

The Healthcare  
Compliance  
Professional's  
Guide to

# Board Reporting

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HCPro

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## About the Author

### **Andrei M. Costantino, MHA, CHC, CPC-H, CPC**

Andrei M. Costantino is the director of organizational integrity at Trinity Health, the fourth largest Catholic health system in the United States. Costantino has more than 20 years of comprehensive experience specializing in third party reimbursement, regulatory compliance issues, Medicare and Medicaid fraud defense work, and compliance and reimbursement education and training.

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An active member of the Health Care Compliance Association, Costantino also participates as an advisory board member for the HCPro Inc. newsletters *Strategies for Health Care Compliance* and *Healthcare Auditing Strategies*.

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## Introduction

Compliance professionals are a valuable resource to senior management, the board of directors, and auditing and compliance subcommittees. This book offers strategies to help compliance officers make the most of their limited time before the board of directors. In this book, you'll learn tips to engage C-suite professionals and obtain tools to help you translate compliance concerns into board priorities.

Wikipedia defines regulatory compliance as:

*"Systems or departments at corporations and public agencies to ensure that personnel are aware of and take steps to comply with relevant laws and regulations."*

The definition is simple but the task of complying can be very difficult, frustrating, and time consuming. On the other hand, the results of an effective compliance program are rewarding.

Government agencies have renewed their attention on the role of the board of directors in assuring compliance with healthcare rules and regulations. The board of directors' function as an agent for compliance is more important now than ever.

For example, in 2007 Centers for Medicare & Medicaid Services (CMS) joined with the Health Care Compliance Association (HCCA) and stakeholders in the long-term care community to examine the role of compliance in providing quality care to patients. In January 2008, the groups jointly published "Driving for Quality in Long-Term Care: A Board of Directors Dashboard." The two groups expect to publish a similar document focusing on hospital boards' role in assuring quality care and compliance in 2009. The emphasis on the role of the *board of directors* in these focus group and guidance documents demonstrates the increased need for compliance officers and board members to work together.

In addition, HCCA and CMS expect to release the results of a multi-year examination of compliance effectiveness in the near future. Preliminary reports about this study emphasize the role of the compliance officer in communicating with the board, and the board's responsibility for compliance program oversight.

Other recent developments regarding the board of director's position in assuring compliance include:

- In November 2007, the Independent Sector and Panel on the Nonprofit Sector outlined roles for the board of directors in the document "Principles for Good Governance and Ethical Practice."

- In a September 2007 presentation, Lewis Morris, chief counsel of the Office of the Inspector General (OIG) said “We are beginning to look to boards to ensure fiscal integrity and [Corporate Integrity Agreement] CIA oversight.”
- On September 13, 2007, the OIG and American Healthcare Lawyers Association (AHLA) issued a joint publication, “Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors.” This publication follows two other releases that emphasize the importance of board knowledge of internal controls in healthcare. These guides are titled:
  - “Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors”
  - “An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors.”
- Both the OIG Compliance Program Guidance for Hospitals and the OIG Supplemental Program Guidance for Hospitals outline the importance of boards’ roles and responsibilities to ensure compliance with rules and regulations.

Such analysis of the interconnected responsibilities of the board and compliance officer represents a shift in corporate thought. A mere 10 years ago, the position of compliance officer did not exist. Now the healthcare industry and government regulators regard such positions as critical to the corporate life of the organization.

But sometimes business savvy board members get lost in the regulatory morass of healthcare compliance or simply struggle to juggle the multiple layers of board responsibilities making it difficult if not impossible to tackle compliance concerns. It falls to compliance officers to explain the role of compliance in the overall integrity of the healthcare organization and to obtain board members’ assistance in preventing compliance missteps that could cause legal trouble for the facility and board members themselves.

How do you accomplish this daunting task when the board of directors allots the compliance team some 20 minutes of agenda time every three months? Read on.

Inside *The Healthcare Compliance Professional’s Guide to Board Reporting* Andrei M. Costantino, MHA, CHC, CPC-H, CPC, director of organizational integrity for Trinity Health, breaks down the essentials of board reporting. Inside he’s included essential information the board needs to know, broken down the roles and responsibilities for both the board members and compliance team, and provided sample tools, tips, reports, charts, memos, policies, and checklists that can easily be adapted to any size facility.

Compliance effectiveness and the board of directors' buy-in represent a lynchpin in the future of solvency of the American healthcare system and the quality of patient care overall. Effective communication between both parties helps ensure the message of compliance is received. The tools in this book can help make reporting compliance efforts to the board seamless.

Happy reporting!





Section I | **The Compliance Culture:  
Rules and Tools to Help  
the Board**

Healthcare providers, administrators, and boards of directors know that a strong, ethical corporate culture stems from managing compliance risks. Compliance programs create a culture of ethics and responsibility throughout a healthcare organization. If a breach in ethics leads to legal violations, effective compliance programs can identify the problem and limit the impact of potential damages. Furthermore, fostering a culture of compliance increases the organization's opportunities to outperform its peers in the healthcare marketplace.

We hear it many times over. A strong ethical corporate culture comes from the top. The top equals the facility's governing body, which, in most cases, means the board of directors. The creation of an atmosphere of trust and confidence in a healthcare organization needs to start with the board. Without the board's endorsement, employees will not take compliance efforts seriously.

Healthcare compliance has faced many changes over the past 30 years. The regulatory environment shifted from lax guidance to stringent regulation, with multiple integrity programs funded by the federal government to combat fraud and abuse. Increasingly, government agencies expect the board of directors and healthcare management, to play an active role in regulatory compliance. Without a doubt, healthcare is one of the most heavily regulated industries in the world.

All of this may lead the board of directors to ask:

- How did we get here?
- What guidance/resources are available to assist us?
- Where is healthcare compliance headed?

To answer these questions compliance officers need to lead the board of directors through a thorough examination of all the pieces of the healthcare compliance puzzle—and teach the board of directors the importance of the role it plays in forming the overall organization’s culture of compliance.

The major compliance pieces include:

**Regulations:** These are the tools the government developed and refined over the years to fight health-care fraud and abuse.

**Funding:** Without funding of enforcement resources, regulations would be meaningless.

**Measurement:** Government needs a measurement tool to prove the success of its healthcare regulatory enforcement activities to Congress.

**Guidance:** Heightened regulatory enforcement resulted in significant sanctions against healthcare providers. The government offered guidance on how to operate in this new heavily regulated arena.

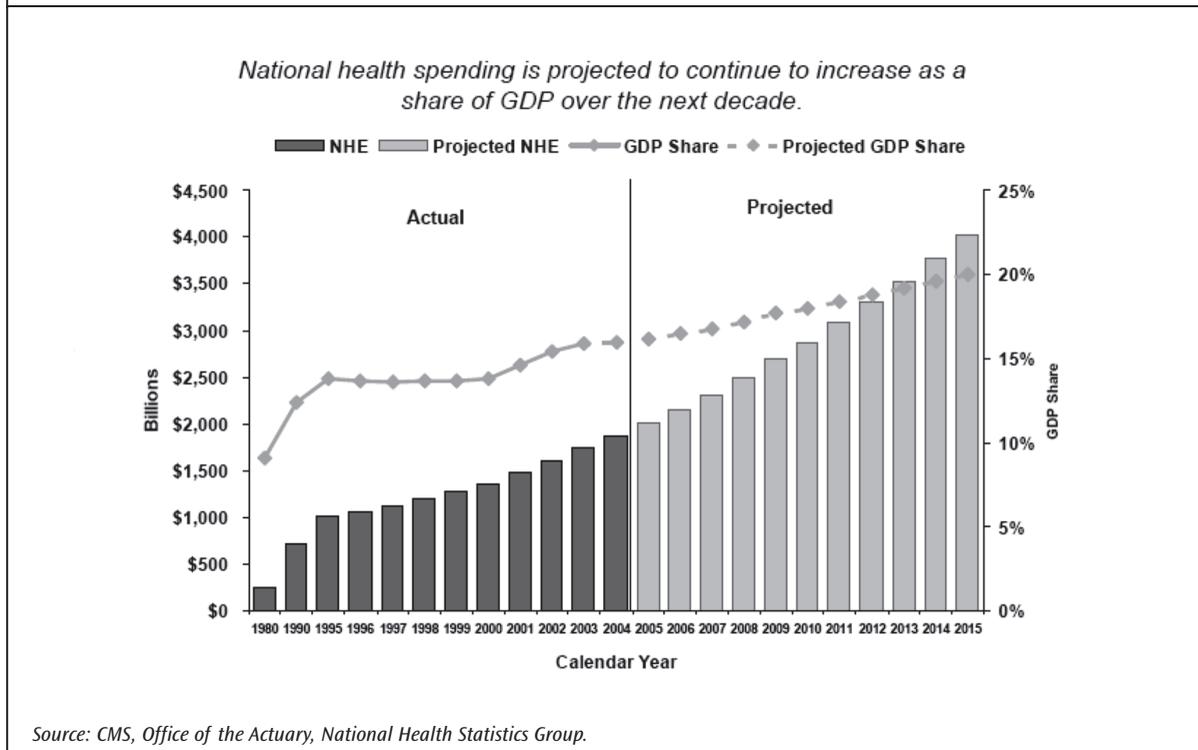
## Regulations

The board of directors must ensure the financial solvency of the healthcare organization, just as government officials must ensure the solvency of its healthcare funding programs. Both sides of this fiscal conundrum face growing financial frustration, and both sides continue to search for an underlying cause to answer the dilemma of expanding healthcare costs. The root cause, however, remains elusive. There is no easy answer to the question most frequently asked: “How did we get here?”

The main reasons for expense escalations include:

- Increased costs
- Reduced reimbursement
- Government regulatory enforcement directives

Figure 1.1 illustrates the National Health Expenditures, as a share of gross domestic product. It is currently 14% and rising as the U.S. population grows older. Actuaries at the Centers for Medicare & Medicaid Services (CMS) project that in 2017, government healthcare funding programs will be bankrupt.

**Figure 1.1 National Health Expenditures (NHE) as a share of gross domestic product (GDP)**

With unsustainable costs, the government continues to search for areas of potential fraud, waste, and abuse. A number of regulations and statutes are in place to catch such items. The board of directors need to understand the implications of three categories of federal fraud and abuse prohibitions:

- The False Claims Act (FCA) for false claims
- The Anti-Kickback Statute (AKS) for kickbacks
- The Stark Law (Stark) for illegal referrals

### The False Claims Act

One of the government's most powerful tools to catch potential healthcare reimbursement abuses is the FCA. Congress enacted the FCA in 1863 to combat fraud perpetrated by companies that sold supplies to the Union Army. The original act included a *qui tam* provision that allowed private citizens to sue companies on the government's behalf. If successful, the relator (private citizen) was entitled to 50% of the money recovered by the government.

In 1943 Congress amended the FCA to include a provision that prohibited *qui tam* lawsuits based on evidence already obtained by the government, which drastically reduced the entitlement provision to almost nothing. The results of the amendments effectively rendered the FCA useless.

In 1986, however, Congress again amended the FCA due to fears of widespread fraud in the defense industry. Amendments included the following provisions:

- Companies that defraud the government are liable for treble damages and a \$5,000–\$10,000 penalty *for each claim*
- Successful whistleblowers are entitled to 15%–30% of the funds recovered by the government

Basically, the FCA prohibits any individual or company from knowingly submitting false or fraudulent claims to secure payment from the federal government for such a claim, or conspiring to get such a claim allowed or paid. Under the statute, the government must prove that the individual or company acted “knowingly.” To establish a violation, the government needs to prove only *one* of the following:

- Evidence of actual knowledge of the falsity of the claim
- Evidence that the individual or company acted in deliberate ignorance of the truth or falsity of the information
- Evidence that the individual or company acted in reckless disregard of the truth or falsity of the information

Compliance officers need to help the board understand the importance of the FCA. Board members need to know that specific intent to defraud the government is not required for there to be a violation of the law.

Furthermore, the board of directors needs to understand the severity of civil penalties for violating the FCA. The individual or company is liable for *each claim* of not less than \$5,000 and not more than \$10,000, *plus up to three times* the amount of damages sustained by the federal government. (See Figure A.1 in the Appendix for a sample FCA educational packet you can adapt and distribute to your board of directors. For a list of the top 20 FCA settlements, see Figure A.2 in the Appendix.)

## Case study

### **Dentist incurs nearly \$19 million in FCA costs**

Take the case of John Lorenzo, DDS, *United States v. Lorenzo*, 768 F. Supp. 1127 (E.D. PA 1991), as an example of the crippling effects of FCA in action. In this case, the Office of Inspector General (OIG) accused Lorenzo of fraudulently billing Medicare false claims for a three-year period. The amount of the Medicare overpayment for this period was \$136,719. Instead of settling with the government, Lorenzo fought the accusations in court. He lost. The finding cost Lorenzo \$18.8 million.

When you lose under the FCA the financial penalties add up quickly. Treble the damages of the original Medicare overpayment of \$136,719 amounted to \$410,157. The \$136,719 consisted of 3,683 claims; multiply the claims by \$5,000 and the result is \$18,415,000; add the treble damages of \$410,157 and the final tally is \$18.8 million.

The example stands to illustrate the huge impact the FCA can have on an individual or company if it chooses to challenge the government in the court and loses.

Even if Lorenzo's legal counsel successfully defended 2,000 of the 3,683 claims, the courts would still apply a minimum fine of \$5,000 to the remaining 1,683 claims, resulting in \$8.4 million in fines plus exclusion from the Medicare and Medicaid programs.

Therein lies the strength of the FCA. It represents the biggest hammer the government can wield against fraud and abuse in healthcare. The threat of the FCA basically keeps providers from challenging the government in the court of law, which is why it is very rare to see one of these cases tried.

Even more destructive to healthcare entities, the FCA also can exclude a provider from participating in any federal health program. This exclusion penalty is known as the “death penalty” in healthcare, because although most providers can survive monetary penalties, a provider cannot survive if excluded from participating in the federal health programs of Medicare and Medicaid.

### **Anti-Kickback Statute and Stark Law**

It is difficult to talk about the Anti-Kickback Statute (AKS) without including a discussion about the Stark Law, because:

- Both prevent healthcare providers from inappropriately profiting from referrals
- Both are part of the Social Security Act
- Both include safe harbors
- Both laws refer to one another
- Both carry stiff penalties

Be careful when presenting these issues to the board of directors. Many people mistake the Stark Law with the AKS. These are not the same laws.

Each provision mandates different actions and falls under two different titles of the Social Security Act. Board members need to be familiar with other differences, too. They include the following:

- Stark pertains only to physician referrals under Medicare and Medicaid. (The term physicians includes chiropractors and dentists but not mid-level providers, such as nurse practitioners and physician assistants.)
- The AKS is far broader than Stark. It affects anyone engaged in business with a federal health-care program.
- Stark does not require malicious intent (i.e., a tainted financial relationship violates the Stark regardless of good intentions).
- The AKS requires intent, but it must be specific intent (i.e., not just intent that might merely be inferred from a pattern of behavior).
- Stark exceptions define the boundaries of permissible behavior. It is a prohibition that can be overcome only by complying explicitly with an exception.

- The AKS “safe harbor” regulations describe transactions that may tend to induce referrals but don’t necessarily violate the law. The safe harbor regulations state clearly that transactions which don’t meet a safe harbor don’t necessarily violate the statute. A prosecutor will evaluate the facts and circumstances to make that determination.
- A Stark violation is punishable by civil penalties.
- An AKS contains criminal penalties.<sup>1</sup>

### ***Stark***

Stark, unlike the AKS, applies only to physicians who refer Medicare and Medicaid patients for specific designated health services (DHS) to entities with which they have a financial relationship.

To get a better understanding of Stark, it is important to understand that Stark began with two principle legislative acts and evolved with additional rulemaking from CMS.

Stark I was enacted in the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) and became effective January 1, 1992. It barred physician self-referrals for clinical laboratory services.

Stark II, enacted in the OBRA 1993, expanded restrictions to a range of additional health services. Stark II became effective January 1, 1995, but CMS did not release the final regulations interpreting the statute until January 4, 2001.

Because Stark can be very confusing and complicated, CMS released different parts of the statute, called *phases*. On January 4, 2001, CMS released Phase I of Stark.

Key elements include:

- The definitions of various categories of DHS
- Creation of new safe harbors
- Clarification of acceptable group practice compensation methods
- Implementation and revision of the “fair market value” exception
- Implementation and revision of the exception for nonmonetary compensation

CMS published Phase II on March 26, 2004. It addressed:

- The statutory exceptions related to ownership and investment interests
- The exceptions for certain compensation arrangements
- The reporting requirements associated with the regulation

The agency released Phase III on September 5, 2007. Although most portions of the rule took effect January 1, 2008, CMS allowed some time for implementation of others, such as the “stand-in-the-shoes” provision, which is expected to take effect in December 2008.

Phase III addresses:

- Items furnished that are “incident to” services normally provided by a physician
- Productivity bonuses and profit sharing
- Elimination of the safe harbor method for establishing fair market value of personnel services
- Recruitment arrangements

One of the biggest changes in Phase III deals with the “stand-in-the-shoes” rule. It reads:

*“A physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization.”<sup>2</sup>*

In other words, if there is a chain of financial relationships involving at least one other entity interposed between the physician and the DHS entity, CMS could consider it a potential indirect compensation arrangement.

CMS understood the hardship the new rule imposed on facilities. Groups would have a hard time incorporating the new language into ongoing or existing physician negotiations. So, it delayed implementation of this piece of the Phase III regulation until December 4, 2008.

Those who violate the provisions of Stark expose the organization to potentially costly penalties. Any claim CMS pays as a result of an improper referral is punishable by a \$100,000 fine and exclusion from participating in federal healthcare programs. Stark violations may also cost the provider \$15,000 in civil

monetary penalties. Such bottom line risks must be a lynchpin in the compliance education that is provided to the board of directors.

### **AKS**

Congress passed the AKS in 1972. The rule made it illegal for healthcare providers to knowingly and willfully accept bribes or other forms of remuneration in return for generating Medicare, Medicaid, or other federal healthcare program business.

Since its inception, the AKS has undergone numerous changes and amendments. Alterations included:

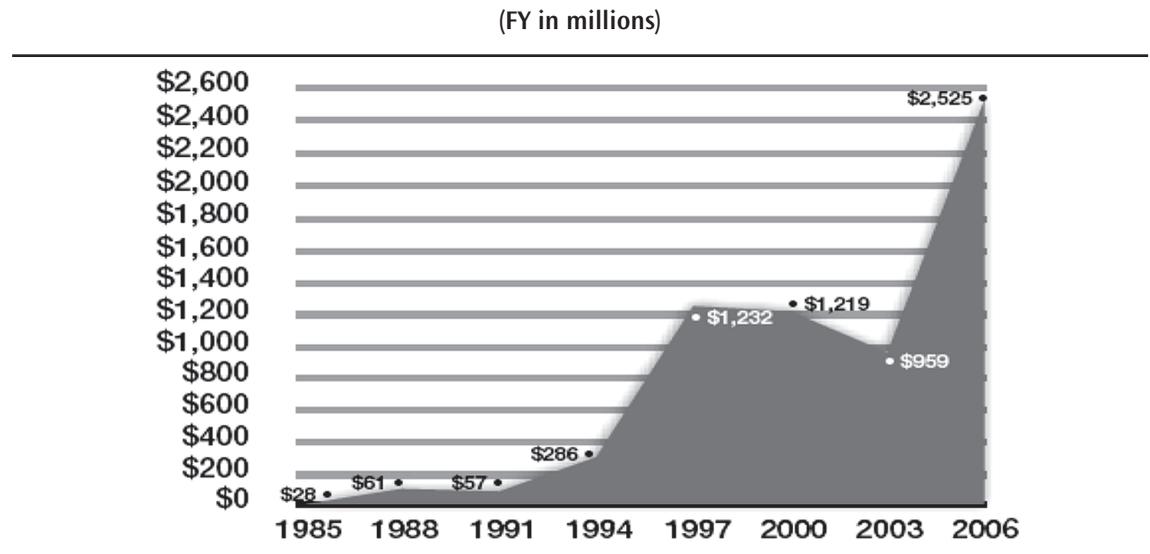
- Expanding the term “any remuneration” by statutorily excluding certain discounts and payments to employees
- Adding the term “knowingly and willfully”
- Adding statutory exceptions for group purchasing organizations
- Adding safe harbors or exceptions that allow conduct that would otherwise violate the statute

Punishment for violations includes up to five years in prison, criminal fines of up to \$25,000, and civil monetary penalties of up to \$50,000 per violation, along with exclusion from participation in any federal healthcare program.

Remember, in every situation where Stark applies the AKS also applies. Encourage your board of directors to allow you to start your compliance program with an analysis of the organization’s risk for Stark violations. If you find potential Stark violations, then an analysis of your facility’s risks under the AKS is also warranted.

The following chart from CMS (see Figure 1.2) illustrates how successful government enforcement of these laws has been. Consider using this chart to demonstrate why the board of directors needs to be aware of Stark and AKS. With millions of dollars at risk, compliance officers need to demonstrate to the board the fiscal impact of noncompliance.

**Figure 1.2 Monetary impositions resulting from OIG health care investigations**



Monetary impositions are rounded to the nearest million and include fines, restitutions, and impositions (including False Claims suits) resulting from OIG investigations related to fraud and abuse against Federal health care programs. These figures represent HHS investigative receivables only; receivables on behalf of other Federal agencies and States are not included.

Source: Department of Health and Human Services, Office of Inspector General.

### Sarbanes-Oxley Act of 2002

Corporate greed neared its apex in the new millennium. Well-known companies such as WorldCom, Enron, Tyco, Qwest, Global Crossing, and Xerox came under federal scrutiny, even collapsing under the weight of the financial implications of their fraudulent acts. Healthcare providers in the nonprofit world are not immune from such scandals. Before Enron and WorldCom, the Allegheny Health, Education, and Research Foundation (AHERF), a nonprofit healthcare provider, filed for bankruptcy due to mismanagement.

At one time, AHERF represented the largest nonprofit organization in Pennsylvania. AHERF expanded rapidly across that state, but on July 21, 1998, AHERF filed for protection under Chapter 11 of the U.S. Bankruptcy Code. The bankruptcy of AHERF, a \$1.3 billion healthcare provider, was the nation’s largest nonprofit healthcare failure.<sup>3</sup> Lack of corporate governance and operational oversight by AHERF’s board of directors bore the brunt of the blame.

In response to the rise in cases of corporate fraud, Congress created the Sarbanes-Oxley Act (SOX) on July 20, 2002. The act was designed to restore public trust in the marketplace.

Its primary goals included:

- Preventing corporate and accounting fraud
- Restoring investor trust and confidence in public markets

To meet these goals, SOX rules require organizations to focus on accounting and auditing, and to communicate those efforts to the board of directors. It protects corporate whistleblowers and increases corporate responsibility by imposing fines and criminal penalties. Penalties for noncompliance include:

- Fines of up to \$5 million
- Prison sentences from five to 20 years

SOX directly applies to publicly traded companies, but the government also wants nonprofit healthcare providers to include SOX compliance in their fundamental principles.

The following two provisions created under SOX directly apply to nonprofit entities:

- Establish a whistleblower program that contains language prohibiting the provider from retaliating against the employee who made the complaint
- The document retention provision, which requires the provider to keep and maintain documents after they become aware of an investigation

### **Fitch Ratings Report cites hospital SOX concerns<sup>4</sup>**

The Fitch Ratings Report identifies the following SOX provisions as being most applicable to nonprofit hospitals and healthcare systems. The report makes the following recommendations:

**“Section 201:** Prohibition of Non-Audit Services by Auditors. Providers should prohibit their independent auditors from providing nonaudit services specified in the act in order to limit potential conflict of interest.”

**“Section 203:** Lead Audit Partner Rotation Every Five Years. Audit partner rotation is a critical means of providing a different perspective on a provider’s audited statements, which may in turn facilitate fair representation of the provider’s financial condition.”

**“Section 204:** Audit Communication with Audit Committees. The public accounting firm conducting a provider’s audit should report certain information regarding the audit process and practices to the provider’s audit committee to ensure that the board is aware of important issues and management practices affecting financial reporting.”

**“Section 301:** Audit Committee Standards. Development of an audit committee that meets the standards set forth in the act is important because it will enable the board to devote adequate attention to the audit processes and outcomes. It will increase the board’s accountability with respect to audits.”

**“Section 302:** Certification of Financial Statements. Certification by an organization’s CEO and chief financial officer that the contents of the annual audit report are accurate and do not misrepresent the organization’s financial condition is a critical practice because of its potential impact on the credibility and accuracy of a provider’s financial statements.”

**“Section 304:** Forfeiture of Certain Bonuses and Profits. Tying compensation to performance-based results may reduce the likelihood of misstatements in financial reporting.”

**“Section 404:** Evaluation of Internal Controls. Section 404 requires an organization to establish and maintain an internal control structure. It requires the creation of procedures for financial reporting and the annual assessment of the effectiveness of those procedures. Despite the significant costs of complying with Section 404, nonprofit hospitals and healthcare systems should perform an assessment of internal controls at least annually.”

**“Section 406:** Adoption of Code of Ethics. Adoption and enforcement of a code of ethics applicable to senior financial officers is another tool for increasing accountability of board members and managers. It is a practice that is becoming increasingly common among providers.”

**“Section 407:** Financial Experts on the Audit Committee. At least one member of the audit committee should be a financial expert. This helps to foster a better understanding of the audit process and thereby ensures greater accountability of the audit committee.”

## Funding

With these powerful regulations in place, the government needed funds to enforce them. To win Congressional approval (and thereby funding) for its enforcement efforts, federal agencies need to show the positive impact of fighting healthcare fraud and abuse.

In May 1995, President William J. Clinton initiated a two-year demonstration project dubbed Operation Restore Trust (ORT). The project started in five states: California, Florida, Illinois, New York, and Texas. At the time, these five states accounted for 40% of the nation's Medicare and Medicaid beneficiaries. The program focused on home health, nursing homes, hospice, and medical equipment and suppliers.

ORT joined the OIG, CMS, the Department of Justice (DOJ), and Medicare and Medicaid contractors. In two years, the demonstration project:<sup>5</sup>

- Identified \$23 in recoveries for every \$1 spent on ORT
- Identified more than \$187.5 million in fines, recoveries, settlements, and civil monetary penalties owed to the federal government
- Achieved 74 criminal convictions, 58 civil actions, and 69 indictments
- Excluded 218 providers from participation in federal healthcare programs

These accomplishments were enough to show the government the importance of healthcare regulatory enforcement.

### Health Insurance Portability and Accountability Act of 1996 (HIPAA)

To maintain ORT's momentum, President Clinton signed HIPAA into law in 1996. Within HIPAA, the government established the Medicare Integrity Program (MIP), which dedicated funds to identify and combat improper healthcare payments.

The MIP, through Medicare contractors, conducts the following activities to safeguard Medicare payments:

- Cost report auditing
- Medical records reviews
- Secondary payment determinations

- Identification and investigation of potential fraud cases
- Education to providers regarding appropriate billing of procedures

In fiscal year 2008, MIP funding totaled \$183 million, with \$45 million allocated to OIG, FBI, DOJ, and other agencies of CMS. MIP reportedly returns \$13 for every \$1 spent.<sup>6</sup>

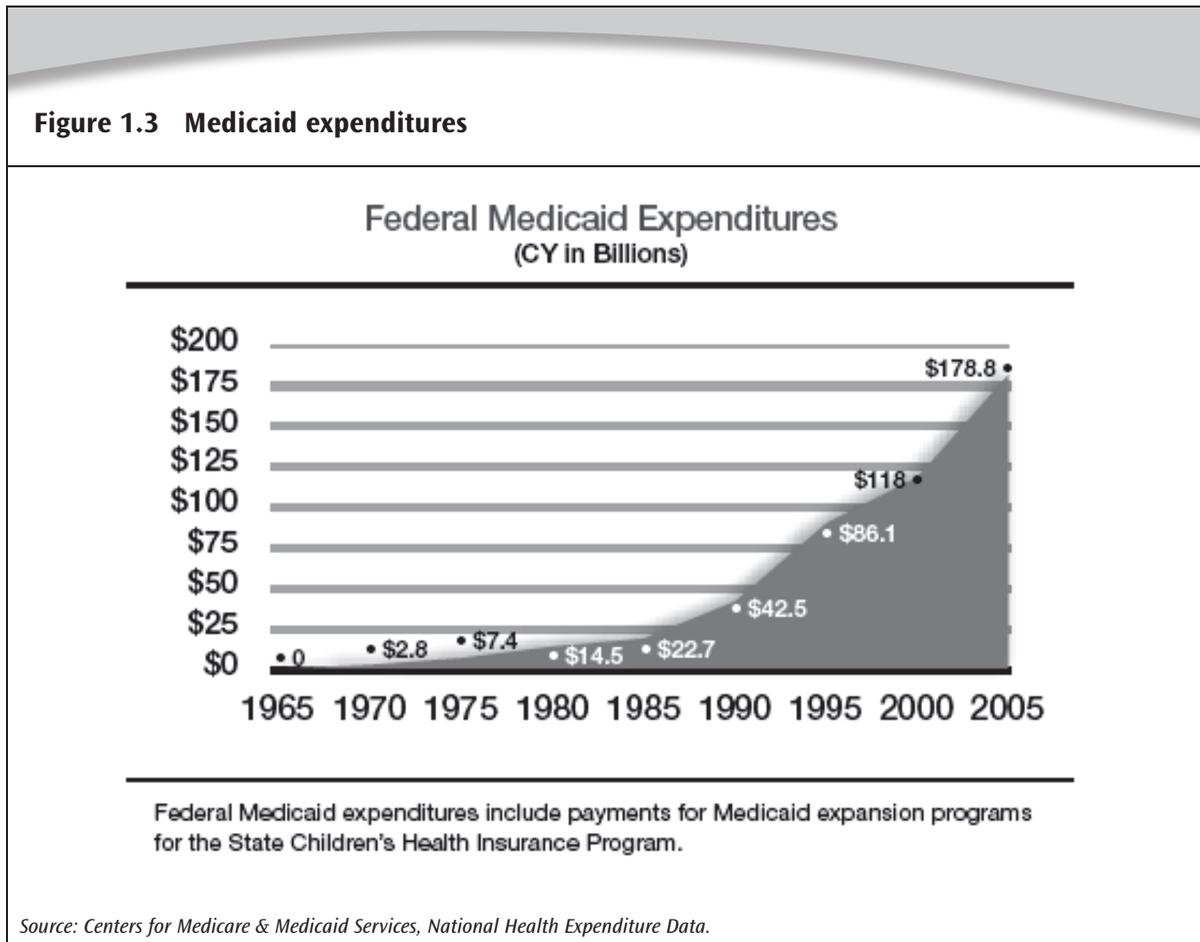
In addition, to underscore its view on board oversight, the OIG encouraged Congress to increase its authority in dealing with boards and board members who are derelict in their oversight responsibilities. The passage of HIPAA that responds to this plea reads:

*“Any individual who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know. . . of the action constituting the basis for the conviction or exclusion. . . or (ii) who is an officer or managing employee. . . of such an entity. . .”*

Thus, through HIPAA, the OIG has the authority to exclude board members from the healthcare industry if they knew or should have known about the activity that gave rise to a conviction or exclusion in the organization.

### **Deficit Reduction Act of 2005**

Despite the MIP’s success since 1996, Medicaid expenditures topped \$178 billion in 2005 (see Figure 1.3). CMS expects the federal portion of Medicaid spending to reach \$384 billion by 2015.



Medicaid represented only a minor player on the healthcare stage in the 1980s and 1990s. So, federal and state enforcement gave little attention and very few resources to policing efforts for Medicaid payments. That changed with the passage of the Deficit Reduction Act of 2005 (DRA). Now, the board of directors and senior management need to know about a range of CMS fraud prevention tactics. Board members and compliance officers must implement a number of new fraud prevention programs in their organizations.

The DRA reduces the growth of the Medicaid program and detects and prevents Medicaid overpayments in areas susceptible to fraud and provider error. The following three main provisions in the DRA directly impact provider compliance:

- Expansion of the MIP to include Medicaid as well as Medicare
- Incentives for states to enact an FCA
- Employee education regarding federal and state FCAs

*MIPs, Medi-Medi, and MIGs*

Section 6035 of the DRA establishes the Medicaid Integrity Program under the secretary of the Department of Health and Human Services (HHS) a means to establish contracts with eligible entities to perform the following tasks:

- Review organizations providing items and services reimbursed by Medicaid
- Review audit payment claims
- Identify Medicaid overpayments to organizations
- Educate service providers, managed care organizations, beneficiaries, and other individuals regarding payment integrity and benefit quality assurance issues

The DRA allows CMS two broad, operational responsibilities under this new program:

1. Reviewing the actions of those providing Medicaid services
2. Providing support and assistance to the states to combat Medicaid fraud, waste, and abuse

Congress specifically required the use of third-party contractors to review the actions of those seeking payment from Medicaid, conduct audits, identify overpayments, and educate providers and others on payment integrity and quality of care. The DRA further mandates that CMS employ 100 full-time equivalent employees to provide support to the states. CMS funding is expected to reach a total of \$75 million annually by fiscal year 2009 and each year thereafter.

Another pilot program receiving additional funding from the DRA provisions is the Medicare-Medicaid match program, called the Medi-Medi Program. The Medi-Medi Program matches claims from Medicare and Medicaid to detect patterns that may not be evident when bills for either program are viewed in isolation.

This project allows CMS to identify vulnerabilities in both programs and quickly recover the federal share of Medicaid dollars. Currently this project looks back at previously billed data, but the goal is to be able to review this data in real time. Funds are appropriated for expansion of the Medi-Medi Program as follows:

- \$12 million for fiscal year 2006
- \$24 million for fiscal year 2007
- \$35 million for fiscal year 2008

- \$48 million for fiscal year 2009
- \$60 million for fiscal year 2010 and each fiscal year thereafter

The DRA now gives government agencies some of the same tools that are effective in safeguarding the Medicare program for the Medicaid program. To bring this all together CMS developed the Medicaid Integrity Group (MIG).

The MIG will employ the following major strategies to ensure success:

- **Collaboration and coordination:** The MIG will work closely with the states on all aspects of the audit program, including the state program integrity units and federal and state law enforcement agencies.
- **Consultation with interested parties:** CMS knows that the success of the MIP relies on working with and consulting with the DOJ, FBI, OIG, and HHS, to just name a few.
- **Targeting vulnerabilities:** Through consultations with other departments in government, the MIG will focus on the following initial areas:
  - Nursing and personal care, such as fraud related to long-term care facilities and home health agencies
  - The provisions of prescription drugs to beneficiaries and the underlying costs of those drugs as reported to the states
  - Durable medical equipment and other medical suppliers
  - Improper claims for payment from hospitals and individual practitioners

Considering the numerous variations in states' Medicaid programs, CMS faces additional challenges in accomplishing the tasks set before it in the DRA, including:

- **Balancing Medicaid Integrity Program roles:** The Medicaid Integrity Program must balance training and technical assistance while exercising oversight of the state programs and supporting criminal investigations of suspect providers and while concurrently seeking administrative sanctions.
- **Learning from experience:** The Medicaid Integrity Program will turn the lessons it learns through its own experiences, and those of the states, into directives to prevent future improper payments. The Medicaid Integrity Program believes it will uncover overpayments by auditing, but achieve greater savings from the global strategies it develops from audit experiences.<sup>7</sup>

- **Return on investment:** On an annual basis, the Medicaid Integrity Program will have to document the use and effectiveness of the funds appropriated from Congress. Its annual report will show a calculation of its efforts toward cost saving and cost avoidance.

Currently there are about 10 MIGs. The first one, created in Texas in 2003, saw recoveries and cost-avoidance that amounted to more than \$3 billion. The success of the Texas program spurred many states to adopt their own MIGs. The MIG's main purpose is to reduce and recoup Medicaid reimbursement from fraudulent providers.

#### *State FCA implications*

With Section 6032 of the DRA Congress encouraged states to implement their own false claims provision. If a state's rules meet certain federal requirements, the state can earn an additional 10% of the amount it receives from the federal FCA recoveries.

For example, only a small percentage of states with their own false claims acts have a *qui tam* provision. Most states have a civil false claims act for Medicaid fraud, but few states have modeled their false claims acts based on the statutes of the federal FCA. The DRA expressly requires that a state's false claims act:

- Establish liability that benefits the state Medicaid program based on false or fraudulent Medicaid claims, as described in the federal FCA
- Contain provisions that are at least as effective in rewarding and facilitating *qui tam* actions as those in the federal FCA
- Provide for filing an action under seal for 60 days with review by the state attorney general
- Impose a civil penalty in an amount equal to or greater than the amount authorized by the federal FCA

Figure 1.4 lists states that have a Medicaid-only false claims act and the states that qualify for an additional 10% under the DRA. All of the states in the figure, along with New York City and Chicago, have their own versions of the FCA with *qui tam* provisions, enabling them to recover money at the state or municipal level.

Figure 1.4 False Claims Act citations by state

State False Claims Act Case Citations	
* = Medicaid-only False Claims Act	
✓ = Qualified for Increased Share Under Deficit Reduction Act	
<b>California</b>	CAL. Gov't. Code Sec 12650 et seq. (DEERING 2000). [General]
<b>Delaware</b>	DEL. CODE. ANN. tit. 6, Sec 1201 et seq. (2000). [General]
<b>District of Columbia</b>	D.C. CODE ANN. Sec 1-1188.13 et seq. (2000). [General]
<b>Florida</b>	FLA. STAT. 68.081 et seq. (2007) [General]
<b>Georgia *</b>	State False Medicaid Claims Act. Code of Georgia, Chpt. 4 of Title 49
<b>Hawaii ✓</b>	HAW. REV. STAT. Sec661-22 et seq. (2000). [General]
<b>Illinois ✓</b>	740 ILL. COMP. STAT. ANN. Sec 175/1 et seq. (2000). [General]
<b>Indiana</b>	Indiana Code 5-11-5.5
<b>Louisiana *</b>	LA. REV. STAT. ANN. Sec 46:439.1 et seq. (2000). [Medical Assistance]
<b>Massachusetts ✓</b>	MASS ANN. LAWS CH. 12, Sec 5(A)-(O)
<b>Michigan</b>	MI Public Act 337 Public Acts of 2005
<b>Montana</b>	2005 Mont. Code, CH. 465, HB 146 (2005)
<b>New Hampshire</b>	NEW HAMPSHIRE Section 167:61-b
<b>New Jersey</b>	Signed by Governor, Effective April 15, 2008
<b>New Mexico</b>	Signed by Governor <i>Effective July 1, 2007</i>
<b>New York ✓</b>	Effective April 1, 2007, Signed by Governor
<b>Nevada ✓</b>	NEV. REV. STAT. Sec 357.010 et seq. (1999). [General]
<b>Oklahoma</b>	Oklahoma Medicaid False Claims Act. Despite the name, it is a general FCA. Effective date: November 1, 2007.
<b>Rhode Island</b>	CHAPTER 9-1.1 The State False Claim Act
<b>Tennessee * ✓</b>	TENN. CODE. ANN. Sec 71-5-181 et seq. (2000). [Medicaid]
<b>Texas * ✓</b>	TEX. HUM. RES. CODE Sec 36.001-36.117
<b>Virginia ✓</b>	VIRGINIA Fraud Against Taxpayers Act, signed April 17, 2002; effective Jan. 1, 2003
<b>Wisconsin *</b>	Wisconsin False Claims for Medical Assistance Act

Source: Tax Payers Against Fraud

In addition, Section 6033 of the DRA requires healthcare providers to provide employee education regarding false claim recoveries and whistleblower protections if the provider receives more than \$5 million in Medicaid funds per year. These providers also need to develop a compliance program to qualify for participation in government healthcare programs.

It is important to note that compliance programs have been a voluntary initiative for participating providers in both Medicare and Medicaid. Under the DRA, however, healthcare providers that receive \$5 million or more per year from Medicaid must do the following:

- They must establish written policies for all employees, contractors, and agents explaining:
  - The federal FCA
  - Other administrative remedies for false claims under federal law
  - Any state civil or criminal penalties for false claims
  - The whistleblower protections afforded under such laws, including the role of these laws in preventing and detecting fraud, waste, and abuse in federal health benefit programs
- They must supply detailed provisions regarding their own policies and procedures for detecting and preventing fraud, waste, and abuse
- Those that offer an employee handbook must include specific information regarding the fraud and abuse laws, the rights of the employee to be protected, and the provider's procedures for detecting fraud and abuse. (See the sample employee handbook section in Appendix A.1, also available on the accompanying CD-ROM. Detailed information regarding the False Claims Act is also available in the companion to this book, *The Healthcare Compliance Professional's Guide to the False Claims Act*.)

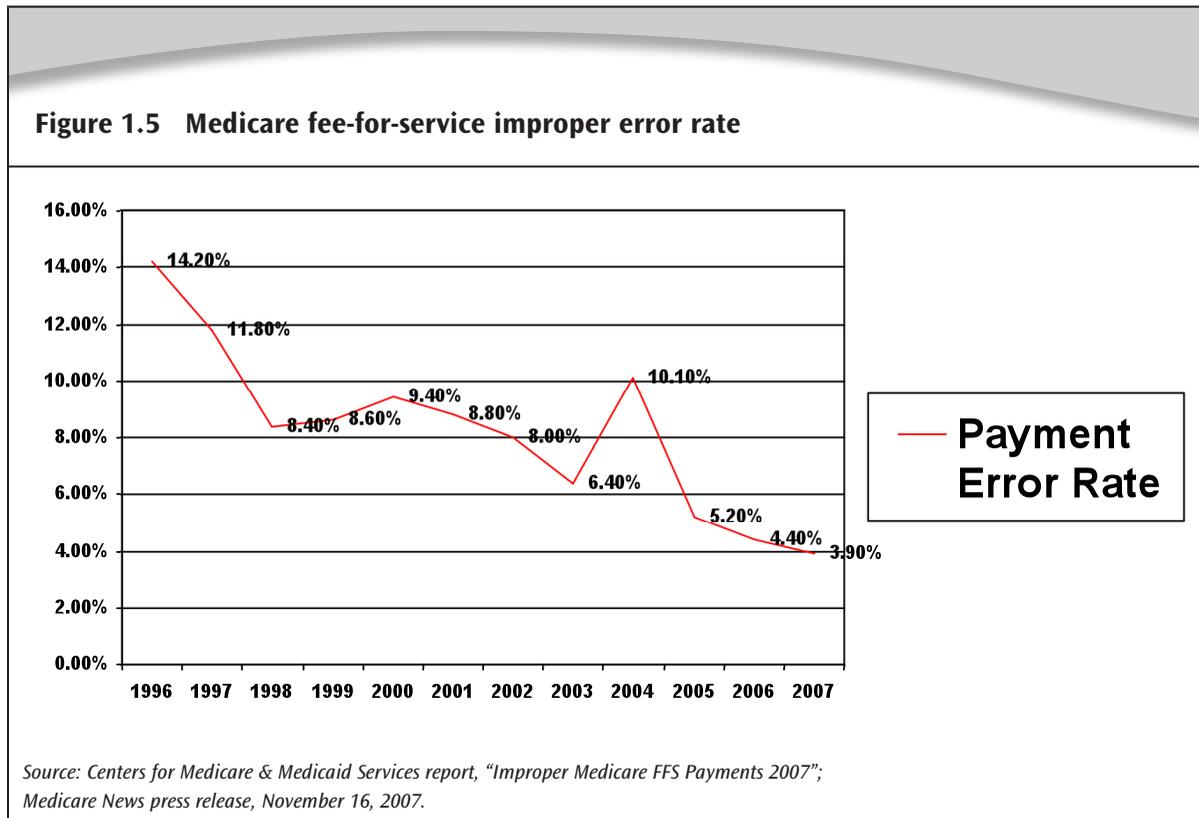
## Measurement

With two of the most important pieces of the puzzle in place—regulations and enforcement funding—the government needed a mechanism to measure improper payments and the success of its recovery efforts.

Before 1996, the government did not have any instrument to gauge the breadth and depth of improper payments or the impact of its enforcement activities. CMS also started to realize that not all improper claims came from fraudulent intent. Instead, most of the improper billing stemmed from misinterpretation of the regulations, lack of rules, or clerical errors.

So, in 1997, the OIG created a statistically valid, improper-fee-for-service claims report that CMS later incorporated into what is now called the Comprehensive Error Rate Testing (CERT) program.

The chart in Figure 1.5 demonstrates the impact of the government’s enforcement initiatives on the Medicare program. The Medicare fee-for-service improper error rate has decreased from 14.20% in 1997 to 3.90% in 2007. With such evidence Congress is willing to continue funding the government’s efforts.



Medicaid has not had a program in place that provides detailed information regarding Medicaid overpayments until recently, with the establishment of the Payment Error Rate Measurement (PERM) program. The PERM program was established to comply with the Improper Payments Information Act of 2002.

CMS is using three contractors to perform statistical calculations, medical records collection, and medical/data processing review from state Medicaid fee-for-service and managed care claims.

The final rule for the PERM program was published August 31, 2007. This rule expanded the PERM program to include reviews of fee-for-service and managed care claims and beneficiary eligibility in both Medicaid and the State Children's Health Insurance Program. Now CMS has a tool in place to measure overpayments and the effect of their enforcement efforts on reducing improper payments to Medicaid programs across the country. In other words, CERT is to Medicare what PERM is to Medicaid.

## Guidance

With regulations, funding, and measurement tools in place the government needed to add the final piece to its cost reduction arsenal—prevention. The government knew that it needed help with enforcement, and providers also wanted to comply with all applicable healthcare regulations. The simple answer was the development of a compliance program. The basic definition of a compliance program is a system of policies and procedures developed to assure compliance with, and conformity to, all applicable federal and state laws governing the organization.

To get a better understanding of a compliance program and to develop guidance from the government, it's important to see how these programs started.

### Corporate Integrity Agreements

Earlier in this section, we looked at three powerful laws—the FCA, the Stark Law, and the AKS—which the government uses to fight fraud and abuse in the healthcare environment. If a provider is found guilty of violating any of these provisions, the government can exclude the provider from participating in all federal healthcare programs (i.e., Medicare, Medicaid) for up to five years. No provider can survive this economic death penalty, because it would not be able to receive any revenues from the Medicare or Medicaid program.

Even if the provider believes it is innocent of fraud charges, the risk of going to court is too great because if the provider loses, the government can exclude the provider from federal healthcare reimbursement programs. Therefore, virtually all providers end up settling with the government. In settlement negotiations, however, the exclusion provision is generally taken off the table in favor of a corporate integrity agreement (CIA). A CIA is an agreement between the OIG and the provider to abide by certain compliance obligations, usually for a term of up to five years.

Back in the mid-1990s, the government led a nationwide investigation it called “Operation Bad Bundle.” This investigation dealt with hospitals submitting separate charges for certain laboratory tests that should have been billed as a single charge, with the hospital receiving a lower reimbursement rate. The settlement agreements included a three-year CIA that made the provider establish a compliance program. More than 150 settlements affected just as many hospitals.

An effective compliance program can limit sanctions imposed by the government. The government’s decision on sanctions relies heavily on how effective the provider’s compliance program is related to the auditing function.

The difference can be whether a provider gets a full-blown CIA or a lesser agreement called a certificate of compliance agreement (CCA). In 2001, Inspector General Janet Rehnquist introduced this concept of releasing the provider from a CIA. In an open letter, she said that in certain cases it may be appropriate to release the OIG’s administrative exclusion authorities without a CIA.

The letter listed the following criteria to determine whether a CIA is appropriate:

- Whether the provider self-disclosed the alleged misconduct
- The monetary damage to the federal healthcare programs
- Whether the case involves successor liability
- Whether the provider is still participating in the federal healthcare program or in the line of business that gave rise to the fraudulent conduct
- Whether the alleged conduct is capable of repetition
- The age of the conduct (when it occurred)
- Whether the provider has an effective compliance program and would agree to limited compliance or integrity measures and would annually certify such compliance to the OIG
- Other circumstances, as appropriate

CIA's have come a long way in regard to content from when they were issued in the early 1990s. The early settlement agreements were about five to six pages in length and left a lot of the details up to the provider. CIA enforcement generally lasted three to five years and imposed some annual reporting requirements.

Today's CIA's can be very cost-prohibitive and disruptive for the provider. Here is an example of some current requirements:

- Mandated compliance policies and procedures
- Training and education requirements (some CIA's specifically outline how many hours per employee)
- Engagement of an independent review organization to conduct an annual audit

Along with these requirements, CIA's often require the submission of an annual report to the government. This reporting requirement is the most time- and resource-intensive aspect of any CIA. An annual report usually contains the following:

- Results of audits
- Documentation of the training and education programs
- Compliance policies and procedures
- Confirmation and activity of a confidential disclosure program (e.g., hotline)
- Certification by the compliance officer that the provider is in compliance with the CIA

This is not an exhaustive list. CIA's may require reporting other elements to the government. Some CIA's contain board-level obligations. For example, the 2006 Tenet Healthcare Corporation CIA includes the following board-specific commitments:

- Review and oversee the performance of the compliance staff
- Annually review the effectiveness of the compliance program
- Engage an independent compliance consultant to assist the board in its review and oversight of Tenet's compliance staff
- Submit to the OIG a resolution summarizing its review of Tenet's compliance with the CIA and federal healthcare program requirements

In the past several years, some CIAs included onerous penalties for material violations of the agreement. Basically, the penalties provide a way for the government to enforce the agreements; such as a fine that ranges from \$1,000–\$2,500 per day. Also, the OIG has extended some CIAs in large cases for eight years.

CIAs essentially force a facility to create and monitor its compliance program for effectiveness. This task is most often set before the board of directors and the hospital senior management. Conversely, a facility with a robust and effective compliance program already in place can help protect the board and upper management from personal liability for any wrongdoing.

Caremark, a for-profit corporation that provided patient care and managed care services, represents a good case study for this situation. In 1994, Caremark was indicted under federal healthcare laws, including the AKS and the FCA. Caremark entered a guilty plea and paid more than \$250 million in civil and criminal fines.

After this guilty plea, Caremark's shareholders filed a suit against the board of directors for breach of their fiduciary duties by failing to effectively monitor the conduct of employees who violated various state and federal laws regarding payment to healthcare providers. The court had to analyze whether Caremark had a compliance program and control measures in place prior to the lawsuit.

After its review, the court expressed the following:

*"A director's obligation includes a duty to attempt in good faith to assure that corporate information and reporting system, which the board concludes is adequate, exists, and that failure to do so under some circumstances may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards."<sup>8</sup>*

Basically, the court concluded that a director does have a general duty to ensure that a company has effective compliance and control systems and the failure to do so could leave the directors individually liable.

The government recognized that just having a compliance program was not enough, and because of the rampant corporate fraud that occurred in the late 1990s and early 2000s, they knew the next evolution of the compliance program had to focus on organizations creating and promoting a culture committed to ethical business conduct.

## Sentencing Guidelines

However, there was not a lot of guidance regarding compliance programs for healthcare providers. The only guidance during this time came from the 1991 U.S. *Sentencing Guidelines* that provided information for corporations on the design and implementation of compliance and ethics programs. Basically, providers were on their own in developing compliance programs.

The federal *Sentencing Guidelines* provide guidance to judges during sentencing for federal crimes. This includes advice as to when sentences might be reduced for corporations with effective compliance programs. However, judges are not legally bound by the *Guidelines*, and they are not directly applicable to the civil and administrative legal trouble that healthcare organizations most often face.

In 1991, the *Guidelines* provided guidance for the design and implementation of compliance and ethics programs. Basically, an organization convicted of a criminal offense can substantially mitigate its punishment if it can show that it has an effective compliance program in place. Beyond its relevance in the sentencing context, regulators and prosecutors can also use the *Guidelines* to mitigate penalties in civil matters.

On November 1, 2004, significant amendments were made to the *Guidelines* for organizations. The current *Guidelines* reemphasize the prevention and detection of criminal conduct, but the new amendments require organizations to promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

The amendments elaborate on the original seven criteria and impose significantly greater responsibilities on the organizations governing authority and executive leadership. Here is a list of the original seven criteria along with the amendments:<sup>9</sup>

1. *Original*: Standards and procedures to prevent and detect criminal conduct.

*Amended*: Standards and procedures encompass “standards of conduct and internal controls that are reasonably capable of reducing the likelihood of criminal conduct.”

2. *Original*: “Specific individual(s) within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance.”

*Amended*: The organization’s governing authority must “be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.” (The *Guidelines* define *governing authority* as the board of directors.)

*Note:* These new guidelines mandate that the individual must be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority. Also, the board of directors must receive reports from the person responsible for overseeing compliance on an annual basis.

3. *Original:* Effective education and training.

*Amended:* The amended guidelines make compliance and ethics training a requirement and extend the training requirements to senior leadership, including the board of directors. Also, the training obligation is ongoing, requiring “periodic” updates.

4. *Original:* Auditing and monitoring of compliance programs.

*Amended:* The *Guidelines* add the specific requirement that the organization periodically evaluate the effectiveness of its compliance and ethics program. The *Guidelines* expand the focus of internal reporting from simply reporting “the criminal conduct . . . of others” to using internal systems to either “report or seek guidance regarding potential or actual criminal conduct.” Seeking guidance is consistent with the increased focus of this guideline on the prevention and deterrence of wrongdoing within organizations.

5. *Original:* Reporting systems without fear of retribution.

*Amended:* The original section that referenced “reporting systems without fear of retribution” was amended with the more specific suggestion that the organization must have:

*“A system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization’s employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.”<sup>10</sup>*

6. *Original:* Appropriate disciplinary mechanisms.

*Amended:* The amended language broadens the existing language that the compliance standards be enforced through disciplinary measures by adding that such standards also be encouraged through “appropriate incentives to perform in accordance with the compliance and ethics program.” These incentives could include making compliance and ethics a component of regular employee performance evaluations and of business units and employees’ performance goals and objectives.

7. *Original*: Investigation and remediation of systemic problems.

*Retained*: The requirement that an organization take reasonable steps to respond to, and prevent, further similar criminal conduct was retained. The organization has a duty to address both specific instances of misconduct and systemic shortcomings that compromise the deterrent effect of its compliance and ethics program.

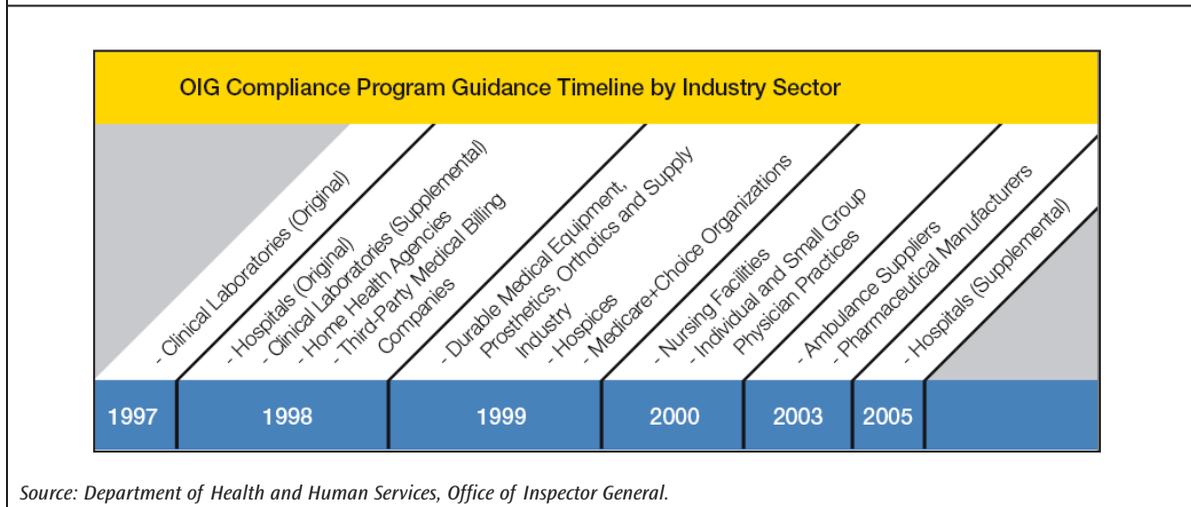
The amendments enhance, strengthen, and clarify the existing seven minimum requirements of an effective compliance program. More importantly, an effective compliance program not only helps to build an ethical culture, but it could also provide important protections against criminal and civil liability and the potential mitigation of both criminal penalties and civil damage awards.

**Compliance programs**

In this vacuum, the OIG entered the compliance arena to develop and publish its Compliance Program Guidance (CPG) for the healthcare industry. The OIG based its guidance on its experience with compliance coupled with communications with the healthcare provider community.

The first CPG introduced by the OIG was for clinical laboratories based on their findings from “Operation Bad Bundle.” From 1997 through 2005, the OIG developed 13 different CPGs covering all major healthcare industry sectors. The timeline in Figure 1.6 illustrates the history of the OIG’s Compliance Program Guidance.

**Figure 1.6 Timeline of compliance program guidance development**



Through all its guidances, the OIG stated that a reliable compliance program should include the ability to:

- Demonstrate to the employees and the community the commitment to honest and responsible provider and corporate conduct
- Identify and prevent criminal and unethical conduct
- Improve the quality of patient care
- Create a centralized source of information on healthcare regulations
- Develop a way that encourages employees to report potential problems
- Develop procedures that allow the prompt, thorough investigation of alleged misconduct
- Initiate immediate and appropriate corrective action
- Minimize government loss due to false claims, and thereby reduce exposure to civil damages and penalties, criminal sanctions, and program exclusion

The seven elements for any corporate compliance program are the following:

- Written standards of conduct
- Designating a chief compliance officer and other appropriate bodies
- Effective education and training
- Audits and evaluation techniques to monitor compliance
- Reporting processes and procedures for complaints
- Appropriate disciplinary mechanisms
- Investigation and remediation of systemic problems

Voluntary compliance programs, however, are expensive and labor-intensive. Healthcare officials didn't want to put their money into a program that wasn't mandated by law when so much else required the attention of valuable healthcare dollars. So, many providers bought off-the-shelf compliance programs that sat in someone's office collecting dust. But developing and refining a compliance program is a dynamic process that needs committed resources.

The best compliance program in the world is only a document. If those who lead the organization—from the administrators to the board of directors—do not expend the necessary time and resources, even the best-laid compliance plans are worthless.

The key to a compliance program is its effectiveness. There are several benefits of having an effective compliance program:

- It demonstrates the healthcare providers' commitment to honest and responsible corporate conduct
- It increases the likelihood of preventing, identifying, and correcting unlawful and unethical behavior at an early stage
- It encourages employees to report potential problems to allow for appropriate internal inquiry and corrective action
- It may mitigate any sanction imposed by the government
- It may protect corporate directors from personal liability

This list is not all-inclusive, but it displays some of the positive aspects of having an effective compliance program.

#### ***Supplemental Hospital Compliance Guidance***

Not long after the release of the amended 2004 U.S. *Sentencing Guidelines*, on January 31, 2005 the OIG issued *Supplemental Hospital Compliance Guidance* that enhanced the earlier version released in 1998.<sup>11</sup> This new guide focused on:

- Current areas of risk
- Future OIG enforcement activity
- Fostering of organizational commitment to compliance
- The need for the provider to perform a periodic review of the effectiveness of its compliance program

In the *Supplemental Guidance*, the OIG lists eight areas hospitals face regarding risk and liability:

- The submission of claims
- Physician self-referral and anti-kickback statutes
- Gainsharing arrangements

- Emergency Medical Treatment and Labor Act of 1986
- Substandard care
- Relationships with federal healthcare beneficiaries
- HIPAA privacy and security rules
- Billing Medicare and Medicaid substantially in excess of usual charges

All of these areas are still concerns today, especially the area of physician relationships.

Unlike the U.S. *Sentencing Guidelines*, on which the *OIG Hospital Compliance Guidance* is based, the *Supplemental Guidance* focuses more on hospital compliance program effectiveness. The *OIG Supplemental Guidance* emphasizes that a hospital with an organizational culture that values compliance is more likely to have effective compliance programs. Basically, the *OIG* says there is no magic bullet or precise formula to follow; however, in its opinion successful programs include the following:

- The commitment of the hospital's governance and management at the highest levels
- Structures and processes that create effective internal controls
- Regular self-assessment and enhancement of the existing compliance program

A common theme throughout the *Supplemental Guidance* deals with a strong commitment to compliance by the hospital's governing body and senior management. The structure that holds everything together, the core of an effective compliance program, is the facility's "code of conduct."

It is easy to develop a code of conduct for your own hospital (a sample code is available in the companion to this book, *The Healthcare Compliance Professional's Guide to Policies and Procedures*). But be careful. Just like in the late 1990s and early 2000s, when many providers had off-the-shelf compliance programs that merely gathered dust, it's easy to let a code of conduct become just another stack of paper.

A true and effective code of conduct takes time and commitment from all levels of the organization, including the board of directors and representatives from the medical and clinical staffs, as well as various levels of the organization. More importantly, a code of conduct sends a message to all employees that the hospital's governing body is committed to compliance and sets a standard of broad ethical and legal principles under which the healthcare providers will operate.

The *Supplemental Guidance* expands on how to evaluate the effectiveness of a compliance program. It lists several factors the OIG observed in effective compliance programs. Here is a list of some important factors that help in evaluation of a compliance program. (A PDF of the *Federal Register* notice including the *Supplemental Guidance* is included on the accompanying CD-ROM, Figure A.3, for your convenience.)

**Does the compliance department have sufficient resources, training, authority, and autonomy to carry out its mission?** This area represents one of the biggest weaknesses in many compliance departments. Most facilities employ limited staff to compliance departments. According to the Health Care Compliance Association's (HCCA) tenth annual survey, "2008 Profile of Health Care Compliance Officers," 29% of survey respondents have only one full-time staff member in the compliance department budget.<sup>12</sup>

Budget constraints represent another difficulty. The HCCA survey shows that the greatest number of respondents—20%—spends less than \$100,000 on compliance efforts. With limited resources and budgets it's difficult to effectively impact the auditing of high-risk areas and training education programs.

In today's healthcare environment of reduced reimbursement and increased costs, it is difficult for providers to justify the cost of an effective compliance department. However, the benefits of an effective compliance department greatly outweigh the costs of external investigations, huge civil and monetary penalties, and an onerous CIA. Also, even in today's heightened regulatory arena, many in senior leadership still have the attitude that an investigation can't and won't happen to them.

**Has the hospital developed a risk assessment tool, which is reevaluated on a regular basis, to assess and identify weaknesses and risks in operations?** Development of a risk assessment tool is crucial for a hospital to understand potential liabilities that might exist. (The companion to this book, *The Healthcare Compliance Professional's Guide to Risk Assessments*, walks compliance officers through this process.)

A common practice is to rely heavily on the current OIG's *Work Plan* to evaluate risk. However, numerous other tools also exist and the information included in the *Work Plan* must be augmented by additional analysis from a variety of venues. Look at internal data, prior-year audit results, and other reports from CMS, the OIG, and the DOJ, too.

To further target facility risk areas, compliance officers need to explore information contained in the CERT detailed billing data and keep an eye on evolving challenges contained in the new Recovery Audit Contractor reports.

**Has the hospital established an anonymous hotline or other mechanism so that staff members, contractors, patients, visitors, and medical and clinical staff members can report potential compliance issues?** It's not enough to just have a hotline. It is important that the compliance hotline is well publicized throughout the hospital's intranet and/or newsletters. Also, it is important that all hotline calls are logged and tracked and that the caller is informed and kept up to date on the hospital's response. The results or statistics of this information should be regularly communicated to the board.

**Does the hospital provide and evaluate its training program content on an annual basis to determine the appropriateness of the content?** Training and education are important at all levels of the healthcare organization. The main purpose is to ensure that all employees are capable of performing their duties within the rules, regulations, and standards.

The hospital should have a mechanism in place to document all training completed, as well as sanctions for those employees who fail to attend any required training and education sessions. Two types of training programs should be offered:

- Type I education, which would be conducted for all employees regarding the healthcare organization's standards of conduct
- Type II education, which is training and education on the legal and regulatory requirements specific to associates in carrying out their roles and responsibilities within the organization

The best practice in this area is to have a required minimum number of hours per type of education offered.

**Has the hospital developed a detailed and effective internal auditing and monitoring plan that addresses the proper areas of concern?** For example, are findings from previous years' audits, risk areas, high-volume/high-reimbursement areas, and targeted areas by the OIG identified as part of the annual risk assessment? One of the main areas that the OIG will review to determine whether a hospital's compliance program is effective, and thus limit sanctions and penalties, is the strength of its internal auditing function.

Each of the seven elements of the compliance program is important, but the OIG weighs the results and corrective actions of the auditing and monitoring function more than it does other elements in considering sanctions.

The reason for this is simple: The hospital can provide all the required training and education, provide an effective hotline service, and have its standards of conduct in place, but if it does not measure the results of its compliance program through auditing and monitoring, appropriate follow-up and self-reporting, it is impossible to determine whether all the other activities are working.

It's a Catch-22 because you need to develop strong policies and processes for all the elements to achieve positive results through your auditing and monitoring activities.

**Has the hospital created a response team, consisting of representatives from the compliance, audit, legal, and any other relevant stakeholders, to evaluate detected deficiencies quickly?** This goes hand in hand with a fully developed, effective auditing and monitoring plan. Any results or findings from your facility's auditing and monitoring activity need to have appropriate follow-up and corrective actions. Such actions must take into account the root cause of the potential violation. They must also verify that all corrective actions were implemented successfully to eliminate existing deficiencies.

The verification process usually takes the form of some type of follow-up audit. Also, when audit results identify an overpayment, the hospital has to ensure that the overpayments are promptly repaid to the appropriate fiscal intermediary or carrier (agents of Medicare that pay providers for services).

**Are disciplinary standards well publicized and readily available and consistently enforced across the organization?** By enforcing disciplinary standards, hospitals help to create an organizational culture that emphasizes ethical behavior.

The OIG *Supplemental Hospital Compliance Guidance* goes beyond the seven elements needed in establishing a compliance program to focus on creating an ethical culture around compliance. It also offers suggestions to help hospitals make the compliance program more effective.

The *Guidance* suggests that a hospital should regularly review the effectiveness of its compliance program. The preceding discussion details many areas that should be reviewed to determine compliance

effectiveness, as the results of reviewing all of these areas could identify weaknesses or material deficiencies that need to be corrected. This can be a massive undertaking for a hospital and/or a large hospital system.

One way to perform this review is to use a survey tool on a continuing basis to measure the seven elements of your compliance program to ensure that all measures are achieved. If any deficiencies have been identified, they have to be addressed and remedied on a priority basis. (For a sample compliance program evaluation checklist, see Figure A.4 in this book's Appendix; the figure is also available on the accompanying CD-ROM.)

## Current and Future Compliance Risks

As healthcare costs continue to rise, the government will continue to look at ways to recover Medicare trust fund money through regulatory enforcement. CMS started to apply sophisticated analytical tools to its claims database to track down billing aberrations. The government and its agents' new tool is data mining; further, all of the data the providers use in order to get paid is transparent. In other words, there is nowhere to hide, and compliance officers need to start adopting some of the government's methods and advice to uncover their own billing aberrations before federal agents or *qui tam* relators do.

Every provider has different challenges, but below are some current compliance risk areas and potential areas for future concern.

### Recovery Audit Contractors

To gain a better understanding of why the government created the Recovery Audit Contractor (RAC) program, we only need to review the CERT program results.

The results of the 2007 CERT program estimated that 3.9% of the Medicare reimbursement did not comply with one or more Medicare coverage, coding, billing, or payment rules. This equated to about \$10 billion in Medicare overpayments. Despite the successes of the CERT program in reducing improper payment errors, government officials realized they needed more help. So, it turned to the RAC.

RACs originated from Section 306 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003<sup>13</sup>, which directed the government to use contractors to detect Medicare underpayments and overpayments, and pay the contractors on a contingency fee basis. In other words, the RAC contractors receive a percentage of every dollar they identify in overpayment recoveries.

This represents a groundbreaking and controversial change because the government never hired contractors on a contingency fee basis before. Furthermore, in the past government regulators frowned on consulting firms offering services to providers on a contingency fee basis. The underlying controversy and fear of providers was that if a contractor receives payment based solely on a percentage of its findings, the RAC then becomes more bounty hunter than fact finder, incentivized to ignore the directives established by the government.

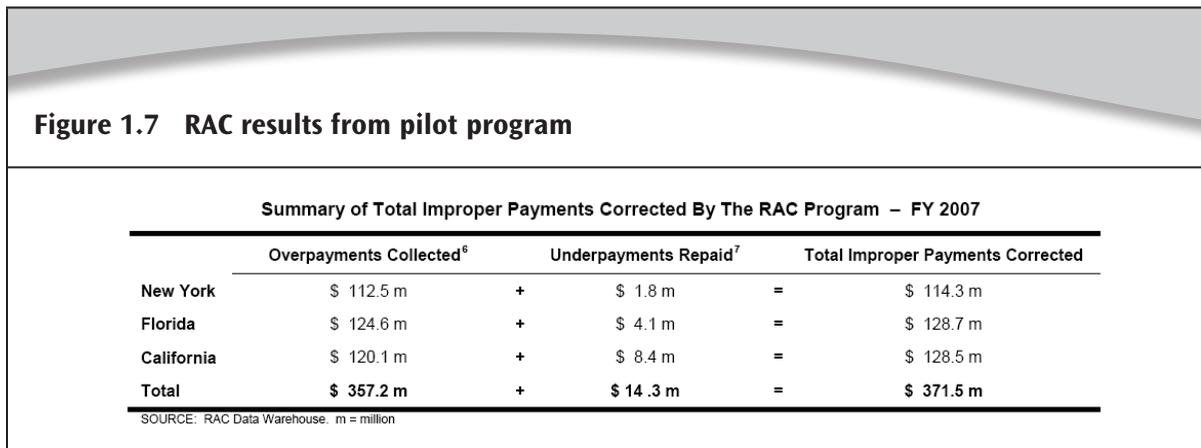
The three-year RAC demonstration project in California, Florida, and New York ended in March 2008. Results of the pilot program are significant. In fiscal year 2007, total improper payments collected amounted to \$357 million (see Figure 1.7).

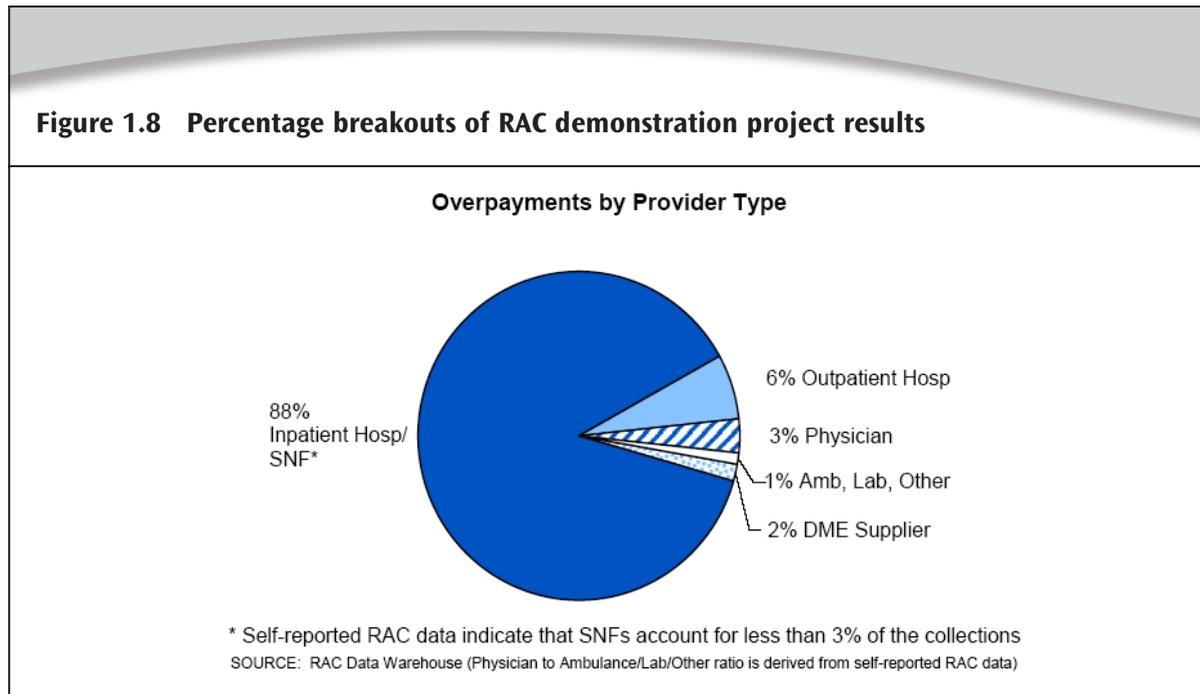
RACs developed data mining tools to determine audit focus areas, searching to see whether a provider failed to bill according to Medicare billing regulations. The RACs identified that most of the overpayments came from inpatient hospital services. (See Figure 1.8 for percentage breakouts of RAC demonstration project results.)

Initial backlash suggested that CMS lacks sufficient oversight to run the RAC program. Nevertheless, the Tax Relief and Health Care Act of 2006 made RACs a permanent fixture in CMS's audit toolkit. By the end of 2009, RAC programs will examine healthcare billing records across the country.

Based on provider concerns, CMS did make the following changes to improve the RAC program:

- The look-back period from claim payment date changed from four years to three years. RACs cannot look any farther back in time than October 1, 2007 for improper payments.
- In the demonstration project, RACs could not look at current-year claims. The permanent program allows RACs to review current-year claims.





- RACs did not have to use certified coders during the demonstration phase. The permanent phase requires the use of certified coders to examine claims.
- In the demonstration project, RACs maintained no medical record request limit. RACs could request as many medical records as they wished. The permanent program sets a limit.
- The permanent RAC program requires that a representative discuss claims denials with the facility medical director. No requirement existed in the demonstration project.
- The RACs had to pay back the contingency fee only if they lost at the first level of appeal. In the permanent program, the RACs will have to pay back the contingency fee at all levels of appeal.
- During the demonstration project, the RACs could determine what type of reviews they wanted to perform without an external validation process from CMS. The permanent program requires that RACs have an external validation process with CMS before conducting medical reviews.

Although the preceding changes represent some favorable provider outcomes, RACs now represent a new area of enforcement for providers to live in and plan for.

The evolution of the RAC agenda represents one more reason for healthcare facilities to engage in robust compliance and auditing programs. It also represents one more step in CMS's efforts to reduce fraud, waste, and abuse—actions which inevitably reflect on the capability and culpability of boards of directors.

## Quality of Care

In its 2000 report, *“To Err Is Human: Building a Safer Health System,”* the Institute of Medicine (IOM) estimated that medical errors lead to nearly one million unnecessary deaths each year. The cost of treating complications due to medical errors has been estimated at \$1 million to \$3 million annually for the average 300-bed hospital.

Eight years after publication of the IOM report, government scrutiny of quality concerns is reaching its pinnacle. The OIG and the DOJ are bringing their arsenal of regulations—Stark Law, AKS, the FCA, and civil monetary penalties—to bear even as CMS generates new payment methodologies to target quality, tracks patient conditions present on admission, and refuses to reimburse for conditions acquired in the hospital. Furthermore, government agents say that providing poor quality of care is the same as providing no care at all. Those who bill for bad care are at risk of violating the FCA.

In addition to their traditional responsibilities for making sure hospital staff members follow federal and state regulations, the compliance officer and the board of directors now play an important role in ensuring that patients receive optimal care. It is no longer acceptable for the board of directors to profess clinical ignorance in light of gross or negligent care.

In June 2008, in a first of its kind settlement agreement, Rosalind S. Lavin, former owner of four personal care facilities in the Philadelphia area, reached a civil settlement with the DOJ that prohibited her from ever owning a patient, personal, or residential care facility again, according to a release from the DOJ.<sup>14</sup> Lavin also agreed to a condition barring her from ever receiving payment from Medicare, Medicaid, and all other federal healthcare programs.

The facility neglected to provide the basic care it billed to CMS. According to the DOJ, residents who lived in the four facilities received inadequate housing and care that included structurally unsafe residences, insufficient food and nutrition, unsanitary, substandard living conditions, and even inadequate and unclean clothing, linens, and bedding.

That’s just one example of government’s increased focus in the area of quality of care. Officials such as HHS Inspector General Daniel Levinson, OIG Chief Counsel Lewis Morris, and New York Medicaid Inspector General James Sheehan all spoke at length about the role of the compliance officer in the quality of care movement during the April 2008 HCCA conference, in New Orleans.

Other developments include the following:

- In August 2003, Tenet Healthcare Redding Medical Center agreed to pay \$54 million to settle a federal suit alleging that it filed claims for unnecessary cardiac procedures. Nearly 800 cardiac patients were involved in the suit. In 2005, the two physicians involved in the suit agreed to pay more than \$1 million in fines.
- On July 29, 2005, The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) was signed into law.
- In May 2007, the DOJ and HHS launched the Medicare Fraud Strike Force.
- In August 2007, Medicare announced it would stop paying for eight preventable medical complications, and in April 2008 it proposed adding nine more preventable complications to the list.
- On September 13, 2007, the OIG and the American Health Lawyers Association issued a joint publication, "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors." A best practice would be for the compliance officer to meet with the clinical/medical director and answer the 10 questions provided in this resource (see Figure A.5 in this book's appendix for the complete list). The questions, answers, and this resource should be provided to the board of directors for their review and input so that they can gain a better understanding of quality and patient safety issues.
- In January 2008, CMS and the HCCA published "Driving for Quality in Long-Term Care: A Board of Directors Dashboard."
- On January 11, 2008, the DOJ announced that Louisiana Lafayette General Medical Center agreed to pay \$1.9 million to settle allegations that it defrauded federal and state health plans, including Medicare, Tricare, the Federal Employee Health Benefit Plan, and Medicaid, by billing those programs for medically unnecessary cardiology procedures.
- Starting in October 2008, New York's state Medicaid program will stop reimbursing hospitals for 14 different types of avoidable medical errors, known as "never events," that can cause serious complications for their patients.

There is a clear directive from CMS, the OIG, and other government agencies that compliance officers and the board of directors must turn a watchful eye to quality-of-care concerns, despite the fact that quality has historically been the purview of other departments.

The compliance officer faces numerous difficulties in determining what regulations apply to quality of care, how to track quality data, and how to develop policies and procedures to work among various quality stakeholders. As CMS increasingly begins to tie its reimbursement with quality-of-care indicators, the potential for providers to misrepresent quality data also grows. Compliance officers must carefully examine the reporting and analysis of such data before the OIG comes to call.

### **Internal Revenue Service (IRS) Form 990**

On February 14, 2008, the IRS released “Governance and Related Topics – 501(c)(3) Organizations,” which stated the IRS’s position that a well-governed charity is more likely to obey the tax laws, safeguard charitable assets, and serve charitable interests than one with poor or lax governance. Therefore, a charity should have clearly articulated purposes describing its mission, a knowledgeable and committed governing body and senior leadership, and sound management practices.<sup>15</sup>

Basically, the IRS revised the 990 form to increase transparency for more than 2,900 private, nonprofit hospitals that earn tax breaks or are tax-exempt. In recent years, the IRS scrutinized nonprofit hospitals, executive pay and perks, and how much subsidized care tax-exempt hospitals provide to justify tax breaks (See Figure A.6 available on the accompanying CD-ROM for an outline of changes).

Tax-exempt hospitals have always reported community benefits on the IRS 990 Form; however, most hospitals did not document their community benefit in its entirety, or they did so inconsistently. Now the form includes bad debt and Medicare losses, and the cost breakdown includes the following eight expense categories:

- Charity care
- Cash and in-kind contributions to community groups
- Community health improvement and community benefits
- Health profession education
- Research
- Subsidized health services
- Unreimbursed Medicaid
- Other unreimbursed public means-tested programs

Another big change is the expanded section on governance policies and executive pay and perks. Again this information has always been on the form, but now it is asking for more detailed information, such as housing allowances and first-class travel, to just name a few.

Also, the board of directors will have to disclose more detailed information regarding their financial interests and business relationships (see Section III of this book for a more detailed discussion and examples). The penalties are stiff if the information is not reported correctly. For example, hospitals can be fined \$100 per day, up to \$50,000 maximum, if members of the board of directors fail to disclose all of the required information, and if directors are found to have been involved in an improper transaction the board would be subject to intermediate sanctions and penalties of up to 225% of the excess benefit.

The bottom line is that as healthcare costs continue to rise, the government is continually looking for ways to secure the Medicare trust fund, and one way is to challenge and remove a nonprofit's tax-exempt status.

Numerous current and future risks will keep a compliance officer up at night, including the DRA, re-search and clinical trials billings, Medicare Severity Diagnosis-Related Groups, present on admission, and physician-hospital relations (Stark). It is important to note that every healthcare provider has its own unique set of challenges, and the risks mentioned in this section do not represent an exhaustive list. Therefore, you should consider all issues when developing a risk assessment and future audit work plan.

Remember, with an effective compliance program and board support, all providers can build an effective auditing and monitoring program to stay ahead of the curve and mitigate the many inherent risks in providing healthcare services.

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