The OIG recommends that the physician practice evaluate claims/services selected to determine if the codes billed and reimbursed were accurately ordered, performed, and reasonable and necessary for the treatment of the patient.

Establish Practice Standards and Procedures

After the internal audit identifies the practice’s risk areas, the next step is to develop a method for dealing with those risks through the practice’s standards and procedures. The OIG believes that standards and procedures are important, and will look for them if there is ever an investigation. The standards and procedures should be appropriate to the practice size. DO NOT put standards and procedures in place that will not be followed. Creating higher standards than required by the laws and regulations is problematic because the government will try to hold the practice to that higher standard.

When determining standards, solicit input from the clinicians and administrative staff as to whether a particular standard will help their practice. Make sure the standard is drafted in concise, easy-to-understand language. Simply copying government/payer rules is not very helpful.

If the practice finds it is difficult to put standards in place, look to a third party’s standards (for example, other physician groups in the community, an IPA, MSO, or billing company). Sharing compliance responsibilities may assist physician practices in rural areas that do not have the staff to perform these functions. Physician practices using another entity’s compliance materials will need to ensure the materials make sense for the practice, and are concise and correct.

Practices should put the standards they develop into a binder that also includes the practice’s clinical forms or treatment guidelines.

If updates to the standards and procedures are necessary, employees must be told. Per OIG recommendations, new employees should be trained in standards and procedures immediately as part of their orientation to the practice. All training must be documented in the employee’s HR file and verified with the employee and supervisor’s signatures.

Specific Risk Areas

The OIG expects that a physician practice have in place, at a minimum, standards and procedures to prevent erroneous or fraudulent conduct in the following areas: (a) coding and billing; (b) reasonable and necessary services; (c) documentation; and (d) improper inducements, kickbacks, and self-referrals.

In its model compliance plan, the OIG lays out specific details for each of the above areas that should be incorporated into the standard.

Testing Technique

Review the OIG Compliance Program Guidance for Individual Physicians and Small Group Practices in its entirety. If you are not familiar with a risk area, make sure you research it. For example, if you are unsure what unbundling is, refer to the definitions provided in the guidance. You could also ask your billing and coding staff for an explanation of risk areas with which you are not familiar.

Coding and Billing

The OIG considers coding and billing to be a major part of any physician practice’s compliance program. In its model plan, the OIG identifies common practices that trigger investigations and audits, including:

- Billing for items or services not rendered or not provided as claimed, such as using a covered code or diagnosis when the practice knows the service is not covered
- Double billing resulting in duplicate payment
- Knowing misuse of provider identification numbers that result in improper billing, such as using another physician’s number because the performing physician does not have a number yet
- Unbundling, or billing for each component of the service instead of billing or using an all-inclusive code (for example, if dressings and instruments are included in a fee for a minor procedure, the provider may not also bill separately for the dressings and instruments)
- Failing to use coding modifiers properly
The U.S. Department of Health & Human Services (HHS) oversees Medicare, Medicaid, public health, medical research, food and drug safety, welfare, child and family services, disease prevention, Indian health, and mental health services; and, it exercises leadership in public health emergency preparedness and combating bioterrorism. The Office of Inspector General (OIG) works from within HHS to identify vulnerabilities in the health care system, to offer compliance guidance to health care facilities and professionals, and to promote accountability and enforce regulation.

Compliance professionals should have a basic understanding of key enforcement laws. Compliance professionals are not expected to know whether a law has been violated, but they should be able to identify potential problems and refer them to the physician and/or legal counsel.

Two laws—The Civil Monetary Penalty Law and the False Claims Act (FCA)—are related to proper claims filing. Mere mistake, which can be remedied by returning overpayments, does not result in violations of these laws.

Two additional laws—the anti-kickback and Stark laws—relate primarily to the relationships between referral sources, such as physicians and hospitals.

### Civil Monetary Penalties

The 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act significantly expanded the privacy and security obligations associated with the Health Insurance Portability and Accountability Act (HIPAA) of 1996. HIPAA privacy regulations restrict the use, access, and disclosure of protected health information (PHI) and other individually identifiable health care information. The Office of Civil Rights (OCR) has enforcement power for violations occurring as a result of willful neglect. OCR can now impose civil monetary penalties of up to $50,000 per violation. These penalties pertain to all health care providers, plans, and clearinghouses. The federal Civil Monetary Penalty (CMP) statutes and regulations provide the OIG with a variety of tools to address health care violations.

### Testing Technique

Review the Code of Federal Regulations (http://ecfr.gpoaccess.gov), U.S.C. 1320-7(a) and 42 CFR Part 100. COs should be aware of maximum penalties for violating the laws discussed in this chapter; however, a CO would not determine the penalty. The CO takes a proactive approach to prevent fraud and abuse. When the CO determines there is a compliance risk, a health care attorney should be consulted prior to self-disclosure, to determine the best course of action.

Congress has increased the strength of the civil monetary penalty law over the years. For example, HIPAA (1) increased the maximum penalty amounts per false claim from $2,000 to $11,000, plus the assessment of not more than three times the amount claimed for damages; (2) allowed CMPs to be assessed for incorrect coding, medically unnecessary services, and offering remuneration to beneficiaries to influence their choice of provider or supplier; and (3) established a new CMP for physicians’ false certification of eligibility for Medicare-covered home health services.

The Health Reform Act now requires providers to refund an overpayment to Medicare within 60 days of “identifying” it, and provides that an overpayment retained beyond that deadline is an “obligation” under the FCA (discussed in more detail, below).

Principal provisions of the CMP law concern:

1. items or services that the person knows, or should know, were not provided as claimed, to include claims with codes that will result in greater payment
2. submitting false or fraudulent claims
3. presenting claims related to unlicensed or improperly licensed physicians
Payments to Induce Reduction or Limitation of Services

Hospitals are prohibited from making payments, directly or indirectly, to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid patients. The hospital is subject to a civil money penalty of not more than $2,000 for each individual for whom the payment is made. When arrangements are based on quality payments, it is important to track that patients receive the same, or higher level, care.

False Claims Act

The FCA 31 U.S.C. §§ 3729-3733, is invoked frequently in the health care context. The FCA imposes civil liability on persons who knowingly submit a false or fraudulent claim, or engage in various types of misconduct involving federal government money or property. Health care program false claims include billing for services not rendered, billing for unnecessary medical services, double billing for the same service or equipment, or billing for services at a higher rate than provided (“upcoding”). Penalties under the FCA include treble damages, plus a penalty of $5,500 to $11,000 for each false claim filed.

Example:

Simple wound closures are bundled with lesion excisions. Intermediate and complex closures may be reported separately with lesion excisions, if performed and medically necessary. If a provider performs a simple closure with a lesion excision and submits the claim as an intermediate repair for additional reimbursement, he or she would be committing fraud.

As the government’s primary enforcement tool, the civil FCA covers offenses committed with knowledge of the falsity of the claim, reckless disregard, or deliberate ignorance of the falsity of the claim. The FCA does not encompass mistakes, errors, or negligence. For criminal penalties, the standard is even higher—criminal intent to defraud must be proved beyond a reasonable doubt.

Qui Tam Action

Civil actions may be brought in federal district court under the FCA by the Attorney General, or by a person known as a relator (eg, a “whistleblower”), in what is termed a qui tam action. Qui tam actions are a powerful weapon against health care fraud because a private party with independent knowledge of wrongdoing may initiate the action. Successful whistleblowers can receive 15-30 percent of the monetary proceeds of any settlement the government recovers. FCA recoveries fund government programs, and thus are a big part of paying for health reform.

Many attorneys specialize in bringing cases against providers, and there are even professional whistleblowers who go from provider to provider looking for evidence of wrongdoing. Many times, the whistleblower is involved in creating the issue that he or she alleges is wrong, or the “wrong” is really just a mistake. The government in these cases generally will not join (intervene) in the case, which makes it difficult for the whistleblower to continue his case.

Congressional amendments have supported expansion of the FCA. In 2009, Congress passed the Fraud Enforcement Recovery Act (FERA), which created a “reverse false claims” provision that imposes treble damages on any person who “knowingly and improperly avoids or decreases an obligation to pay or transmit money to the government.” PPACA also changed several provisions related to FCA requirements of public disclosure and original sources.

With regard to public disclosure, whistleblowers cannot bring claims based on information that has been disclosed in (1) a criminal, civil, or administrative hearing; (2) in a congressional, administrative, or Government
Chapter Review Questions

1. In what situations can a covered entity disclose protected information?
   A. To individuals (or their personal representatives), specifically when the individual requests access to, or an accounting of disclosures of, his or her protected health information
   B. To HHS when it is undertaking a compliance investigation or review or enforcement action
   C. A and B
   D. To attorneys in a compliance investigation

2. Which of the following is not a permitted use or disclosure?
   A. A covered entity may use and disclose protected health information for its own treatment, payment, and health care operations.
   B. Where the individual is incapacitated, in an emergency situation, or not available, covered entities generally may make such uses and disclosures if, in the exercise of their professional judgment, the use or disclosure is determined to be in the best interests of the individual.
   C. To an attorney with an executed business associate agreement.
   D. Without an individual’s authorization or permission, for health surveillance due to OSHA.

3. What is not required for an authorization for any use or disclosure of protected health information?
   A. An authorization must be written in specific terms.
   B. An authorization may allow use and disclosure of protected health information by the covered entity seeking the authorization, or by a third party.
   C. An authorization must contain specific information regarding the information to be disclosed or used, and the person(s) disclosing and receiving the information.
   D. All authorizations must be in formal language.

4. Which is a technical safeguard to ensure data security?
   A. Locked doors, signs warning of restricted areas, surveillance cameras, alarms, and identification numbers and security cables on computers.
   B. Procedures to protect ePHI when the building or facility has repairs or modifications.
   C. Privacy screens, enabling password protected screen savers, or logging off the workstation.
   D. Assigning each user of your system a unique user identifier.
Communication and Problem Resolution
Communication problems are often behind both human resources and compliance issues. Compliance and human resource personnel must provide employees with plenty of opportunities to communicate. Managers should be held accountable in reviews for their ability to engage employees. You don’t want the compliance hotline to be the only place employees feel they can ask questions.

Performance Reviews
Compliance should be a measured part of employee performance from top to bottom in an organization. To discourage whistleblowers, performance reviews are a good time for people to acknowledge concerns in writing, and to explain whether (and how) those concerns have been addressed.

Employee Health and Safety
Policies and programs for employee health and safety are important. Employees should be encouraged to immediately report any safety issues. Many companies have a designated health care clinic or provider for employee illness or injury. Employee Assistance Plans (EAPs) are a good way to help employees address personal issues that can affect job performance. Wellness programs and fitness memberships are also popular employment perks.

Companies may want to evaluate the ergonomics in the office to identify situations that could result in musculoskeletal disorders. This could include a job analysis of awkward positions, forceful lifting, pushing or pulling, prolonged repetitive motion, contact stress, and vibration.

Smoke and Drug Free Workplace
Human resources policies should be clear that the office or facility locations are smoke and drug free. Cite local ordinances regarding smoking inside or near doorways, if applicable. Also caution against the security risks of propping a door open to go outside and smoke. Provide referrals to smoking cessation programs for employees. Ensure signs are posted so that patients, contractors, and visitors know there is no smoking.

It is acceptable to perform pre-employment drug screens of employees as a condition of employment. A drug screen also can be done if an employee is involved in an accident, or if the employee is involved in a recovery program. Employees who drive vehicles should be subject to random testing.

Family Medical Leave Act
The Family Medical Leave Act (FMLA) provides job protection to eligible employees for certain family and medical reasons. Under federal law (state law may differ), the maximum time is 12 weeks. Companies can decide how to incorporate paid time off or sick time, and how employees will provide notice subject to state law requirements.

Time Records, Breaks, Overtime, and Time Off
Companies need to communicate, clearly and in writing, job expectations regarding time.

A company should have a specific policy for time records and when pay periods start. They may want to have a time care attendance terminal for hourly employees to swipe their name tag. Be clear that employees may check in themselves only: having another employee swipe you in is cause for disciplinary action.

Generally, hourly employees receive rest breaks and meal breaks for set hours, as determined by state law. If scheduling permits, in some departments hour breaks can be used. Meal breaks are not paid time and the company needs to have a policy about skipping meal breaks or rest breaks to leave work early. Also, in provider settings, the issue of breaks interfering with immediate patient care needs to be addressed.

Non-exempt, hourly employees also must be paid overtime in accordance with state law. Supervisor responsibilities when deciding to use overtime, how to ask employees to perform overtime, and when overtime is no longer necessary, should be clear.

The company should also have a clear policy on paid time off (PTO) and how it is accrued, requested, and vested as a benefit. There should also be policies on sick and disability leave, funeral leave, and jury duty.
Private or government investigations usually start with a request for records. In some situations, the FBI or state Medicaid fraud unit could show up and take records pursuant to a search warrant. It is helpful to have a policy that addresses search warrants, as well as an experienced government investigations attorney you can call for advice. It is best practice to educate employees that a subpoena does not automatically allow someone access to PHI. Knowing which agencies are involved with the investigation can be very useful in determining the source and scope of the investigation.

**Example:**
- A provider who treats the elderly (typically a sicker population) bills for higher levels of E/M service compared to physicians of the same specialty in the same geographic areas. The billing patterns may be considered an outlier and be selected for an audit.
- A provider who supervises a number of NPs or PAs that bill incident to under the physician’s provider number. The number of services billed under the physician’s NPI number may trigger an audit.

**U.S. Attorney’s Office**
At the top level of concern is the United States Attorney’s Office. The U.S. Attorney’s Office is typically involved in whistleblower actions, national investigations, or both. When you bring on legal counsel, ask the source of the investigation. If there is a national investigation, sometimes providers band together in their defense. Smaller providers could argue to be included to increase the sheer numbers.

If the case involves a single whistleblower, the immediate issue will be convincing the government not to get involved in the case. It’s easier to win dismissal in court or negotiate a settlement with one party.

**Office of the Inspector General**
At the next level is the Office of Inspector General (OIG), whose main responsibility is to investigate health care fraud and abuse. The OIG may have received a hotline call; referral from the Medicare Administrative Contractor, Recovery Audit Contractor, or Zone Program Integrity Contractor; or (more likely) is reviewing a particular billing issue and any red-flagged areas of concern regarding a provider.

The OIG also conducts national investigations and projects under various names, such as “operation bad bundle.” Hospitals or nursing homes are the usual targets of these investigations, but physicians may be asked to participate in the defense.

**State Investigations**
State investigations can involve many different agencies, including licensure, Medicaid, and state enforcement branches such as the State Attorney General. Any action involving the Attorney General is more serious. It is also not uncommon for state and federal agencies to work together.

**Medicare Administrative Contractor (MAC) or Private Payers**
MACs can initiate an investigation if there is a complaint, or if something about the billing profile is triggering flags. If quality concerns are an issue, the CMS Regional Office, the state surveyors, or the state Quality Improvement Organization (QIO) may be involved. QIOs can initiate investigations on their own, but most often send document requests for quality studies they are undertaking.

Private payers will send letters to providers directly, although some are now turning to third party agencies.
Auditing and monitoring are important components of any compliance plan, to verify you are following applicable coding and billing regulations and guidelines. In this chapter, we will discuss documentation requirements, medical necessity, and key risk areas.

**Documentation**

Each provider is personally and specifically responsible for properly documenting the services he or she provides. The provider must ensure that the documentation supports the medical necessity of the office visit, and use the appropriate procedure and diagnosis code. Documentation must be legible for review by persons other than the provider. Always observe the rule, “If it’s not documented, it wasn’t done.” Don’t assume anything when auditing the medical record.

Most providers use what are called SOAP notes. The note includes the Subjective, Objective, Assessment, and Plan of treatment for the patient’s office visit (encounter). In addition, all procedures completed at the time of service must be documented in the patient’s chart and on the charge ticket.

**Encounter Requirements**

Encounter (office visit) documentation must include:

1. Reason for encounter
2. Relevant history
3. Physical examination
4. Prior diagnostic test results
5. Assessment
6. Clinical impression/diagnosis
7. Plan for care
8. Date and legible identity of the observer

If not documented, rationale for ordering diagnostic and/or ancillary services must be easily inferred. Any past/present diagnoses should be accessible to the treating and/or consulting provider, and any health risk factors should be identified. Patient progress, response to and changes in treatment, and revisions to patient’s diagnosis should be documented. CPT®, HCPCS Level II and ICD-9-CM codes reported on claim forms must be supported by documentation in the medical record.

**Medical Necessity**

The Medicare program covers services that are deemed reasonable and necessary. No Medicare payment shall be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Services that are covered under the program may be limited in coverage due to:

- Diagnoses: A service may be covered, but that coverage may be limited to certain diagnoses.

**Example:**

Vitamin B-12 injections are covered, but only for diagnoses such as pernicious anemia and dementias secondary to vitamin B-12 deficiency.

- Frequency/Utilization: A service may be covered, but that coverage may be limited if the service is provided more frequently than allowed under a national coverage determination (NCD), a local coverage determination (LCD), or a clinically accepted standard of practice.

**Example:**

A screening colonoscopy (G0105) may be paid once every 24 months for beneficiaries who are at high risk for colorectal cancer; otherwise, the service is limited to once every 10 years and not within 48 months of a screening sigmoidoscopy.