RICHARD P. KUSSEROW

Ineffective Compliance Programs

Richard P. Kusserow served as the HHS Inspector General for over 11 years and is the CEO of Strategic Management (www.compliance.com), a firm that has provided compliance advisory services and due diligence reviews to over 3000 organizations and entities since 1992. He is the author of nine books related to compliance. For more information, contact him at rkusserow@strategicm.com, or call him at 703/535-1411.

Common Compliance Program Failures that Lead to Major Enforcement Actions

There are eight common compliance program failures that the government would view as evidence of an "ineffective compliance program," which in turn results in increased fines, penalties, and settlement terms. The U.S. Sentencing Guidelines for effective compliance programs was first adopted in 1991 and has been updated frequently thereafter.[1] The Office of Inspector General (OIG) followed with a number of compliance guidance documents[2] relating to specific health care sectors. The result has been that compliance programs have taken root in the health care sector and most organizations have built programs to one degree or another that follow the guidance.

It is worth noting that the guidance offered were for voluntarily developed and implemented programs, but not following them is risky business. Many organizations faced fines and penalties for noncompliance with applicable laws and regulations. The Patient Protection and Affordable Care Act has added fuel to the drive for more effective compliance programs by requiring the Centers for Medicare & Medicaid Services (CMS) to develop mandated compliance program standards but to date has only issued mandates for health care providers enrolled in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).[3]

Over the last 20 years, expectations for compliance have continued to evolve and have grown in enforcement decision-making. A little over a year ago, the U.S. Department of Justice (DOJ) Criminal Division announced[4] hiring of Hui Chen as Compliance Counsel to assist in assessing the quality and effectiveness of companies' corporate compliance programs under scrutiny by the DOJ, in order to assist prosecutors in evaluating corporate compliance and remediation measures.[5] The OIG has also sharpened and deepened its efforts on the subject of mandated compliance programs in its corporate integrity agreements (CIAs)[6] that in many cases are more costly than the DOJ financial settlements. With all this in mind, it is worthwhile to consider the eight most

common compliance program failures that lead to major enforcement actions by the DOJ, with follow-up mandates to correct them in OIG CIAs.

Common Compliance Failures

1. "Sham Programs"

Many compliance programs began with a "plan" supported by many pages that includes a code of conduct, policy statements, resolution for the organization of the program, engagement of a compliance officer, and other information in keeping with the seven standard elements of a compliance program. However, a plan is a statement of intent that requires implementation of an effective program. Failing to do that is viewed by the OIG and DOJ as a "sham program," which is seen as worse than no program at all. Having a plan only means that the organization "knew" what it should have done but failed to properly implement it. That knowledge element immediately puts the organization in the category of being negligent, grossly negligent, or worse with the adverse action level rising significantly. This underscores the importance of compliance officers providing evidence of an active and growing program that goes beyond paper documentation and process information. The key is to evidence that the program is effective in reducing the likelihood of wrongful behavior that could give rise to liabilities.

2. Weak Board Oversight

The OIG, DOJ, U.S. Sentencing Commission, Sarbanes-Oxley Act, and other authorities all agree that an effective compliance program is a "top-down" program beginning with the board. For years, the OIG and American Health Lawyers Association (AHLA) have published "white papers" calling for boards to be more accountable for proper oversight of compliance within their organizations. These include *Integrated Approach to Corporate Compliance: A Resource for Boards of Directors*,[7] *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors*,[8] and *Practical Guidance for Health Care Governing Boards on Compliance Oversight*.[9] They speak to how the OIG continues to evolve in its thinking,[10] expectations, and focus regarding board accountability for providing proper oversight of its organization's compliance program.[11] Unfortunately, most boards fall short of meeting the fiduciary duties and obligations described by the OIG, and this failure can result in serious enforcement actions. CIAs now mandate boards engage a compliance expert[12] to assist them in meeting their obligations of oversight, and their report is made part of each Annual Report filing. The board members then have to personally certify their compliance program.

3. Lack of Executive Support

Both the OIG and DOJ have been focusing more closely on making executives more personally accountable for wrongful activities of their organizations. When they find this is not the case, it is considered a major organization failure. The OIG instituted the Responsible Corporate Executive Doctrine,[13] which holds owners, officers, and managing employees accountable for corporate misconduct.[14] The DOJ later issued its Yates Memorandum[15] announcing that the DOJ has increased attention on personal liability for executives that contributed to the wrongdoing, by action or dereliction. The OIG CIAs now mandate that the chief executive officer (CEO), chief financial officer (CFO), compliance officer, and program executives provide certification that they had monitored and overseen activities within their areas of authority and are in compliance with applicable laws and terms of the CIA. There is a stipulated penalty of $50,000 for each false certification[16] as well as potential implication of the False Claims Act. This puts each certifying party at personal risk.

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4. Inadequately Empowered Compliance Officers

The government has determined that in organizations found in violation of law that their compliance officers were not properly empowered to prevent wrongdoing. In many cases the government found the office's authority on paper, but not in actuality. The regulatory and enforcement agencies expect compliance officers to be part of executive leadership, reporting directly to the CEO, and have access to the board. Reporting through the legal counsel, CFO, or other executives is viewed as a curtailment on the authority of the position and lacking in independence.

In addition, there should be an Executive Compliance Committee that includes the CEO and senior executives and program managers with the compliance officer playing a leading role. The Committee should serve a dual role of supporting and empowering the compliance officer while providing oversight and questioning how effectively the program is functioning. Any indication that the compliance officer is limited in meeting obligations is considered a serious compliance program failure.

5. Improper Arrangements/Incentives[17]

The corrupting influence of money in medical decision-making has been a serious concern going back to the initiation of the Medicare and Medicaid programs. The first anti-kickback statute (AKS) passed in 1972 and has been amended and strengthened legislatively many times since. Any arrangement[18] that has a purpose to induce or reward referrals can implicate the AKS, regardless of whether there are additional, legitimate reasons for it. This remains the number one enforcement priority for both the OIG and DOJ.

Most cases involve arrangements with physicians to provide part-time services to an entity as a medical advisor or director. However, there are also a number of cases relating to incentive compensation for field sales representatives and executives. The government's view is that all claims arising from a corrupt arrangement violating the AKS or Stark laws are false and fraudulent.

Notwithstanding this being the highest risk area for most organizations, many compliance officers are hesitant to question arrangements because they believe this to be the preserve of legal counsel. However, with hundreds of organizations having been found violating the law with physician arrangements, always deferring to legal counsel is clearly not the answer. To overcome this problem, many compliance officers find that turning to outside experts may be the answer to the problem.

6. Poor Compliance Communication Channels

The great majority of significant civil fraud cases and CIAs are predicated by "whistleblowers,"[19] and most of them claim that they reported to the government because their organization's compliance program was not open to acting upon complaints from employees. The failure to have and support adequate compliance communication channels (*e.g.*, a hotline) results in health care organizations paying out many hundreds of millions of dollars a year in fines and penalties, plus having to submit to costly CIA mandates. In 2016 alone there were 702 *qui tam* suits filed with the DOJ, an average of about 14 new cases a week. Out of $4.7 billion civil fraud settlements and judgments arising from them, $2.5 billion were from health care entities.

In addition, more than nearly a quarter million whistleblowers contacted the OIG directly or through their hotline during the same period. Having a hotline without adequately supporting it results in driving such information externally to government agencies, litigating attorneys, media, et cetera. Receiving and resolving issues internally is the right approach, and not doing so can result in potential liabilities, headaches, and a lot of remedial work. It is important to promote a culture that

encourages employees to raise concerns and report perceived problems.

Managers should be counseled that employees' complaints are opportunities for improvement in the organization. By doing this, employees will be more comfortable in raising concerns informally and resolving matters within the company's management structure, ultimately lessening the perceived need to become a whistleblower to external parties.

7. Inadequate Risk Assessments

The U.S. Sentencing Commission guidelines specifically call for organizations to "evaluate periodically the effectiveness of the organization's compliance and ethics program."[20] OIG compliance guidance calls for ongoing monitoring and auditing of all operations.[21] Ongoing monitoring should be a continuous control monitoring process and method to detect compliance and risk issues associated with an organization's operational environment. This is a program manager's responsibility, not the compliance officer's. It includes keeping current with changes in rules, regulations, and applicable laws; developing internal controls, policies, and procedures to comply with them; training their staff on these rules; and taking steps in monitoring or verifying compliance with these new guidelines. It also should be designed to test for inconsistencies, duplication, errors, policy violations, missing approvals, incomplete data, dollar or volume limit errors, or other possible breakdowns in internal controls.

Monitoring techniques may include sampling protocols that permit program managers to identify and review variations from an established baseline. On the other hand, ongoing auditing is reviewing the ongoing monitoring process and verifying it is effective in achieving the desired outcome. This includes confirming that controls are in place and functioning as intended or identifying weaknesses in the program that need to be addressed. CIAs underscore this and over the years have evolved with many requirements to ensure this is being done. They underscore the obligations that organizations have in identifying high-risk areas and engaging in ongoing monitoring and auditing to ensure compliance. This means:

- identifying and prioritizing risk;
- developing internal audit work plans related to the identified risk areas;
- implementing internal audit work plans;
- developing corrective action plans as a result of any internal audits performed; and
- tracking corrective action plan implementation so as to assess plan effectiveness of such plans.

8. Failure of Compliance Controls

All compliance programs are expected to implement a variety of compliance-related policies and procedures to act as internal controls against improper action. Compliance programs are expected to ensure there is ongoing monitoring and auditing of high-risk areas identified by risk assessment. Program managers should be responsible for monitoring their own operations, which includes:

- remaining current with legal and regulatory requirements;
- translating them into written guidance for their staff;
- training their staff on how to follow them; and
- verifying that they are doing so.

In addition, there should be ongoing auditing of the programs by people independent of the operations to verify proper ongoing monitoring is taking place and then validating that the controls are effective in achieving the desired outcome. The absence of or inadequacy of this process is at the root of virtually all regulatory and enforcement action.

Endnotes:

1. www.ussc.gov/guidelines/archive
2. oig.hhs.gov/authorities/docs/cpghosp.pdf
3. www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf

4. www.justice.gov/criminal-fraud/file/790236/download
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