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The Brave New World of Health Care Compliance Programs

Thomas E. Bartrum
L. Edward Bryant, Jr.*

INTRODUCTION

Eradication of health care fraud and abuse has become the federal government's mantra of the 1990s. In fact, Janet Reno, United States Attorney General, has declared fraud and abuse her agency's number two priority behind violent crime. In this area, at least, the statistics back up the government's bravado. The government will investigate approximately 2000 cases of health care fraud and abuse this fiscal year. This represents a 100% increase since fiscal year 1993. At the same time, the number of criminal and civil cases filed against health care providers since 1992 has doubled. Further, the government has been very successful in its attempt to prosecute health care fraud; in 1997, the Department of Justice ("DOJ") announced that health care fraud convictions had increased 270% during the Clinton administration. If that were not enough, of the 333

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2. DOJ Interested in Looking at More "Quality of Care" Cases, Official Says, 4 PREVENTION OF CORP. LIABILITY: CURRENT REPORT (BNA) 5 (Mar. 10, 1997) (citing numbers used by Debra Cohn, special counsel for health care fraud at the Department of Justice, in a speech delivered to the National Health Lawyers Association) [hereinafter DOJ Interested].

3. Id. at 5.

qui tam suits brought under the civil False Claims Act in 1996, 178 alleged health care fraud.

The government’s recovery record is equally impressive. In 1994, an investigation of National Medical Enterprises (“NME”) conducted by six different federal agencies and several United States Attorneys’ offices culminated in a settlement of $379 million for alleged Medicare billing fraud. Likewise, the government’s highly publicized settlement with Caremark Inc. resulted in the company paying $161 million to the federal government and affected state governments. In March of 1997, SmithKline Beecham Clinical Laboratories, Inc. reached a settlement with the DOJ in which it agreed to pay $325 million to satisfy charges that it defrauded Medicare, Medicaid, and other government programs.

This increase in government and private enforcement activity has been paralleled by an equally daunting increase in the scope of what is considered health care fraud. While a false claim was once characterized by an intent to defraud, today false claims are discussed in terms of “patterns of erroneous billings.” Within the last year, the civil False Claims Act has been successfully utilized to “right” such diverse wrongs as poor quality of care in a nursing home and alleged technical violations of the Anti-Kickback statute. The recently enacted Health Insurance

6. DOJ Interested, supra note 2, at 6.
8. Caremark To Pay $161 Million to Settle Fraud, Kickback Cases, 4 BNA'S HEALTH L. REP. 953 (June 22, 1995).
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Portability and Accountability Act of 1996 ("HIPAA") substantially increases both the available scope of health care crimes and the government's resources to pursue such claims.\(^{13}\) The Clinton administration's latest health care fraud initiative, which is currently included in the House Ways and Means Committee markup of the budget, will, among other things, revoke many of the concessions given to the provider community as part of HIPAA.\(^{14}\)

This article initially looks at recent history, which aids in understanding the government's position. It then focuses on the elements necessary for an effective compliance program. Specifically, the article will look to the Federal Sentencing Guidelines for Organizations as providing the minimum requirements for establishing an effective compliance program. However, when appropriate, the article will look to other sources such as government-imposed "corporate integrity programs" or the government-created Model Plan for use by clinical laboratories. After establishing the basics of an effective compliance program, the article will examine the practicalities of implementing a compliance program, including how to minimize potential legal exposure associated with adopting a compliance program.

I. A Look Back Helps to Plan Forward

But it is important to look at how health care has reached this point. The impression given the general public and the Congress by the Office of the Inspector General ("OIG") for many years was that the runaway inflation in federally financed health care costs was largely attributable to rampant fraud and abuse at all levels of providers and suppliers to the Medicare and Medicaid programs. Moreover, the enforcement efforts of the OIG have tended to confuse "fraud" with "abuse" by (1) ignoring the common law distinctions between abuse with criminal intent and abuse that is clearly negligent, (2) seeking supplemental legislation permitting draconian "civil" sanctions that can be imposed under the preponderance of the evidence marshaled rather than the "guilty beyond a reasonable doubt" criminal law standard.

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standard, and (3) the clever use of extremely narrow “safe harbors” in regulations promulgated in 1991 that, effectively, increased materially the scope of what conduct was thereafter unlawful.

Added to this crescendo in 1993 was the determination of the Internal Revenue Service (“IRS”) to assist the OIG in punishing fraud and abuse through the loss of exempt status for hospitals “violating public policy”; the no-longer-latent paranoia of tax-exempt hospitals became pronounced nationwide. The IRS announcement was followed on October 14, 1994 by a highly publicized settlement agreement between the IRS and the Hermann Hospital in Houston, Texas.15 The terms of the settlement were well known in large part because one of the requirements was that the hospital publish the agreement in its entirety. Directly analogous to the criminal fraud cases settled by the DOJ with required corporate integrity programs, the IRS required that the nationally published Hermann Hospital settlement agreement include a detailed set of hospital-physician contracting “guidelines.”

There is much legal significance to such nationally published “guidelines,” to the publicity accorded the IRS’s coordinated examination program for auditing tax-exempt institutions, and to the published corporate integrity programs from Medicare fraud settlements. It is both burdensome and politically problematic under the Administrative Procedure Act16 for governmental agencies to have to publish regulations regarding civil sanctions. Among other things, they would have to distinguish clearly between those violations of law that are civil in nature and those that are criminal. It is fundamental constitutional law that criminal statutes must be clear enough on their face so that regulations are not required for a citizen to know what is unlawful. Otherwise, the statute is deemed to be “void for vagueness.” It was the constant allegation for years of lawyers and defendants that the Medicare Fraud and Abuse Law was such a statute,17 which caused Congress in 1987 to require the OIG by statute to promulgate regulations to define what conduct would not be prosecuted criminally. This was a task so disliked by the OIG

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that it took four years to promulgate extremely narrow "safe harbors."

Increasingly in the 1990s, honest health care providers must ask what they can do to prevent being caught up in this maelstrom of the government's health care anti-fraud activity. The best, although by no means perfect, answer is the implementation of a corporate compliance program. Even though other industries have already undertaken significant compliance efforts, health care compliance programs are relatively new. This emphasis on corporate compliance has its genesis in the United States Sentencing Commission's promulgation of Federal Sentencing Guidelines for Organizations. The Guidelines, which became effective November 1, 1991, are significant because they impose severe economic sanctions on corporations convicted of criminal wrongdoing and eliminate most judicial discretion in corporate sentencing. Further, the Guidelines provide that corporations can significantly reduce sanctions by adopting "an effective program to prevent and detect violations of law."

The real catalysts for the widespread adoption of health care compliance programs, however, have been the DOJ and the OIG. These agencies have recently required all organizations settling health care fraud charges to adopt government-supervised corporate integrity programs as part of the defendants' settlement agreements. These government-imposed compliance programs usually require corporations to commit substantial assets to compliance and involve significant government and private oversight. Additionally, these programs typically prohibit the organization from recouping any of its compliance ex-

18. See Karl A. Groskaufmanis, Corporate Compliance Programs as a Mitigating Factor, in ORGANIZATIONAL SENTENCING GUIDELINES § 5.02 (Jed S. Rakoff ed., 1993).
20. Id. § 8C2.5(f).
21. Even the Internal Revenue Service has acknowledged that the existence of a compliance program may help an organization when problems are detected during an audit. Corporate Compliance Plans May Help Companies Even If Problems Are Found, 6 BNA's HEALTH L. REP. 19 (May 8, 1997).
22. OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., FRAUD AND ABUSE CONTROL PROGRAM AS MANDATED BY THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, GUIDELINES FOR IMPLEMENTATION, III.E.3 (Jan. 24, 1997) (requiring settlements of health care fraud issues to include either a compliance agreement or compliance provisions to prevent future wrongdoing) (on file with the author).
penses as allowable costs "for government contract accounting and for Medicare reimbursement expenses."23

In a realization that government investigation and enforcement is an expensive endeavor, the government is now actively encouraging health care organizations to voluntarily adopt compliance programs. In an open letter to health care providers, the Inspector General of the Department of Health and Human Services invited the nation's health care providers to join the OIG in fighting fraud and abuse by adopting compliance programs that "promot[e] a high level of ethical and lawful corporate conduct."24 To assist such providers, the OIG announced its intention to "expeditiously produce sector-specific compliance programs for each of the health care provider components doing business with the Government."25 The first of these model compliance programs, released March 3, 1997, applies to clinical laboratories ("the Model Plan").26

In addition to any reduction in criminal penalties provided by the Guidelines, compliance programs also provide a number of other benefits. In fact, most organizations adopt compliance programs to prevent a criminal conviction in the first place. Compliance programs can accomplish this prophylactic effect in different ways. Most significantly, by providing meaningful guidance to employees, corporations reduce the likelihood that an employee will inadvertently violate existing laws and regulations. Further, a corporation that clearly sends a message to all employees that violations of law will not be tolerated reduces the likelihood that an employee will intentionally violate the law in an attempt at career advancement. Such an environment also encourages employees to take their complaints and concerns to management instead of going directly to the government or the media, which may reduce the risk of qui tam or whistle-blower suits.

In the event that a violation does occur, a compliance program and management's diligent effort to minimize employee


25. Id.

transgressions may demonstrate to an investigator that the organization should either not be prosecuted or should only be subjected to civil sanctions.\textsuperscript{27} As a practical matter, if the government does decide to pursue a criminal prosecution of the organization, the organization’s efforts to prevent such behavior make it more difficult for the prosecutor to prove intent.\textsuperscript{28} Finally, a compliance program can assist an organization undergoing an investigation by providing guidance on how the organization should respond in such situations. Such guidance should improve the organization’s ability to appropriately respond to investigations in a timely manner.

II. \textbf{The Essential Elements of a Compliance Program}

The Guidelines mandate that federal courts impose severe economic sanctions on organizations convicted in federal courts of criminal violations. By removing judicial discretion and imposing significant economic sanctions on convicted organizations, the Federal Sentencing Commission sought to “provide just punishment, adequate deterrence, and incentives for organizations to maintain internal mechanisms for preventing, detecting, and reporting criminal conduct.”\textsuperscript{29} To accomplish this goal, the Guidelines require the sentencing judge to base the corporation’s criminal fine on the seriousness of the offense and the culpability of the organization.\textsuperscript{30} This is accomplished by a series of determinations that result in an offense level,\textsuperscript{31} a base fine,\textsuperscript{32} a culpability score,\textsuperscript{33} minimum and maximum multipli-
ers,\textsuperscript{34} and finally, a fine range.\textsuperscript{35} Using these scores and multipliers, the judge determines the sanction to be imposed.

Particular facts affect the score and multipliers, particularly the specific organization's culpability as measured by several statutorily significant factors. For instance, the fact that high-level personnel "participated in, condoned, or [were] willfully ignorant" of the behavior resulting in the conviction increases the culpability score.\textsuperscript{36} On the other hand, the culpability score of organizations with an "effective program to prevent and detect violations of law" is reduced.\textsuperscript{37} Further, if the organization reported the violation, cooperated in the investigation, and accepted responsibility for its actions, its culpability score is again reduced.\textsuperscript{38}

These reductions in the culpability score significantly reduce an organization's potential fines. For instance, assume an organization has adopted a corporate compliance program that detects a potential violation. After an internal investigation, the corporation determines that a criminal violation did in fact occur and reports the violation to the appropriate authorities. Further, the corporation continues to cooperate with federal investigators and accepts responsibility for its actions. Assuming that no facts exist that would increase the organization's culpability, the organization's initial culpability score of five is reduced by eight points, resulting in a culpability score of negative three. The Guidelines provide an eighty to ninety-five percent base fine reduction for organizations with a culpability score of zero or less.\textsuperscript{39} Thus, if the base fine was $1.2 million, the allowable fine range would be $240,000 to $60,000.\textsuperscript{40} Further, the organization's low culpability score would weigh in favor of imposing the minimum fine.\textsuperscript{41}

Accordingly, there are real pecuniary benefits to implementing an effective compliance program. However, whether a com-

\begin{itemize}
  \item \textsuperscript{34} \textit{Id.} § 8C2.6.
  \item \textsuperscript{35} \textit{Id.} § 8C2.7. For a detailed explanation of the fines, and the effect a compliance program can have on a fine, see Faddick, \textit{supra} note 13, at III(A), (B).
  \item \textsuperscript{36} \textit{Id.} § 8C2.5(b)(1) (providing a five-point increase for organizations with 5000 or more employees); § 8C2.5(b)(5) (providing a one-point increase for organizations with ten or more employees).
  \item \textsuperscript{37} \textit{Id.} § 8C2.5(f).
  \item \textsuperscript{38} \textit{Id.} § 8C2.5(f).
  \item \textsuperscript{39} \textit{Id.} § 8C2.6.
  \item \textsuperscript{40} This example is reasonable since the Guidelines provide for base fines between $5000 and $72,500,000. \textit{See id.} § 8C2.4(d).
  \item \textsuperscript{41} \textit{See id.} § 8C2.8(a)(8).
\end{itemize}
pliance program will be deemed effective is a question of fact. The Guidelines specifically provide that the effectiveness of a compliance program does not rest on the program’s inability to prevent the offense from occurring in the first place. However, the participation in, acceptance of, or willful ignorance of the offense by certain high-level personnel, including the individual in charge of the compliance program, automatically results in an ineffective compliance program. Further, the participation of an individual with “substantial authority” in the offense results in a rebuttable presumption that the compliance program was ineffective. The Guidelines also condition the mitigating effect of an effective compliance program on the organization reporting any discovered offense without unreasonable delay.

The Guidelines do not set out specific requirements to be included in a compliance program in order for the program to be deemed effective. Instead, the Guidelines define an effective compliance program as “a program that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct.” The appropriate inquiry is whether the organization “exercised due diligence in seeking to prevent and detect criminal conduct by its employees and other agents.” The Guidelines define seven minimum elements necessary to a finding that the organization exercised due diligence in implementing its compliance program:

- Develops compliance standards and procedures “reasonably capable of reducing the prospect of criminal conduct”;
- Assigns compliance responsibility to sufficiently high-level personnel;
- Avoids assigning substantial discretionary authority to individuals who the organization knows, or should have known, have a propensity to engage in illegal activities;

42. Id. § 8C2.5(f).

43. Most organizations assign responsibility for their compliance program to a compliance officer. Larger organizations, however, may find the combination of a compliance officer and committee makes the implementation process more manageable.

44. Id.

45. Id. “Substantial authority personnel” includes “individuals who within the scope of their authority exercise a substantial measure of discretion in acting on behalf of an organization.” Id. § 8A1.2 Application Note 3(c).

46. See id. § 8C2.5(f).

47. Id. § 8A1.2 Application Note 3(k).

48. Id.
Communicates compliance standards and procedures to employees and agents through effective means, such as compliance training programs;

- Takes reasonable steps to achieve compliance with its standards such as implementing monitoring and auditing systems and mechanisms to allow employees to report instances of noncompliance;

- Enforces compliance standards in a consistent manner through "appropriate disciplinary mechanisms"; and

- If an offense occurs, takes "all reasonable steps to respond appropriately to the offense and to prevent further similar offenses." 49

Although such general statements may not seem very helpful to an organization attempting to implement a compliance program, the Guidelines' flexibility is intended to allow corporations to tailor their compliance programs to meet their specific objectives. 50 The Guidelines, however, do identify four factors that will determine the appropriate scope of an organization's compliance program. First, the size of the organization will dictate the degree of formality required for a compliance program to be found effective. 51 Generally, the larger the organization, the more formality that is expected of the program. It is possible smaller organizations may not even have to adopt written standards; 52 however, written standards are strongly recommended for all organizations because the organization will bear the burden of proving that its compliance program was effective.

Second, if the nature of the organization's business exposes it to a "substantial risk that certain types of offenses will occur, management must [take] steps to prevent and detect those types of offenses." 53 Since large health care organizations typically file tens of thousands of Medicare claims annually and a very real risk of filing false claims exists, the effectiveness of a health care organization's compliance program would necessarily be dependent on it including a Medicare billing component. 54 Few facilities, however, have the resources necessary to adopt an all-

49. Id.

50. This flexible approach has also been adopted by the OIG. See Model Plan, supra note 26, at 9435.

51. GUIDELINES, supra note 19, § 8A1.2 Application Note 7(i).

52. See id.

53. Id. § 8A1.2 Application Note 7(ii).

54. In developing a compliance program, health care organizations should not neglect legal standards generally applicable to businesses, such as the Americans with Disabilities Act, 42 U.S.C. § 12101-12213 (1995).
inclusive compliance program in one fell swoop. There are just too many laws that impact health care facilities. Accordingly, it is necessary to prioritize. For most hospitals, Medicare billing, especially in the area of clinical laboratories, is a concern. Accordingly, a compliance program should be implemented for this area first. Then, after the Medicare billing compliance program is functioning, resources can be committed to developing the next area of concern, which may address antitrust issues, practice acquisitions, physician recruitment, or conflicts of interest.

Third, the organization’s history will dictate whether its compliance program is effective. An organization’s compliance program must address prior misconduct or criminal offenses committed by the organization. Accordingly, if an organization settled with the government as part of the three-day window project, the Guidelines would require the organization to include standards for compliance with the three-day window rule in its compliance program. Failure to include these standards could result in the judge or government finding the compliance program ineffective even though the charged offense had nothing whatsoever to do with the three-day window rule.

Fourth, the organization must consider what similar organizations within the industry are doing with regard to their compliance programs. Specifically, the Guidelines state: “[F]ailure to incorporate and follow applicable industry practice or the standards called for by any applicable governmental regulation weighs against a finding of an effective program.” Accordingly, health care organizations may want to check with their trade associations to determine the scope of other organizations’ compliance programs. For instance, both the American Hospital Association and the American Academy of Healthcare Attorneys are developing model hospital compliance programs to assist members in developing their own programs.

55. GUIDELINES, supra note 19, § 8A1.2 Application Note 7(iii).
56. Id.
58. GUIDELINES, supra note 19, § 8A1.2 Application Note 3(k).
59. Id.
III. IMPLEMENTING A COMPLIANCE PROGRAM

A. Preliminary Matters

The first step in developing a successful compliance program is to obtain the support of upper management and the board of directors. This usually encompasses evaluating the benefits and costs associated with development and implementation of a compliance program. The cost of a compliance program may seem high; however, unlike criminal penalties, such costs are usually deductible as business expenses. Furthermore, the cost of a compliance program becomes more bearable when compared with typical government recoveries in the health care industry.

Once a decision to proceed is made, management must commit to the idea of corporate compliance. Commitment requires more than just the level of involvement required by the Guidelines. The Guidelines can be satisfied by either creating a compliance committee and/or appointing a corporate compliance officer. The officer and/or committee should report directly to the corporation’s board of directors, and should ultimately be responsible for the program. Realistically, however, the compliance program has little chance of success, especially to prevent future occurrences, if senior management does not actively support the effort.

Such high-level commitment is necessary to create a corporate culture where employees feel obligated both to act within the bounds of the law and to report those who do not. One vocal dissident in upper management could send employees the message that the organization is just abiding by another set of regulations imposed by the legal department. When an employee has to make a judgment call that has potential legal consequences for the organization, such mixed messages may be interpreted by the employees as approval of or acquiescence in improper behavior. Hence, the effectiveness of the compliance program can be undermined. If upper management cannot support a corporate environment of compliance, the implementation of a compliance program amounts to a waste of capital and can, in some instances, hold the organization to a higher standard of care than if the organization had not adopted a compliance program at all.60

Accordingly, once management support is obtained, the organization should make a concerted effort to communicate management’s support of the compliance initiative. The elaborateness of this communication effort depends on the organization. In some instances, press releases and an announcement at the annual shareholders’ meeting might be appropriate. In other environments, department heads and supervisors might announce the organization’s new compliance initiative. Regardless of how the announcement is made, it is necessary to inform employees that the organization is committed to compliance and over the next couple of months will be moving forward with the adoption of a code of conduct and procedures necessary to comply with it. As more fully discussed below, many organizations will find it necessary to conduct a regulatory audit of the organization in order to gauge the organization’s current level of compliance and degree of legal exposure. At this stage, employees should be informed of the audit and understand that their cooperation will be necessary to develop an effective compliance program. From this point onward, all employees should understand that the continued success of the organization and, consequently, their continued employment are dependent upon compliance with applicable legal requirements, as expressed in the organization’s code of conduct.

After upper management support is obtained and the program is introduced to employees, the organization should develop a strategy for moving forward with its compliance efforts. This strategy, often referred to as a work plan, will describe the organization’s goals in adopting a compliance program and establish a working schedule for implementation. The work plan will include the personnel needed for implementation and their respective duties. The process of developing a work plan also provides the organization with an opportunity to shape the compliance program to best fit within the existing corporate culture and to identify any latent issues that might undermine the organization’s compliance efforts.

B. Audits

As part of the work plan, most organizations will want to conduct a regulatory audit to determine the laws and regulations that affect their organization and to gauge the current level of compliance. This preliminary step also allows the organization to establish its priorities in adopting a compliance strategy.
Most health care organizations have already undertaken significant compliance efforts. For instance, both the Clinical Laboratory Improvement Amendments of 1988\(^\text{61}\) and the Occupational Safety and Health Administration’s Bloodborne Pathogens Standard\(^\text{62}\) impose a great deal of oversight obligation on health care organizations. These existing compliance efforts should be evaluated and incorporated as appropriate into the organization’s compliance program.

The first step in conducting a legal audit is to assemble an audit team. Organizations vary in the composition of their audit teams. At a minimum, this team should consist of outside counsel, a billing expert, a representative from human resources, and internal personnel familiar with the facility’s operations, such as in-house counsel, a risk manager, and an individual from the finance area. If a compliance officer has already been identified, then that individual should lead the audit team. If the organization uses a compliance committee, the committee may also serve as the audit team.

Opinions differ as to the extent outside counsel should be involved in this process;\(^\text{63}\) at a minimum, any internal investigations should be conducted so as to maximize the likelihood that any reports generated will fall within applicable privileges.\(^\text{64}\) For instance, several courts have denied organizations the use of the attorney-client privilege when organizations have utilized their in-house counsel.\(^\text{65}\) The issue is whether the in-house counsel is acting as a business or operations advisor or a legal advisor. Unless the organization takes appropriate steps to assure itself that its in-house counsel should be treated as a legal advisor, it is


\(^{63}\) Compare Daniel R. Roach, Implementing a Fraud and Abuse Compliance Program: Practical Tips and Difficult Issues, in 1 AMERICAN ACAD. OF HEALTH CARE ATT'YS THIRTIETH ANNUAL MEETING 669, 676 (Jun. 22-25, 1997) (suggesting the role of counsel may not be that important), with DAVID D. QUEEN & ELIZABETH E. FRASHER, DESIGNING A HEALTH CARE CORPORATE COMPLIANCE PROGRAM 43 (1995) (generally recommending that outside counsel conduct or supervise the audit).


suggested that outside counsel be retained to oversee the audit. Organizations should also be aware that there is no legal protection for reports generated by consultants. If it becomes necessary to bring in a consultant to assist with the legal audit, outside counsel usually retains the consultant so that the consultant’s reports fall within the attorney-client privilege.

Even when using outside counsel, the organization should take precautions to increase the likelihood that any reports generated will be privileged. For instance, the engagement letter with outside counsel should specifically state that counsel is being retained in anticipation of litigation and set forth facts and events that support the reasonableness of the organization’s anticipation. Care must be taken that incriminating information is not spelled out, as this letter may be used to support the need for the privilege and thus will be produced. The organization’s board may also consider adopting a resolution clearly stating that counsel is being retained in anticipation of litigation and for the purpose of rendering legal advice. In developing the work plan, the audit team should carefully consider all opportunities to maximize the likelihood that any documents generated by the audit will be privileged. Courts have a natural predisposition toward allowing discovery, especially when the perception is that the organization is trying to hide criminal conduct; therefore, it is essential to bolster any arguments the corporation might have for document protection from the outset.

The audit team should also lay out the parameters of the audit before it begins. It should identify individuals to be interviewed and documents to be reviewed. Most organizations will find it helpful to review the following documents: existing compliance standards and procedures, agreements with potential referral sources, billing procedures, research and grant agreements, space and equipment leases, employment agreements, joint venture and partnership arrangements, third-party payor agreements, marketing materials, and the results of any recent external investigations or audits.

Once the audit has been conducted, the audit team should incorporate this information into its work plan. Upon completion, the work plan should generally be presented to the board of directors, who should review the work plan and adopt a resolution approving it. If a compliance officer or committee has not already been appointed, the board should direct the chief executive officer to do so. Although the Guidelines do not necessarily
require that an organization create a compliance officer position, they do require that oversight responsibility be assigned to a "director; an executive officer; an individual in charge of a major business or functional unit of the organization;" or "an individual with a substantial ownership interest." This individual should serve as a resource for compliance questions, monitor the effectiveness of the compliance program, enforce its standards, and report to the board of directors on a regular basis.

C. Developing a Compliance Manual

The organization is now ready to develop its written standards of compliance, which will be assembled as the organization's compliance manual. Here again, the appropriate role of counsel depends on the organization. Many organizations will have either in-house or outside counsel draft the compliance standards. Other organizations will have the compliance officer draft the standards and use counsel to review the standards. Whichever approach is chosen, it is essential for counsel and the compliance officer to work closely to develop a compliance manual that is both effective and easy to understand. With some work forces, this will require the organization to publish the compliance standards in more than one language. In addition, standards should be reviewed by persons with day-to-day operational experience in the particular departments impacted by each standard. If the standards do not take into account how employees actually operate, the program has little chance of success.

Although compliance programs may differ in scope, at a minimum, standards should be developed that address the following areas:

- applicable federal and state laws and regulations;
- applicable civil and ethical standards;
- the organization's policies and procedures for (a) disseminating the compliance manual, (b) the methods and frequency of employee and agent training, and (c) documenting such training;
- the organization's employment policies and procedures, including employee background verification when appropriate;

66. GUIDELINES, supra note 19, § 8A1.2 Application Note 3(b), (k)(2).
67. See MODEL PLAN, supra note 26, at 9439.
• the organization’s record retention policies and procedures, including a systematic policy for the destruction of records;
• the organization’s policies and procedures for reporting, investigating, and disciplining violations of the compliance standards; and
• the organization’s policies and procedures for responding to a government investigation.

Many organizations’ compliance manuals consist of two parts: a code of conduct and specific standards for complying with the code of conduct. The code of conduct will typically provide an overview of the compliance program and applicable standards, acknowledge the organization’s commitment to compliance, provide an overview of training requirements, establish disciplinary standards, and identify individuals with oversight responsibility. The code of conduct is then distributed to all employees, while the specific compliance standards are only distributed to employees affected by the standard. For instance, procedures for complying with antitrust standards would be necessary for the director of a health system’s management service organization. However, a floor nurse would not need such specific guidance on antitrust issues. Further, standards addressing antitrust issues for practice acquisitions would be different than those for the marketer of a health system’s home health agency. This two-step approach is simply a realization that the laws impacting modern health care organizations are too complex to require all employees to become experts in all areas of the law. Such an approach also allows for task-specific training, which should be more effective than general compliance training. However, distributing the code of conduct to all employees is still important because each employee needs to understand the organization’s overall commitment to compliance.

Once written standards are drafted and reviewed by the chief executive officer, the compliance manual should be presented to the board of directors for approval. Once again, board approval serves two purposes: (1) it sends a message that the compliance program is supported at the highest levels of the organization, and (2) it facilitates accountability by requiring periodic updates to the board.

D. Delegation of Authority

The Guidelines provide that “due care” should be exercised to avoid delegating substantial discretionary authority to any in-

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individual who the organization knows, or should have known, has “a propensity to engage in illegal activities.” For new hires, this does not present much of an issue. With regard to those individuals, the organization should implement a policy against hiring anyone (1) convicted of a felony or misdemeanor offense related to honesty or integrity, or (2) excluded from participating in any federally funded health care programs. The organization should verify employment history and conduct a background search to find any indications of a propensity to engage in illegal activities. State laws must be consulted to determine whether there are any restrictions on the type of information prospective employers may ask of applicants. Requiring the applicant to divulge past criminal convictions and to submit to a background check, however, is generally allowed. On the other hand, the use of polygraphs to screen employees is generally prohibited. Government-imposed compliance programs require the organization to make a reasonable inquiry into the General Services Administration’s List of Parties Excluded from Federal Programs and the HHS/OIG Cumulative Sanctions Report to determine the status of any potential employee, agent, or contractor.

68. GUIDELINES, supra note 19, § 8A1.2 Application Note 3(k)(3).

69. For instance, Illinois considers using an arrest record “as a basis to refuse to hire” a civil rights violation, but permits access to criminal conviction information for “evaluating the qualifications and character of an employee or a prospective employee.” 775 ILL. COMP. STAT. 5/2-103 (1996). For a discussion on the availability of criminal records, see Gary D. Miller & James W. Fenton, Jr., Negligent Hiring and Criminal Record Information: A Muddled Area of Employment Law, 42 LAB. L.J. 186, 189-91 (1991) (listing Massachusetts and North Carolina as denying access to private employers and Florida as allowing public access to both conviction and arrest records).

70. See, e.g., ALA. CODE § 36-1-8(a) (Supp. 1996); ALASKA STAT. § 23.10.037 (a) (Michie 1996); CAL. LAB. CODE § 432.2(a) (West 1989); CONN. GEN. STAT. ANN. § 31-51g (West 1987); DEL CODE ANN. tit. 19, § 704(b) (1985); IDAHO CODE § 44-903 (1997); IOWA CODE ANN. § 730.4(2) (West 1993); ME. REV. STAT. ANN. tit. 32, § 7166 (West 1988); MASS. ANN. LAWS ch. 149, § 19B(2) (LAW. CO-OP. 1989); MICH. COMP. LAWS ANN. § 37.203 (West 1985); MONT. CODE ANN. § 39-2-304 (1995); OR. REV. STAT. § 659.337(1) (Supp. 1996); 18 PA. CONS. STAT. ANN. § 7321 (West 1983); R.I. GEN. LAWS § 28-6.1-1 (1995); VA. STAT. ANN. § 40.1-51:4.3, -51:4.4 (Michie 1997); WASH. REV. CODE ANN. § 49.44.120 (West 1990); W. VA. CODE § 21-5-5b (1996); WIS. STAT. ANN. § 111.37(2) (West 1997). See also Annotation, Validity and Construction of Statute Prohibiting Employers from Suggesting or Requiring Polygraph or Similar Tests as Condition of Employment or Continued Employment, 23 A.L.R. 4TH 187 (1983).

71. NME Integrity Agreement, supra note 7, ¶ 12, at 13. This list is also published in the Federal Register.
Existing employees, however, present more of a challenge. If the organization does not have a policy setting forth the organization's response when employees are charged with criminal conduct that may relate to their employment, one should be adopted. Ideally, the individuals should be suspended pending resolution of the criminal matter. (When a union is involved, such changes to employee discipline procedures may subject the organization to collective bargaining.)

All employees should be monitored to assure compliance with existing standards. To further promote the organization's commitment to compliance, organizations may want to use individual compliance efforts as a factor in promoting employees to supervisory positions.\(^\text{72}\)

**E. Employee Training Programs**

A compliance program's success is limited by management's ability to effectively communicate the program's standards to its employees. The scope of the organization's training program will depend on the size of the organization and its different business lines.\(^\text{73}\) Regardless of the scope of the training program, it should be designed with two goals in mind: (1) all employees will receive training on how to perform their jobs in compliance with any applicable standards, and (2) each employee should understand that compliance is a condition of continued employment. The organization's training programs should also provide training for agents and independent contractors because the Guidelines require that an organization's compliance program also embrace these relationships.\(^\text{74}\)

Employee training should be an ongoing process. In addition to the initial training sessions explaining the compliance program, the organization must provide periodic refresher courses and sessions for new employees as well as employees whose responsibilities change. Government-imposed compliance programs typically require all employees to attend annual training.

\(^{72}\) Id. § 8, at 9; Model Plan, supra note 26, at 9436.

\(^{73}\) In simplest terms, "[t]he 'right' method is that which best communicates the appropriate message to the particular audience." Dan K. Webb & Steven F. Molo, *Some Practical Considerations in Developing Effective Compliance Programs: A Framework for Meeting the Requirements of the Sentencing Guidelines*, 71 Wash. U. L.Q. 375, 394 (1993).

\(^{74}\) Guidelines, supra note 19, § 8A1.2 Application Note 3(k)(4).
programs, and usually require newly hired employees to receive compliance training within sixty days of their hire.

Employers are free to determine the training methods that are most effective for its employees. Organizations have utilized video tapes, workbooks, seminars, newsletters, and interactive software to assist in their training efforts. The key is to determine the training program most appropriate for the audience. Larger organizations will usually find it necessary to implement several different training programs based on the audience's job description. For example, although floor nurses will need to know about billing standards in order to adequately document medical necessity, their billing compliance training will be less encompassing than that of the billing clerks.

The organization should always document its training efforts, including the date, topics covered, and attendance of each training session. In addition, many organizations require attendees to certify that they received training. Also the annual employee training program might be a good time to require each employee to certify compliance with any professional continuing education requirements.

F. Monitoring Compliance

All of the effort that the organization has put into its compliance program can be undermined by its failure to assure that its employees and agents are complying with its standards. The commentary to the Guidelines provides two examples of how an organization might monitor compliance with its standards. The organization can implement (1) "monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents," and (2) "a reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution." Monitoring refers to concurrent oversight of the program. This includes obtaining employee feedback on how the compliance program can be more effective, modifying the program to

75. See, e.g., NME Integrity Agreement, supra note 7, ¶ 6(c), at 8; MODEL PLAN, supra note 26, at 9439.
76. See id. ¶ 6(b), at 7 (requiring training within four weeks of employment); Caremark Corporate Integrity Agreement, ¶ 13 (stemming from several suits brought by the United States) (June, 1995) (requiring training within eight weeks of employment).
77. See MODEL PLAN, supra note 26, at 9439.
78. GUIDELINES, supra note 19, ¶ 8A1.2 Application Note 3(k)(5).
incorporate changes in regulations or the organization's business lines, identifying any areas where the compliance efforts break down, training employees, and consistently enforcing the compliance standards. Monitoring assures that the program is evolving to meet the needs of the organization. Such efforts differentiate an effective compliance program from one adopted merely for "paper" protection, which is drafted and then soon forgotten.

Auditing refers to an after-the-fact evaluation of the effectiveness of the program. Audits should be conducted periodically to assure that the organization's compliance efforts are effective. Periodic audits raise the same concerns about generating unprotected documents as the initial legal audit. 79 Although retaining outside auditors is not required, the auditors should be sufficiently independent that they are insulated from any pressure asserted by those being audited. Enforced programs, however, typically require that an independent reviewer audit the organization's compliance efforts. 80

The OIG's Model Plan provides insight as to those areas of compliance that the OIG is particularly concerned about auditing. In the area of clinical laboratories, the Model Plan suggests that "particular attention [be] paid to billing, sales, marketing, notices, and disclosures to physicians, requisition forms, pricing, and activities of phlebotomists and others involved in the ordering of laboratory services." 81 From this laundry list, the OIG's chief concerns in the area of billing can be inferred: (1) that bills are accurately coded and reflect the services provided, (2) that any services or items provided are medically necessary, and (3) that no incentives for unnecessary services exist.

Like the legal audit, the compliance audit will typically consist of an on-site visit, interviews with personnel in key areas of concern, and reviews of written materials and documentation. Many organizations also will use a billing consultant to determine their level of billing compliance. The Model Plan encourages organizations to include trend analysis studies as a part of their audits. 82 These studies look at the historical frequency of a test or service. If the current usage is significantly higher than

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79. See supra section III(B) of this article.
80. See, e.g., Montgomery Hospital (Norristown, Pa.), Anesthesia Services Settlement Agreement ¶ 2(a) (Feb., 1996).
81. MODEL PLAN, supra note 26, at 9439.
82. Id. at 9440.
the historical trend, the organization should determine the cause of this increase. If the organization is unable to explain this increase, the government assumes that fraudulent or abusive behavior accounts for the increase in utilization. Identifying in the audit report any areas where corrective action may be necessary is also a good idea.83

Another facet of an effective monitoring and auditing system is determining whether employees are encouraged to report any suspected violations of the compliance standards. Typically, all employees should have easy access to the compliance officer. This may entail having the compliance officer extend normal office hours on a periodic basis or spend days at various facilities. All employees should feel that the compliance officer is available to hear their complaints and suggestions.

Additionally, a mechanism should be established that allows employees to anonymously report suspected violations. Since employees may be concerned about potential retribution or being viewed as a traitor to their colleagues, organizations should implement a system that includes an anonymous reporting option, such as an employee hotline, voice mail, or written reports. Although such a system may be subject to abuse at the outset, it is usually better to allow free access to encourage participation. If employees start anonymously reporting as a means to settle grudges, incorporating disciplinary procedures for such abusive behavior may be necessary. Equally as important is making sure that all employees are made aware of the mechanism. This can be accomplished by explaining the reporting options during the annual compliance training programs, by posting notices on employee bulletin boards, and by periodic written reminders.

When a report is made, the compliance officer should investigate the allegation to determine whether a violation of the compliance program has occurred. Regardless of the outcome of this investigation, a written report should be filed indicating both that a suspected violation was reported and that the compliance officer followed up on this report by conducting an investigation. Under the Model Plan, if the integrity of the investigation is compromised by the presence of the employee under investigation, it is appropriate to remove the employee until the investigation is complete.84 If the investigation reveals

83. Id.
84. Id.
that a violation did occur, the offending employee should be appropriately disciplined.

G. **Enforcement and Discipline**

The Guidelines express a concern over inconsistent employee discipline.\(^{85}\) The concern is that many organizations are unwilling to discipline high-level personnel. Such favoritism can undermine the organization's entire compliance program. Therefore, organizations must make a commitment to discipline each violator in a prompt, effective, and consistent manner from the outset. If the organization cannot make this commitment, the organization should consider whether development of a compliance program is the best use of its resources.

However, in all likelihood the organization already has policies regarding employee discipline. Such polices should be reviewed to encompass the scope of the compliance program. All disciplinary actions should be taken by the compliance officer. The disciplinary standards should provide progressively more severe punishment, including eventual termination, for repeat offenders. An often overlooked requirement of the Guidelines is that the organization also should discipline individuals for failing to detect offenses.\(^{86}\)

Any disciplinary action taken should be well documented. Often employees will assert that they were not informed of a particular standard. Certification by the employee of receiving the compliance training, acknowledging an obligation to comply with all applicable standards, and attending the annual training program should be sufficient to overcome such assertions. In designing disciplinary standards, the compliance officer should be mindful of any state or contractual due process rights, including those required by medical staff bylaws. Such due process procedures should be incorporated into the compliance program.

H. **Corrective Action**

Two corrective measures have already been discussed: investigating suspected violations of the compliance program and employee discipline. Most commentators, however, interpret the Guidelines as requiring additional corrective action.\(^{87}\) For in-

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86. *Id.*
87. See, e.g., *Queen & Frasher*, supra note 63, at 77-81.
stance, the Model Plan provides that violations of criminal law as well as "material violation[s] of the civil law [and] rules and regulations governing federally funded health care programs" be reported to the government within sixty days of "receipt of the credible evidence of misconduct." \(^{88}\) As previously mentioned, a compliance program will not mitigate any criminal penalties under the Guidelines "if after becoming aware of an offense, the organization unreasonably delayed reporting the offense to appropriate governmental authorities." \(^{89}\) However, not all violations of the compliance program must be reported. The organization should check with counsel to determine whether it has a duty to report and how such disclosure should be handled. If there is no obligation to report, the organization must then determine whether voluntary disclosure is appropriate or beneficial. If the organization does disclose, the disclosure should be made in a manner that assures that the organization receives the credit to which it is entitled under the Guidelines. \(^{90}\)

Corrective action under the Model Plan also requires the organization to immediately return to the government any overpayments. \(^{91}\) Since the Guidelines do not define corrective action, such a broad interpretation is possible. Further, once an organization has knowledge that it was not entitled to funds obtained through Medicare or Medicaid, it may be under a legal duty to disclose such overpayment. \(^{92}\)

Finally, the organization should determine the cause of the misconduct and how its compliance program can be altered to prevent similar misconduct. Did the compliance program fail to inform the employee that such behavior was prohibited? Or did the employee choose to disobey the organization’s standards? If the cause of the misconduct was the organization’s failure to inform, it must reevaluate its standards and training programs to determine whether a higher level of compliance can be obtained. If the cause of the misconduct was the latter, the organization must determine how the program broke down and whether a similar breakdown can be prevented in the future.

88. \textit{Model Plan}, supra note 26, at 9440.
89. \textit{Guidelines}, supra note 19, § 8C2.5(f).
91. \textit{Model Plan}, supra note 26, at 9440.
Did management send mixed signals to employees suggesting that the standards would not be enforced? Were the disciplinary standards too mild, suggesting that the organization did not consider the standard important? Or was the employee’s misconduct simply willful behavior? The organization should document such internal investigations and modify its compliance program appropriately.

**CONCLUSION**

As should be clear by now, compliance is a moving target. Every organization is a unique entity. Additionally, both the regulations that impact health care organizations and the organizations themselves change at a dizzying pace. This dynamic is further complicated by the fact that every organization is comprised of individuals, with different attitudes, aptitudes, and opinions. Not only must an effective compliance program take into account all of these factors, but it must be adaptable in order to endure. Accordingly, “canned” compliance programs will be ineffective. Furthermore, an organization cannot develop compliance standards and then consider itself finished with the task.

An effective compliance program is more than simply a mechanism for reducing criminal penalties. It should prevent, detect, and correct any violations of law. Further, it is a means by which a health care organization can communicate to its employees, patients, purchasers, and the community it serves that it is a good corporate citizen. The ultimate goal should be that everyone associated with the health care organization takes responsibility for compliance with the organization’s high ethical and legal standards.