must be taken into consideration in all contracts and dealings with related parties, such as family members or other organizations in which the practitioner has a financial interest (CMS 2015a; StarkLaw.org 2013).

Stark allows for certain exceptions so that the normal activities of the medical practice are not impeded. Those exceptions are noted in exhibit 4.4. Congress provides guidance to CMS in creating these exceptions, which is founded in a quote from Representative Stark (Teplitzky 1999):

What is needed is what lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the types of arrangements that are permissible and the types that are prohibited. If the law is clear and the penalties are severe, we can rely on self-enforcement in the great majority of cases.

EXHIBIT 4.2

Comparison of
the Anti-Kickback
Statute and Stark
Law*

	THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(b))	THE STARK LAW (42 USC § 1395nn)
Prohibition	Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business	- Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies - Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral
Referrals	Referrals from anyone	Referrals from a physician
Items/ Services	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	- No intent standard for overpayment (strict liability) - Intent required for civil monetary penalties for <i>knowing</i> violations
Penalties	Criminal: - Fines up to \$25,000 per violation - Up to a 5 year prison term per violation Civil/Administrative: - False Claims Act liability - Civil monetary penalties and program exclusion - Potential \$50,000 CMP per violation - Civil assessment of up to three times amount of kickback	Civil: - Overpayment/refund obligation - False Claims Act liability - Civil monetary penalties and program exclusion for <i>knowing</i> violations - Potential \$15,000 CMP for each service - Civil assessment of up to three times the amount claimed
Exceptions	<i>Voluntary</i> safe harbors	<i>Mandatory</i> exceptions
Federal Health Care Programs	All	Medicare/Medicaid

*This chart is for illustrative purposes only and is not a substitute for consulting the statutes and their regulations.

Source: Reprinted from OIG (2016).

Audit

A careful review of
financial records to
verify their accuracy.

All members of the medical practice who are involved in contracting and developing relationships with third-party providers or considering merger or acquisition activity must be familiar with Stark and the AKS. Also important is that all providers and staff in the practice have a thorough understanding of the provisions of the Stark law that apply to the practice. Policies and procedures need to be in place to safeguard the practice from any violations, and periodic **audits** should be undertaken to ensure that all billing practices and

Clinical laboratory services
Physical therapy services
Occupational therapy services
Outpatient speech-language pathology services
Radiology and certain other imaging services
Radiation therapy services and supplies
Durable medical equipment and supplies
Parenteral and enteral nutrients, equipment, and supplies
Prosthetics, orthotics, and prosthetic devices and supplies
Home health services
Outpatient prescription drugs
Inpatient and outpatient hospital services

EXHIBIT 4.3

Designated Health
Services Defined
by the Stark Law

Source: CMS (2015a).

contractual relationships are in compliance with the Stark law. Even the inadvertent violation of Stark's provisions can result in heavy fines and possibly endanger the practice's existence.

REGULATION OF BILLING IN MEDICAL PRACTICES

The complicated nature of billing and payment processes in the medical practice and the constant addition and revision of billing regulations has made compliance a major issue. Unlike in many industries, erroneous billing of medical services may not only cause unhappy patients but also lead to legal action by state and federal government. The practice manager and leaders must ensure the highest integrity in their billing practices. To meet this expectation, standards for ethical and accurate billing must be established and staff must be well trained not only about the intent of the practice's billing standards but also on the details of the billing process. Innocent mistakes can result in substantial penalties, and willful deceit or careless disregard for proper procedures can lead to criminal enforcement (CMS 2015b).

Medical billing has become a profession unto itself. Wise practice leaders consider employing or contracting with certified professional coders (CPCs) and other billing specialists. CPCs undergo a rigorous training and examination process to reach this professional designation, leading many of them to become among the best qualified individuals to provide coding and billing activities for the practice (AAPC 2017).

Like so many areas, being familiar with the resources that provide guidance and information to organizations on billing, coding, and other management concerns is important

EXHIBIT 4.4General Exceptions
to the Stark Law

Physician services (section 411)
 In-office ancillary services (section 412)
 Prepaid plans (section 413)
 Intrafamily rural referrals (section 414)
 Academic medical centers (section 415)
 Implants furnished by an ASC (section 416.1)
 EPO and other dialysis-related drugs furnished or ordered by an ESRD facility (section 416.2)
 Preventive screening tests, immunizations, and vaccines (section 416.3)
 Eyeglasses and contact lenses following cataract surgery (section 416.4)

Source: LegisWorks (2017).

Note: ASC = ambulatory surgical center; EPO = erythropoietin; ESRD = end-stage renal disease.

because the field changes rapidly and the amount of information available is beyond the scope of any textbook. All practice managers and leaders must continuously seek new knowledge, updates, and information and look for credible websites to follow on a regular basis. Many of these sites offer daily updates that deliver news and information to the practice leadership by e-mail. A few of the many reputable and reliable websites include the following:

- ◆ www.ache.org (the American College of Healthcare Executives home page)
- ◆ www.cms.gov (the CMS home page)
- ◆ www.aafp.org/practice-management.html (the Practice Management page of the American Academy of Family Physicians)
- ◆ <http://medicaleconomics.modernmedicine.com> (the Medical Economics website, part of the Modern Medicine Network)
- ◆ www.medscape.com/resource/medical-practice-management (the Practice Management & Strategy page of the Medscape website)
- ◆ www.mgma.com (the Medical Group Management Association home page)
- ◆ www.amga.org (the home page for the organization formerly known as the American Medical Group Association)

In addition to the organization, agency, and reference sites listed, virtually every medical specialty society has practice management information, much of which is specific

to the specialty. Choose the sites that serve the particular practice best, as the vast amount of information available can easily be overwhelming, and follow them. Information that is received but unused is of no value; be thoughtful about what you choose to read and digest.

MEDICAL RECORDS REGULATIONS

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

HIPAA was enacted in 1996 by Congress and signed by President Bill Clinton the same year (GPO 1996). The act is among the most important laws affecting the medical practice in the area of patient privacy. HIPAA establishes strict rules and accountability for protecting patient health information (PHI) in any form: written, oral, or electronic (HHS 2016b).

The act allows the sharing of PHI on an as-needed basis in three principal areas (GPO 1996):

1. Treatment: one or more providers may discuss PHI when providing, managing, or coordinating care.
2. Payment: allows the medical practice to disclose PHI in order to receive payment for services rendered.
3. Healthcare operations: this can include a significant number of activities related to the operation of the medical practice including:
 - a) quality assessment and improvement activities, including case management and care coordination;
 - b) competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation;
 - c) conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs;
 - d) specified insurance functions, such as underwriting, risk rating, and reinsuring risk;
 - e) business planning, development, management, and administration; and
 - f) business management and general administrative activities of the entity, including but not limited to: de-identifying protected health information, creating a limited data set, and certain fundraising for the benefit of the covered entity.

HIPAA PRIVACY BREACH MANAGEMENT

As discussed in chapter 3, HIPAA violations are on the increase, at least in part because of the increased use of electronic records. Criminals no longer have to steal a physical record

in order to breach the privacy of a patient; locking the medical records room door is no longer an adequate safeguard of the patient record.

Social media has also provided new ways to breach privacy, often in unintended ways. The innocent posting of a picture, a tweet, or a blog comment can lead to a privacy violation. One of the best ways to prevent privacy breaches is to have in place carefully crafted social media and medical record access policies that are in compliance with HIPAA. Several key privacy principles should be included as part of any such policy (GPO 1996):

- ◆ Recognition of the professional and ethical responsibility to protect patient privacy
- ◆ Strict limitation on or prohibition of transmitting patient images
- ◆ Prohibition of the posting or publishing of any information that could lead to the identification of the patient
- ◆ Compliance with all practice policies regarding the use of electronic devices
- ◆ Maintenance of a professional relationship with the patient at all times

RETENTION OF MEDICAL RECORDS

The retention guidelines of a medical record vary by state. The state medical board should be able to provide guidance on this issue. In most cases, the records of children need to be maintained longer than those of adults. New digital technologies make the task of medical record retention easier and less expensive than old paper records. The practice manager should be versed in the medical record retention regulations in the state where the practice is located (AHIMA 2013).

MALPRACTICE

Malpractice can be defined as professional activity that is careless, illegal, or improper. In medicine, malpractice is a special type of personal liability related to professional practice and the physician–patient relationship, which is considered an implied contractual relationship. Although in the eyes of the law the physician–patient relationship is contractual, it is different from those in many other aspects of our lives (e.g., the purchase of a car or home). It is essentially an agreement between the physician and the patient that the physician will provide the patient with treatment.

Furthermore, the law has very specific definitions of treatment. Malpractice law varies by state, so, as with each area of law considered in this chapter, the practice leader must be knowledgeable about the laws of the state where the practice is located.

These state laws, as well as additional federal legislation, regulate the operations of the medical practice and, importantly, the relationship of the medical practice with its physicians and with third parties. Examples of the third parties affected by malpractice laws and regulations include the following:

- ◆ Federal contracts, such as those with Medicare and Medicaid and other government payers
- ◆ Commercial insurance contracts
- ◆ Provider agreements with hospitals and other healthcare organizations

The most common contract in the medical practice is the provider agreement between the physicians of the practice and the organization.

THE MEDICAL PRACTICES ACT

The federal Medical Practices Act requires that all physicians who practice in the United States be licensed. It sets out general definitions of professional and unprofessional conduct and creates licensing bodies to regulate medical practice. The act prohibits the splitting of bills for services between providers and generally regulates such aspects of medical practices as marketing management relationships; fee sharing; and related arrangements between physicians, their practice, and other parties.

ADDITIONAL MEDICAL PRACTICE LEGISLATION: MORE ON THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

Although the HIPAA patient privacy provisions tend to receive the most attention, the law was passed with this main purpose (GPO 1996):

[T]o amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and healthcare delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.

Medical practices must be sure to maintain policies and procedures that protect the privacy of their patients. These should include having private spaces available to discuss personal issues related to their financial obligations, treatment plans, and scheduling of procedures to ensure that others cannot see or hear the reason for other patients' visits.

Information visible on computer screens and tablets and documents used at the appointment desk or nurses' station must also be protected if it contains personal health information.

Certificate of need (CON)

Approval issued by a governmental body to an individual or organization proposing to construct or modify a health facility or to offer a new or different service.

CERTIFICATE-OF-NEED LAWS

Some states require a **certificate of need** be granted for hospital or health system building projects that expand the capacity of the practice. Certificate-of-need (CON) laws are intended to encourage effective allocation of healthcare resources. In most states that require a CON for expansion of services, the state's health plan indicates the level of need for certain services on the basis of specific community and population characteristics. Some states have repealed their CON laws, so the practice must understand CON as it relates to its jurisdiction and maintain awareness of political shifts that may influence CON decisions.

RISK ASSESSMENT

Assessing risk is an important aspect of practice management. Risk occurs in a number of domains, and all should be considered when creating a risk mitigation program:

- ◆ Malpractice risk
- ◆ Risk due to the physical environment
- ◆ Employee safety and security
- ◆ Financial risk
- ◆ Compliance risk

Additional areas of risk, including emergency management and cybersecurity, are discussed in detail in chapter 11.

INSURING AGAINST RISK

Although they may expend great effort to act prudently in all respects of their operations, many practices purchase insurance against many of the risks that may arise. Types of insurance include the following:

- ◆ General business liability insurance, which protects against a variety of risks that can occur at the medical practice. Examples are a visitor falling in the waiting room or an accident occurring in the parking lot.

- ◆ Business property insurance, which protects against the loss of equipment or damage to the practice building.
- ◆ Business income protection, which provides coverage for a loss of income to the practice for reasons such as the building being damaged by fire.
- ◆ Data breach protection insurance, a new line of insurance that provides assistance and economic protection from the consequences of a data breach.
- ◆ Officers and directors insurance, which provides protection against actions by the officers and directors of the practice that may result in lawsuits such as employment discrimination or wrongful dismissal.

Medical practice leaders must have a firm grasp of the terms of all insurance policy coverage and ensure that the practice is adequately protected from the hazard intended to be covered. Specifically, most policies contain exclusions and limitations of coverage that need to be understood before purchasing the policies. Also important is to deal with reputable agents and insurance companies; in the end, the protection will only be as good as the company behind the policy.

MEDICAL MALPRACTICE INSURANCE

Malpractice is a special category of insurance of particular interest to medical practices. Malpractice insurance is offered in three primary forms:

- ◆ *Claims made coverage.* This type of coverage pays for claims and the defense of claims taking place during the time that the policy is in force. For example, for a policy issued on January 1, 2016, and expiring on December 31, 2016, only those claims made in 2016, and only for actions occurring during that time leading to the claims made, would be covered. The advantage of this type of policy is that the premiums are relatively inexpensive; however, the practice needs to make sure its coverage does not lapse without an extended policy endorsement.
- ◆ *Occurrence coverage.* This type of coverage pays for any claim that occurred during the policy. For example, if a policy was issued on January 1, 2016, and expired on December 31, 2016, any alleged malpractice that occurred during that time would be covered regardless of when the claim of that malpractice was made.
- ◆ *Extended reporting endorsement.* These policies are offered to providers and medical practices to extend the coverage of claims made policies. They

essentially convert a claims made policy into an occurrence policy so that any alleged act of malpractice that occurred during the policy is covered. This type of coverage can be helpful when considering changes in employment, practice arrangements, retirement, or other situations that may cause a claims made policy to expire. Whether to purchase an extended reporting endorsement for a provider can be a significant point of discussion during contract negotiations because of the expense of these policies.

The practice must carefully consider the type of malpractice coverage it purchases for the protection of its providers, including the potential consequences triggered by providers joining and leaving the organization.

COVERAGE LIMITS FOR MALPRACTICE INSURANCE

When contemplating coverage limits for malpractice insurance, the risk of claims and the historical amount of claim settlements should be considered. Historically, obstetrics and gynecology, neurosurgery, and orthopedic surgery are the higher-risk specialties. Claims tend to be more frequent for these specialties, and settlements tend to be more substantial, than for other types of practice. Because of this history, practices specializing in these areas often purchase higher limits of coverage than practices specializing in areas that are considered less of an insurance risk, such as pediatrics and family medicine.

Premiums can vary dramatically from state to state on the basis of the tort laws that govern malpractice claims and adjudication. In states where damages are limited, malpractice costs tend to be lower than in states that do not place a cap on damages. Each practice needs to consider malpractice coverage options in the context of its state's laws.

Medical malpractice coverage should be obtained for both the practice and the individual practitioners. Medical practice liability cannot be shielded by any corporate form from malpractice liability; this point differentiates malpractice from other types of liability. Finally, the majority of medical malpractice claims are brought against a relatively small number of providers, and this number is closely correlated with the number of patient complaints received by those providers (Hickson et al. 2002).

RISK MITIGATION PROGRAMS

As the old saying goes, "An ounce of prevention is worth a pound of cure." That maxim holds true in medical malpractice. In this arena, prevention is typically carried out through risk mitigation programs. Risk mitigation requires (1) active and continuous monitoring by the practice manager of the behavior of all members of the practice and (2) intervention when violation of expected behavior occurs. Hickson and his colleagues at Vanderbilt

University School of Medicine have undertaken substantial work on the factors that influence malpractice claims and how they can be prevented (Vanderbilt Center for Patient and Professional Advocacy 2017). Disruptive behavior and the lack of professionalism have been found to be two causes at the root of malpractice cases (Reiter, Pichert, and Hickson 2011; Catron et al. 2015; Pichert et al. 2013).

An effective risk management program for reducing malpractice claims and improving the patient experience is founded on the following principles (Hickson, Moore, and Pichert 2012):

- ◆ Professionals are willing to engage in all aspects of the job—tedious or otherwise—to the best of their ability.
- ◆ Professionals commit to
 - technical and cognitive competence,
 - clear and effective communication,
 - being available,
 - modeling respect, and
 - self-awareness.
- ◆ Professionalism demands self- and group regulation.

Another important benefit of a risk management program is improved employee satisfaction. Medical practices are stressful enough without having additional tensions imposed by the detrimental behaviors of practice members. Additional information about managing staff issues is found in chapter 8.

DISCUSSION QUESTIONS

1. Discuss some of the major regulations and laws that govern contracting for medical practices.
2. What are designated health services, and what is their significance to the medical practice?
3. What are some exceptions to the Stark law?
4. What components of a contract are required for it to be legally binding?
5. Why are “claims made” malpractice insurance policies so popular?

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