This chapter provides a brief overview of some of the most pertinent federal laws related to the business of healthcare. Certain laws apply to businesses of any size, while others apply only to entities with a minimum number of employees. Individual states may have additional regulations beyond that which is required by federal statute. Common state laws will be mentioned as applicable, but every practitioner is encouraged to check with state and local laws to ensure compliance.

**EMPLOYMENT LAW**

**Fair Labor Standards Act**

The Fair Labor Standards Act applies to virtually all employers in the United States. The Act establishes standards for minimum wage, overtime pay, recordkeeping and child labor. All employee positions must be designated as either “exempt” or “nonexempt” for overtime pay requirements. Exempt employees may not be covered by the overtime pay and minimum wage provisions of the Act. Because exemptions are narrowly defined, employers are encouraged to contact their local Department of Labor Wage and Hour Division for guidelines for categorizing specific positions.

**Minimum Wage**

Employees who are classified as nonexempt must receive at least the federal minimum wage ($7.25/hour as of July 24, 2009; increased by Executive Order 13658 to $10.35/hour as of January 1, 2018). Employers in states, cities or counties with minimum wage rates higher than the federal rate are required to pay the higher rate.
Overtime Pay

Nonexempt employees must also be paid at least 1.5 times their regular pay rate for working more than 40 hours per week. Each work week stands alone: if someone works 30 hours 1 week and 50 hours the next, their hours cannot be averaged for purposes of overtime pay. However, hours that an employee is out for sick leave or vacation do not count toward overtime pay because the employee was not physically on the job. The Act does not limit either the number of hours in a day or the number of days in a week that an employer may require an employee to work, as long as the employee is at least 16 years old. Similarly, the Act does not limit the number of hours of overtime that may be scheduled. Additional requirements can be found from the Department of Labor’s Wage and Hour Division.

Antidiscrimination Laws

A number of federal and state laws protect workers against discrimination. These will be addressed below by topic rather than by Act. The most notable governing federal law is Title VII of the Civil Rights Act, which applies to employers with 15 or more employees and prohibits discrimination because of race, color, religion, sex (including pregnancy), and national origin. The Age Discrimination in Employment Act protects employees ages 40 and older from discrimination in employment based on age. The Americans with Disabilities Act is covered in a separate section because it applies both to employment and to patient services. Most states also have antidiscrimination statutes, and some states prohibit discrimination based on additional characteristics, such as marital status, sexual orientation, or personal appearance. State laws may apply to employers with fewer than 15 employees.

Antidiscrimination laws and regulations cover virtually all aspects of employment—job advertisements and recruitment, interviewing and hiring decisions, compensation, promotion, firing, and retirement plans. Details of the regulations, including rules for documentation,
retention of records, and required workplace posters, are available from the Equal Employment Opportunity Commission (EEOC).

**Sexual Harassment**

Title VII of the Civil Rights Act protects workers from sexual harassment and gives the employer responsibility for the (mis)conduct of others—both employees and nonemployees, including patients and vendors. Although the federal law applies only to businesses with 15 or more employees, many states have laws covering sexual harassment that apply to employers with fewer employees.

The courts have recognized two basic types of sexual harassment. The first is “quid pro quo” harassment, where a supervisor conditions employment, compensation or promotion on the employee’s submission to sexual advances. The second is “hostile environment” sexual harassment, in which sexually-oriented conduct is sufficiently severe or pervasive such that it creates an intimidating, hostile, offensive or abusive work environment.

The following are examples of conduct found by the courts to be illegal sexual harassment:

- Repeated sexual innuendo, off-color jokes, and lewd remarks
- Letters, notes, e-mail, and graffiti of a sexual nature
- Sexual touching, propositions, insults, and threats
- Sexually-oriented demeaning names

The EEOC encourages employers to clearly communicate to employees that sexual harassment will not be tolerated and to establish an effective complaint process. Employers are required to take immediate and appropriate action when an employee complains. Experts in this field recommend developing written policies regarding sexual harassment, including the complaint process and sanctions, and conducting a training session to sensitize employees and
communicate the policies. Employees should also be educated that anti-discrimination laws protect employees against retaliation – meaning it is unlawful for employers to punish an employee for filing a complaint about harassment or discrimination.

**Pregnancy Discrimination**
The Pregnancy Discrimination Act (PDA), an amendment to Title VII of the Civil Rights Act, prohibits discrimination against women on the basis of pregnancy, childbirth or related medical conditions. As an amendment to the Civil Rights Act, it applies only to employers with at least 15 employees. The Act prohibits discrimination based on pregnancy or related condition to all aspects of employment, including hiring, firing, pay, job assignments, promotions, layoffs, training and health insurance or other fringe benefits. Women affected by pregnancy or related conditions must be treated in the same manner as other applicants or employees with similar abilities or limitations. For instance, if an employee is temporarily unable to do her job because of pregnancy, the employer must treat her the same as any other temporarily disabled employee; for example, by providing light duty, modified tasks, alternative assignments, disability leave or unpaid leave. Unlike Family Medical Leave Act (FMLA), 12 months of employment is not required prior to taking a leave under the PDA.

**Age Discrimination**
The Age Discrimination in Employment Act protects individuals who are aged 40 years or older from employment discrimination based on age. The regulations protect both employees and job applicants and apply to employers with 20 or more employees (this differs from Title VII of the Civil Rights Act, which has a threshold of applicability at 15 employees). Although the law does not specifically prohibit asking an applicant’s age or date of birth, the EEOC closely scrutinizes requests for age information because such inquiries might deter older workers from applying or might indicate intent to discriminate. Similarly, a job application should not ask for
dates of military service or school graduation; these can be considered proxies for inquiries about age. Details about requirements of the age discrimination law are available from the EEOC.

*Compensation Discrimination*

Two federal acts serve as primary regulatory source of compensation discrimination: the Civil Rights Act and the Equal Pay Act.

Title VII of the Civil Rights Act prohibits discrimination based on race, color, religion, sex and national origin. Accordingly, employment compensation cannot be based on sex. Like other aspects of the Civil Rights Act, this provision applies only to employers with at least 15 employees. The Equal Pay Act prohibits compensation discrimination and requires employers to pay men and women equally for equal work performed in the same establishment under similar conditions. Because it was passed as an amendment to the Fair Labor Standards Act, the Equal Pay Act applies to most employers, regardless of size.

*Limited English Proficiency*

Title VI of the Civil Rights Act requires physicians who receive Medicaid or State Children’s Health Insurance Program (CHIP) reimbursement to take adequate steps to provide language assistance to patients with limited English proficiency. The type of assistance that must be provided to meet this requirement depends on factors such as the size of your practice, the frequency with which particular languages or patients with limited English proficiency are encountered and alternatives that are available for patients to access the type of services you provide. The Office of Civil Rights investigates complaints about possible noncompliance.
Family and Medical Leave Act

The Family and Medical Leave Act (FMLA) affects employers with at least 50 employees. Employees are eligible for FMLA benefits if they have been at the = at least 12 months and worked at least 1,250 hours over the past 12 months.

FMLA requires employers to allow eligible employees to take job-protected, unpaid leave for up to 12 weeks in a 12-month period for any of the following reasons:

• Birth, adoption, or foster-care placement of a child
• Care of a child, spouse, or parent with a serious health condition
• A serious health condition of the employee

The law also requires the employee be restored to the same or an equivalent position upon completion of the leave. Additionally, employers must continue the employee’s group health benefits coverage during the leave. FMLA, however, does not require the continuation of other fringe benefits; an employee’s right to those benefits depends on the employer’s established policies.

Details about the regulations are available from the Department of Labor’s Wage and Hour Division. Many states also have laws regarding family and medical leave that may differ from the federal law.

PRIVACY

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established standards to protect the privacy of personal health information. Every medical practice or practitioner
that conducts certain electronic transactions must comply with HIPAA’s three sets of regulations: 1) transaction and code sets, 2) security, and 3) privacy.

There are stiff penalties for violations of the HIPAA regulations. Civil monetary penalties may be imposed for unknowing violation(s) or for willful neglect. The secretary of Health and Human Services (HHS) has discretion in determining the amount of the penalty, but fines can range from a minimum of $100 per violation to a maximum of $50,000 per violation. Purposeful or “knowing” violations could result in criminal penalties, including fines of up to $250,000 and 10 years in prison.

TIP
Your state might have privacy or security requirements that are more stringent than those of the Health Insurance Portability and Accountability Act. Check with your state medical society or a consultant to find out how the two sets of regulations apply to your practice.

*What is Protected Health Information?*

Protected health information is broadly defined by HIPAA and includes patient information transmitted or maintained in any form—by electronic means, on paper, or through oral communications. Protected health information has three defining criteria:

1. It is created or received by a health care provider, health plan, employer, or health care clearinghouse.
2. It relates to the past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; or the past, present, or future payment for health care.
3. It identifies the patient or includes information that could be used to identify the patient. Identifying information is broadly defined by HIPAA and includes such information as
names, geographic subdivisions smaller than a state, all elements of dates (except year) for
dates directly related to an individual, telephone numbers, fax numbers, electronic mail
addresses, social security numbers, medical record numbers, health plan beneficiary numbers,
account numbers, license numbers, vehicle identifiers or serial numbers, URLs, IP address
numbers, finger or voice prints, identifiable photographic images, and any other unique
identifier.

Transaction and Code Sets Rule
The Transaction and Code Sets are rules to standardize the electronic exchange of patient-
identifiable, health-related information. Vendors, insurance companies, and providers must
comply with these standards for electronic claims filing and related activities, such as checking
on eligibility, obtaining referrals and authorizations, and following up on claims. Health care
providers are responsible for making sure the software they use and the vendors with whom
they contract are compliant with HIPAA standards. Claims filing software must be tested for
filing Medicare claims successfully. The American College
of Obstetricians and Gynecologists worked with expert consultants to develop a complete
about how to comply with the Transaction and Code Sets Rule.

Security Rule
The Security Rule set up administrative, physical, and technical safeguards to ensure the
confidentiality, integrity and security of protected health information that is sent or maintained
electronically. Because of the wide variations in the places where it will be implemented—from
hospitals to solo office practices—the HIPAA Security Rule has quite a bit of flexibility built in.
Of its 41 specifications, 20 are required to be implemented by all providers and 21 are
considered “addressable,” which means they should be considered and implemented if they are
“reasonable and appropriate” for a given practice. Providers must document the actions taken on all 41 specifications. If an addressable specification is not considered to be reasonable and appropriate for a specific provider or practice, an explanation must be documented and an “equivalent alternative measure if reasonable and appropriate” must be implemented.

Following is a summary of both the required and the addressable Security Rule specifications (some have been combined):

• Designate a security officer who has final responsibility for the practice’s security compliance (may be the same individual as the privacy officer).
• Analyze the risks to the confidentiality and integrity of the practice’s electronic patient information.
• Establish procedures for electronic auditing, which tracks who has accessed the computer files, what was done, and when.
• Create a “workforce clearance system”—background checks on employees and use of procedures that allow access to records only to authorized users.
• Protect access to computer files through procedures such as use of passwords and automatic time-out features when a computer is idle.
• Use encryption or secure messaging to communicate with patients or vendors electronically.
• Use computer data protection programs, including antivirus software, firewalls, spyware, and back-up-and-recovery programs.
• Establish policies for reporting both accidental and intentional security incidents.
• Develop a contingency plan to protect data during emergencies, such as floods, fires, or terrorism.
• Implement business associate contracts governing information created or transmitted electronically.
• Develop policies and procedures for security of all computer workstations, including personal digital assistants and laptops, and evaluate the policies and procedures periodically.
• Train all physicians and staff.
• Establish a sanction policy that holds all staff and business associates accountable to the practice’s security policies.

All of these requirements are explained in ACOG’s HIPAA Security Rule Manual: A How-To Guide for Your Medical Practice. In addition to definitions and explanations, the manual includes sample policies and procedures and checklists.

Privacy Rule
The HIPAA Privacy Rule applies directly to most obstetric–gynecologic practices and regulates how a practice may use and disclose protected health information. Physician practices are required to:
• Notify patients of their privacy rights and of the office privacy practices and obtain patients’ written acknowledgment of receiving the notice.
• Designate a privacy officer responsible for developing and implementing privacy policies and procedures (may be the same individual as the security officer).
• Provide training to all employees about the HIPAA regulations and the practice’s privacy policies and procedures.
• Make written agreements with business associates about disclosure of patient health information.
• Use or disclose personal health information only as permitted by the Privacy Rule.
• Disclose only the minimum amount of patient information necessary to achieve the purpose of the disclosure.
• Permit patients to inspect and get a copy of their health information.
The Privacy Rule specifies that patients can ask to amend inaccurate medical records. You may deny the request, but you must provide a written statement explaining the reason for the denial. *HIPAA Privacy Manual: A How To Guide for Your Medical Practice*, published by ACOG, is an excellent source of the policies, contracts, and forms that are needed to comply with the Privacy Rule.

Business associates are individuals or companies that receive or create patient information from you to perform nonpatient-care services, such as billing, accounting, collecting, or consulting. You must have a written agreement with each business associate that requires them to safeguard the information. If you do not give patient health information to the other party, a business association agreement is not needed for HIPAA requirements. For example, agreements are not needed with a janitorial service or photocopier repair service.

**TIP**

Situations involving disclosure of patient information to other providers for treatment of a patient do not require a business associate contract.

**OCCUPATIONAL SAFETY**

**Occupational Safety and Health Administration**

A number of regulations issued by the Occupational Safety and Health Administration (OSHA) apply to all medical practices, regardless of size. Other OSHA regulations apply only to facilities with 10 or more employees.
Medical practices must comply with OSHA standards for seven areas of workplace safety:

1. **Bloodborne pathogens.** Practices must abide by the following procedures:
   - Establish an exposure control plan and update it annually.
   - Use devices for protection, such as sharps disposal containers and self-sheathing needles.
   - Enforce safety procedures, such as hand-washing and use of protective equipment.
   - Provide personal protective equipment, such as gloves, gowns, and masks.
   - Make hepatitis B vaccinations available free to employees with potential exposure.
   - Provide testing and other follow-up activities to workers who have been exposed.
   - Use warning labels and signs on storage and refuse containers.
   - Provide information and training to employees.
   - Maintain employee medical and training records.

2. **Hazardous chemicals.** Practices must have a written list of the hazardous chemicals of any kind that are stored or used. For each chemical, employees must have access to the manufacturer’s data sheet on handling the chemical and containing spills.

3. **Emergency exits.** Safe exits must exist for emergencies, and easily visible evacuation diagrams must be posted.

4. **Electrical use.** OSHA rules apply to the safe use and location of electrical equipment, including computers, sterilizers, refrigerators, and microwaves.

5. **Reporting injuries and illnesses.** Although the federal OSHA regulations exempt medical offices from keeping an injury and illness log, some states require it. Check into your state requirements.

6. **Occupational Safety and Health Administration poster.** Every practice must display OSHA’s poster notifying employees of their rights to a safe workplace. Free posters can be downloaded from OSHA’s web site (www.osha.gov) or ordered at 800-321-6742 (OSHA).
7. Ionizing radiation. Practices that offer X-ray services must designate restricted areas, give employees in those areas personal radiation monitors, and post caution signs on rooms and equipment.

Additionally, if the medical practice has a laboratory, OSHA standards for Occupational Exposure to Hazardous Chemicals in Laboratories may apply. Other areas related to workplace safety are not regulated by OSHA, but the agency provides recommendations and links to help employers ensure a safe environment. For example, OSHA’s web site includes resources related to latex sensitivity, workplace ergonomics, and workplace violence.

**TIP: Free Consultation Available**

The Occupational Safety and Health Administration offers a free, confidential consultation service on request. A trained professional will schedule a visit to examine your operations and facility for potential safety hazards. The consultant will give you a written report and recommendations and also will provide training and help you implement the recommendations. No safety violations are reported to OSHA enforcement staff. More information can be found at [www.osha.gov/dcsp/smallbusiness/consult.html](http://www.osha.gov/dcsp/smallbusiness/consult.html).

**Clinical Laboratory Improvement Amendments**

The Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing on human specimens. Any office that performs laboratory tests must have a CLIA certificate. (If specimens, including blood, are only collected, a CLIA certificate number is not required.) A certificate of registration and CLIA number allow physicians to operate an office laboratory and receive Medicare reimbursement. However, CLIA standards apply whether or not Medicare claims are filed.
The Centers for Medicare & Medicaid Services (CMS) runs the CLIA program, including registering laboratories and enforcing compliance. To register a laboratory in your office, complete an application (form CMS-116 available from the CMS web site at cms.hhs.gov/clia/cliaapp.asp) and send it to the appropriate agency in your state—usually the state health department or a CMS regional office.

The CLIA program issues five types of laboratory certificates:

1. **Waiver.** A Certificate of Waiver allows a laboratory to perform only “waived tests,” tests that are considered to be so simple that there is little risk of error or patient harm. They include pregnancy tests, fecal occult blood tests, and some urine tests. For the complete list of tests approved by the FDA for certificate of waiver status, go to http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm. Laboratories with a certificate of waiver pay a minimal fee every 2 years and follow manufacturers’ instructions for testing. These laboratories are not subject to routine surveys.

2. **Provider-Performed Microscopy Procedures, most commonly referred to as PPMP.** This certificate permits a laboratory to perform waived tests as well as a subset of CLIA-defined moderate-complexity tests. The tests must be performed by a physician or midlevel practitioner. They include wet mount preps, pinworm examinations, fecal leukocyte examinations, and urine sediment examinations. Laboratories pay a minimal fee every 2 years, and routine laboratory surveys are not required.

3. **Registration.** This certificate is issued initially to laboratories applying to conduct moderate- or high-complexity tests. It permits the laboratory to perform the tests until it receives a certificate of compliance or accreditation.

4. **Compliance.** Laboratories performing moderate- or high-complexity tests are surveyed onsite and determined to be in compliance with the relevant CLIA standards before receiving this certificate.
5. Accreditation. An accredited laboratory goes through a process that includes an onsite survey conducted either by CMS, a state laboratory licensure program, or one of several private accrediting agencies, such as the Commission on Office Laboratory Accreditation, the College of American Pathologists, or the Joint Commission on Accreditation of Healthcare Organizations.

**Americans with Disabilities Act**

The Americans with Disabilities Act (ADA) cuts a wide swath—it prohibits discrimination in public accommodations, employment, transportation, government services, and telecommunications. ADA regulations regarding employment discrimination apply only to employers that have 15 or more employees. The regulations for public accommodations apply to all physician offices. To offset costs of complying with ADA regulations, small businesses can take a tax credit; a tax deduction may be available to businesses for barrier removal and alterations. The EEOC has responsibility for enforcing the employment provisions of the ADA. The Department of Justice handles complaints about other ADA violations.

**Americans with Disabilities Act Regulations for Employment**

Employers with 15 or more employees are prohibited from discriminating against “qualified individuals with disabilities.” A qualified individual with a disability is an individual who meets the requirements of a job and can perform the “essential functions” of the position with or without reasonable accommodation. If someone is qualified to do the job except for limitations caused by a disability, you must consider if making “reasonable accommodation” would enable him or her to do the job.

**Who is Protected**

An individual is considered to have a disability if any of the following criteria apply:
• Current physical or mental impairment. The impairment must substantially limit a major life activity, such as seeing, hearing, speaking, walking, breathing, performing manual tasks, learning, caring for oneself, and working. A minor short-term condition, such as a sprain, broken limb, or the flu, would not be covered.

• History of such an impairment. Individuals are protected by the ADA if they have a record of a disability, such as an individual who has recovered from cancer or mental illness.

• Perceived disability. Individuals who are regarded as having a substantially limiting impairment, even though they may not be functionally impaired, fall under the definition of a protected individual. In addition, the ADA protects individuals discriminated against because they have a known association or relationship with certain individuals. For example, someone who works as a volunteer with patients who have acquired immunodeficiency syndrome (AIDS) is protected from biases an employer may have about that association.

**Reasonable Accommodation**

The ADA uses the term “reasonable accommodation” to describe a modification to a job or the work environment that will enable an applicant to participate in the application process or enable an employee to perform essential job functions. Examples of reasonable accommodation include making your office readily accessible to an individual with a disability, restructuring a job, modifying work schedules, and buying or changing equipment. You are not required to make an accommodation if it would impose an “undue hardship,” meaning that it is excessively costly or disruptive to your practice.

**Americans with Disabilities Act Regulations for Public Accommodations**

The ADA requirements regarding accessibility and communication apply to all facilities open to the public, including physician practices.
Accessibility

New facilities must be built to be accessible to individuals with disabilities, and existing buildings must be modified when it is “readily achievable,” meaning it can be done “without much difficulty or expense.” Examples of modifications that typically are considered to be readily achievable include: installing a bathroom grab bar; lowering a paper towel dispenser; rearranging furniture; installing offset hinges to widen a doorway; or painting new lines to create an accessible parking space. For leased office space, the ADA makes the landlord and tenant jointly responsible for removing barriers or providing auxiliary aids. The landlord and tenant may decide by lease agreement who will actually make the changes, but both remain legally responsible.

Communication

To communicate effectively with hearing-impaired patients, the ADA requires practices to provide auxiliary aids based on the patient’s stated needs. These can include sign language interpreters, assisted listening devices, notetakers, written materials, television encoders, or telecommunications devices for the deaf. The law does not require a practice to provide an aid or service that would be an “undue hardship.” Undue hardship is defined as an action that is excessively costly, extensive, substantial, or disruptive or that would fundamentally alter the nature or operation of the business. Factors to consider include the cost of the aid, financial resources of the provider, and the difficulty of locating or providing the aid.

FINANCIAL RELATIONSHIPS

Antitrust
Federal antitrust laws are designed to protect free-market competition and are enforced by the Department of Justice and the Federal Trade Commission. Violations can result in severe penalties and even criminal prosecution.

Generally, you cannot collaborate with physicians outside your own practice about fees, discounts, boycotts, or other actions that would restrain trade or competition. Following are examples of activities that could violate antitrust laws:

• Agreeing with competing physicians about increasing fees by a certain percentage or charging interest on past due accounts
• Jointly threatening a boycott of a health maintenance organization or insurance company
• Agreeing with competing practices on “market allocation” arrangements—dividing up the territory where you will promote your practice

The legal role of physicians in negotiating with managed care plans has been an issue of concern since the 1990s. Legislation has been passed in some states allowing physicians to negotiate collectively, and several physician advocacy groups, including the American Medical Association, have supported bills introduced in Congress to afford relief from the restrictions on joint physician negotiating. This area is in a state of flux as physicians look for legal ways to gain leverage with managed care plans. If you are involved in collective negotiations of any kind, you should seek legal counsel to avoid antitrust implications.

**Stark Laws**

Two sets of federal laws, commonly known as Stark I and Stark II (after the laws’ main legislative sponsor, Representative Fortney “Pete” Stark), prohibit referring Medicare or Medicaid patients for certain health services if you or an immediate family member have a
financial relationship to the referred service. The Stark laws are “strict liability” because the laws can be violated even without an intention to do so.

Penalties for a violation of Stark regulations include denial of payment for the bill submitted, refund of any payment previously received, civil fines of up to $15,000 for each service, and penalties of up to $100,000 for “circumvention schemes.” Additionally, physicians and entities that violate the Stark law may be barred from participating in Medicare and Medicaid.

A violation of the Stark law occurs when all of the following elements apply:

- You refer a Medicare or Medicaid patient to a health care entity in which you or an immediate family member has a financial interest.
- The referral is for one of a list of designated health services.
- No Stark-rule exception applies.

**Definition of Financial Interest**
A financial relationship means having a direct or indirect ownership or investment interest in another entity or receiving compensation—again, directly or indirectly—from an entity. Such entities include hospitals and other organizations providing any of the designated health services.

The interpretation of indirect compensation can be subtle. If a hospital recruits you and gives you an incentive bonus or other monetary relocation package, it would be a Stark violation if any of the following conditions apply:

- The compensation is contingent on referrals or establishing exclusive privileges at that hospital
- You are required to refer patients to the hospital
- You are barred from establishing staff privileges at another hospital
As long as the relocation incentive is not tied to referrals, it is not in violation of Stark.

**Definition of Immediate Family**
The usual definition of immediate family includes parents, spouse, children, and siblings. In addition, the Stark definition includes in-laws, grandparents, grandchildren, stepparents, stepchildren, stepsiblings, and stepgrandparents.

**Designated Health Services**
Stark specifies the following categories of health services as subject to restrictions on referrals:

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

**Exceptions**
Some of the most significant exceptions to Stark violations include:

- Physician services given by or supervised by a physician in the same group as the referring physician
- Some in-office ancillary services when certain location, supervision, and billing requirements are met
• Services furnished to enrollees of prepaid plans
• Certain services that are subject to frequency limitations under Medicare rules, including screening mammography and ultrasound bone density measurement
• Compensation from an entity to a physician that is based on fair market value of the services and not on the volume or value of the referrals

**Medicare Billing Fraud**

A number of federal laws address misrepresentation of health care claims. The prohibition against filing false claims applies to individuals who “know or should know” that the services were not provided as claimed. The HIPAA regulations further clarified that there need not be proof of specific intent to defraud to prove that someone is in violation of this law.

A false claim is one in which any statement made to secure reimbursement is inaccurate. Thus, claims with even minor infractions—mistakes in dates, provider numbers, or place of service, for example—could be considered false under this broad definition. Generally, such individual clerical mistakes are not of great concern to regulators. Instead, they look much more closely at patterns of behavior.

The most common forms of Medicare fraud include:

• Billing for services not provided
• Misrepresenting the diagnosis to justify payment
• Soliciting, offering, or receiving a kickback
• Unbundling or “expanding” charges
• Falsifying certificates of medical necessity, treatment plans, or other medical records to justify payment
• Submitting duplicate reimbursement claims
• Upcoding—billing for a higher-level procedure than the one actually provided
The Office of the Inspector General for the US Department of Health and Human Services investigates Medicare fraud complaints. Practices or providers suspected of fraudulent activity are subject to an extensive audit and, if convicted, face stiff penalties. Civil penalties imposed range from $2,000 to $10,000 per improper item on the claim form plus triple the original charge. Additionally, violators can face prison time, deportation (if not a US citizen) and may be excluded from the Medicare program for a set period.

TIP
Your practice should develop and maintain a Medicare compliance plan—written rules and procedures to reduce the chance of improperly billing Medicare. Although it is not required by law, having such a plan is helpful in the event of an audit. Most important, the plan serves as an internal tool to establish clear policies for filing claims and teaching staff and physicians about compliance.

Seven steps are suggested by the Office of the Inspector General for an effective compliance program:
1. Develop standards and procedures. Establish a commitment to compliance and outline expectations for billing and coding, patient care, documentation, and payer relationships.
2. Designate someone with oversight responsibilities. A high-level individual should oversee development and enforcement of the compliance plan. This compliance officer should have authority to implement compliance procedures in all areas of the practice, regardless of his or her role in the practice.
3. Conduct effective training. Cover compliance procedures during training for all new employees. Further, training for coding and billing staff should be conducted at least annually. Be sure to document all meetings and retain copies of agendas and attendance sheets.
4. Develop lines of communication. Create a mechanism for employees to report suspected violations—anonymously, if possible. The system also should protect complainants from possible retaliation.

5. Create monitoring and auditing systems. Audit bills and medical records for compliance with billing, coding, and documentation requirements.

6. Investigate problems and take disciplinary action. Set up a system to consistently investigate allegations of improper activities. Potential sanctions range from oral warnings and written reprimands to demotion, temporary suspension, and termination.

7. Respond to offenses and initiate corrective action. If a practice discovers credible evidence of its own possible violation, it must report such conduct to the appropriate government agencies. In a governmental audit, such prior reporting will be in your favor and generally will reduce the penalties.

Sources of Information

Employment Law

- Department of Labor Wage and Hour Division: www.wagehour.dol.gov or 866-487-9243
- Equal Employment Opportunity Commission: www.eeoc.gov or 800-669-4000
- Office for Civil Rights: www.hhs.gov/ocr or 800-368-1019
- The American Bar Association Guide to Workplace Law: Everything You Need to Know About Your Rights as an Employee or Employer, published by the American Bar Association: www.ababooks.org or 800-285-2221
- Limited English Proficiency: Information and technical assistance: www.lep.gov or (202) 307-2222

Privacy Law
• Health Insurance Portability and Accountability Act: www.hhs.gov/ocr/hipaa or 800-368-1019
• “HIPAA Consult” series in Medical Economics, available free in the magazine’s searchable archives: www.memag.com or 800-226-8887
• HIPAA Policies & Procedures Desk Reference, published by the American Medical Association: www.amapress.com or 800-621-8335
• HIPAA Privacy Manual: A How-To Guide for Your Medical Practice, published by ACOG; it comes with a CD-ROM with model policies, contracts, and forms that can be customized for individual practices: sales.acog.com or 800-762-2264

Occupational Safety
• Occupational Safety and Health Administration: www.osha.gov or 800-321-6742
• Health & Safety Management for Medical Practices, published by the American Medical Association: www.amapress.com or 800-621-8335
• Clinical Laboratory Improvement Amendments: www.cms.hhs.gov/clia or 877-696-6775
• Commission on Office Laboratory Accreditation: www.cola.org or 800-981-9883
• Americans with Disabilities Act: www.ada.gov or 800-514-0301
Financial Relationships

- American Health Lawyers Association has numerous analyses and publications:
  www.healthlawyers.org or 202-833-1100

- Centers for Medicare & Medicaid Services provide a summary of the law and physician resources: www.cms.hhs.gov/medlearn/refphys.asp

- Health Care Fraud and Abuse: A Physician’s Guide to Compliance, published by the American Medical Association: www.amapress.com or 800-621-8335
