

HCCA



**HEALTH CARE
COMPLIANCE
ASSOCIATION**

COMPLIANCE TODAY

**Volume Twelve
Number Three
March 2010
Published Monthly**

**Meet
Richard Kusserow
Former HHS Inspector
General, and CEO,
Strategic Management**

PAGE 14



**Register in MARCH and receive a
free copy of *501 Ideas for Your
Compliance and Ethics Program***

**Feature Focus:
Employment law
compliance in a
changing legal
landscape**

PAGE 33

Earn CEU Credit

WWW.HCCA-INFO.ORG/QUIZ, SEE PAGE 23

**THE FRAUD AND ABUSE
LAWS THAT COMPLIANCE
PROFESSIONALS NEED TO KNOW**

PAGE 24

feature article

Meet Richard Kusserow

Former HHS Inspector General, and CEO, Strategic Management

Editor's note: This interview with Richard Kusserow was conducted by Gabriel L. Imperato, Esq., CHC in December 2009. Mr. Imperato is the Managing Partner of the Fort Lauderdale office of Broad and Cassel, and is board certified as a specialist in health law. He is a past member of HCCA's Board of Directors. Mr. Imperato can be reached by telephone at 954/745-5223 or by e-mail at gimperato@broadandcassel.com.

Richard P. Kusserow is the former DHHS Inspector General and is CEO of Strategic Management, which has been providing specialized compliance advisory services since 1992. For more information, see www.strategicm.com or call him directly at 703/683-9600 x411.

GI: Dick, thank you for agreeing to this interview for **Compliance Today**. Please tell our readers a little about your background and the road you traveled to Strategic Management (SM).

RK: I am honored by the interview. I began my professional career teaching political science and government at what is now California State University at Los Angeles. I subsequently enlisted in the US Marine Corps and attained the rank of Captain. This was followed by working for the Central Intelligence Agency (CIA), where I was as a Case Officer in the Clandestine Services of the Deputy Directorate for Plans. From there, I joined the Federal Bureau of Investigations (FBI), where I became a program fraud expert, and later supervised

and coordinated the seven squads comprising the FBI's Organized Crime Program in Chicago. During my tenure with the FBI, I lectured frequently on fraud and white collar crime at the FBI National Academy, and also published my first book for FBI agents engaged in complex investigations.

In February 1981, I was nominated by President Ronald Reagan to serve as the Inspector General (IG) for the US Department of Health and Human Services (DHHS), and was confirmed by the Senate in June 1981. I served as DHHS IG until my retirement from federal service in July 1992. During my tenure as HHS IG, I served as Vice Chair of the President's Council on Integrity and Efficiency coordinating Inspector General government-wide projects. During this time I was also appointed by President George Bush in 1989 to serve as a National Advisory Commissioner on Law Enforcement.

In 1992, upon leaving federal service, I founded Strategic Management Systems (SMS), a health care compliance consulting firm, addressing many of the same issues that I did while serving as DHHS IG.

GI: What are the services which are provided at Strategic Management?

RK: Strategic Management specializes in developing, implementing, and evaluating health care compliance operations and programs. It provides a broad range of advisory services, including organizational



assessments, financial/legal fact-finding, risk assessments, program analyses, special studies/reports, policy development, and specialized education/training programs. We also provide interim and designated compliance officers for health care organizations. I have been fortunate to recruit to SM a number of former executives with the Department of Justice, various Offices of Inspector General, and the DHHS Centers for Medicare and Medicaid Services (CMS). The collective knowledge of our consultants includes specialized expertise regarding federal and state enforcement activities; health care fraud and abuse issues; debarment, exclusion, and suspension processes; and CMS regulatory issues. Collectively, we have considerable expertise regarding fraud and abuse laws and regulations, including the Anti-kickback

Statute (AKS), the False Claims Act, the Stark Law regarding physician referrals, and integrity issues relating to the Food and Drug Administration (FDA). Our firm has provided consulting assistance to over 800 companies, facilities, organizations and entities, large and small, for-profit and non-profit. It is headquartered in Alexandria, Virginia, with branch offices in Dallas, TX; New York; Greensboro, NC; Chicago, IL; and Boston, MA.

GI: Tell us about your experience in meeting the challenges as one of the original Inspectors General and how it prepared you for the work you do at Strategic Management.

RK: The DHHS OIG was the first Statutory IG established by Congress under the Inspector General Act of 1976 (Public Law 94-505), and subsequently became the model for the Inspectors General Act of 1978, which expanded IGs to all cabinet-level departments. When I arrived at DHHS, little had been done to mold the IG functions into an organization capable of meeting its statutory responsibilities. I am pleased that, during my tenure as IG, we were able to organize the DHHS to identify and address fraud, waste, and abuse in the Department's programs. This necessitates a coordinated effort among the various components, that is: audit services, investigations, evaluations, and legal support, to develop a coordinated strategy and cooperative working relationships.

During my first several years as DHHS IG, I found myself primarily focused on organizational and management issues. This included developing a vision for the organization, developing plans for carrying out its mission, and establishing goals and objectives. The results in audit, evaluation, and investigative accomplishments soared, once the fundamental management issues were

addressed. So, you might say my extensive experience as a career government employee was extremely helpful in undertaking my responsibilities in my early years as IG. Perhaps a background in government affairs was also useful in meeting my early obligations as IG.

There is no question that my background in law enforcement aided me a great deal in meeting the challenges of being the Inspector General. During my eleven years as IG, our successful prosecutions rose twenty times what it was when I first arrived. However, the Office of Investigations only represented about one third of OIG's resources at the time I headed the organization. By far, the largest amount of resources (over 50%) was in the audit and evaluations arena. As a result, I committed considerable time and efforts to learning how to best sue and apply the OIG's audit and evaluation resources. Today, most Offices of Inspector General in the federal government are similarly organized. I might note that in the over 100 Congressional hearings at which I testified, over 90% related to our audit and evaluation activities and reports. So, in final analysis, you might say that an IG has multi-disciplinary responsibilities requiring the integration of various types of disciplines and resources to address the overall mission of promoting economy and efficiency by reducing fraud, waste, and abuse in government programs.

Upon my retirement from federal service, I founded SM with a vision of assisting health care organizations with compliance and program integrity services. I saw the firm as continuing the same mission that I had as IG. In helping health care providers to meet legal, regulatory, and compliance obligations. SM has grown to be a leading compliance and management consulting firm for the health care industry.

At SM, I found myself doing essentially the same work that I did as IG, but to help health



care providers to reduce their vulnerability to fraud, abuse, and waste. In the early days, major health care entities who got into serious trouble with the federal government wanted to repair their reputation and avoid similar problems in the future. After a while, many providers came to our firm to avoid getting into trouble. Therefore, for many years before OIG began providing compliance guidance, our firm was doing precisely that for our clients. Our firm has continued to evolve in its capabilities in developing, implementing, evaluating, and upgrading compliance programs. We now have done this kind of work on behalf of over 800 clients in the health care sector.

GI: What did you see as some of the major milestones and achievements of the DHHS OIG during your tenure as IG?

RK: OIG is responsible for audits, evaluations, and investigations involving Departmental programs, including Medicare and Medicaid. As IG, I sought legislation that resulted in the Civil Monetary Penalties Act of 1981; that in turn was later expanded by Congress across government as the Program Civil Remedies Act. I also sought legislation to provide for enhanced program exclusion authorities. This was granted by the Medicare/Medicaid Program Protection Act

Continued on page 16

of 1987, and resulted in the highly publicized “Safe Harbor Rules” under the federal Anti-kickback Statute.

Other IG responsibilities included audits performed by or on behalf of DHHS, as well as evaluation of program effectiveness. OIG was responsible for the criminal, civil, and administrative investigation of wrongdoing in the DHHS programs, including being the sanction authority for Medicare, Medicaid, and Child and Maternal Health programs. I carried out my duties with a staff of 1,600 auditors, program analysts, and criminal investigators in 68 field offices nationwide.

The year I retired as IG, DHHS had outlays of over \$650 billion per year which represented 38% of the federal government. Our office investigated and supported a number of successful prosecutions and recovered significant amounts in fines, savings, and restitution for the Department’s programs. In the year I retired, the OIG realized over \$6.8 billion in fines, savings, recoveries, and restitution to the taxpayers and programs and supported more than 1,500 criminal and 3,000 administrative prosecutions. Over the eleven years I served as IG, the OIG realized over \$90 billion in fines, savings, restitution, and recovery for the DHHS programs and the Treasury. I felt good about that. OIG has continued to achieve very significant accomplishments. As far as I am concerned, this was evidence of how successful OIG had been in its evolution.

GI: What advice would you give to someone just starting out as a compliance professional and implementing or maintaining a compliance program for a health care organization?

RK: I believe the key consideration is to maintain focus on the mission of a health care organization and how compliance can contribute to it. Compliance is not a simple matter of “painting by the numbers” by only adopting policies and procedures that address

the seven compliance elements identified by OIG. Let me offer some very broad suggestions. Compliance needs to be integrated in the business of the host organization. This requires more than maintaining a process. To be effective compliance must be measured by examining the outcome of the efforts in reducing the exposure of the organization to liabilities, such as may arise from fraud and abuse.

I believe a compliance professional should begin by understanding the mission and vision of the organization. Without this understanding, it will be impossible to build an effective compliance program that is acceptable to the culture of the host organization. Building a compliance program by inserting “model compliance plans” provided by vendors won’t do much without knowing how to graft the compliance program to the foundation and culture of the organization.

Secondly, a compliance professional must become knowledgeable regarding the resources, capabilities, and skills available within the organization and the ability of the staff and professionals in delivering the expected services paid for by third-party payers, either governmental or private. If employees and professionals are deficient in their abilities, knowledge, or capabilities, there is a huge compliance issue.

Third, it almost goes without saying that compliance professionals must become closely acquainted with the various types of governmental and private third-party payer programs and the rules by which they operate. Failure to meet these rules, regulations, legal requirements, and written direction are all compliance issues.

Fourth, there needs to be a real understanding of enforcement authorities and how they are being applied to the industry sector for the compliance professional’s host organization. This certainly would include, but not be limited to, the Anti-kickback Statute,

False Claims Act, and HIPAA.

Fifth, I would recommend that a new compliance professional study a variety of compliance program models to recognize that “one size does not fit all.” The greater the exposure to different compliance program models, the better background they have to find one that works best for their host organization. A good place to learn about various approaches to compliance is in the education and training programs offered by the HCCA.

Sixth, the compliance officer should realize that first and foremost they are in sales. They should be constantly selling compliance to the board, executive leadership, and employees. They need to gain the confidence of all these stakeholders. Without those stakeholders buying into the compliance program, it is not possible to gain much success.

GI: We know that having an “effective” compliance program is critical for health care organizations. How would you define compliance effectiveness?

RK: A very significant percentage of compliance programs in operation today focus on the process, and not outcome. In general terms, process relates to output and most often is related to efficiency. However, OIG has focused on the importance of “effectiveness” of a compliance program. Effectiveness is related to actual outcome. “Output” and “outcome” are not the same. Many do not realize the difference, yet the term “effectiveness,” and other derivations of the root word “effect” appear 19 times in the OIG initial Compliance Guidance for Hospitals. When the government repeats a term over and over in the same document, this should be a clue as to what is important.

Focusing only on output will lead to problems over time. Executives and boards of directors tend to dismiss reports on how many people were screened against the OIG’s List of Excluded Entities and Individuals

(LEIE), trained regarding compliance, or how many hotline calls were received and handled during a given period of time. All these things are process oriented with output measures. They don't answer the question as to whether a training program was effective to achieve desired objectives, or the significance of what is being received through a hotline, or the manner by which the complaints and allegations are being addressed. In short, they do not answer the basic question of whether the organization is less vulnerable to fraud and abuse, or not. Ultimately, to have a successful compliance program depends on being able to show evidence of effectiveness.

There are many ways to evaluate compliance program effectiveness and this would be the subject of a much larger treatise. First, it is important to accept the fact that compliance programs are part of a dynamic and evolving process constantly being redefined by methodologies, expectations, and professionalism. However, the following thoughts come to mind when considering what a compliance professional needs to do in order to be successful:

- Identify risk areas
- Assess the level of risk and vulnerability
- Focus on risk areas
- Remediate risks
- Monitor and audit all aspects of operations on a regular basis

Nothing exemplifies this more than the changing landscape of compliance risks. In its compliance documents, OIG has provided information on areas of risk that it has identified. This is only the starting point. New risks are identified every day by OIG and reported in a variety of ways, such as fraud alerts, advisory opinions, open letters, testimony before Congress, their annual Work Plan, etc. However, this is not the only place to look. Many arise from enforcement actions by the DOJ, as well as new laws, regulations,

payment methodologies, etc. Attention to CMS actions, as well as its contractors, is as important as reviewing what the OIG is saying and doing.

Effective compliance program efforts must include identification of and quantification of risk areas. Following that must be a plan for addressing areas of compliance risk in some sort of priority order. No compliance program can be effective without understanding risk areas and addressing them by ongoing auditing and monitoring. Once risk areas have been addressed with corrective action measures and new internal controls, remediation steps need to be verified. Even then, compliance professionals should not rest. A validation of the whole process should be undertaken to ensure that the measures are working effectively. This whole process needs to be redone, over and over, as part of ongoing auditing and monitoring.

GI: What do you feel have been major challenges for compliance in the health care industry? What do you believe are the biggest challenges yet to come?

RK: Without doubt, the biggest challenge is keeping pace with rising expectations for compliance programs in this ever-changing regulatory and enforcement environment. After a decade of OIG promoting compliance programs, there is a growing expectation by both the government and payer organizations that compliance programs will reduce risks and vulnerabilities to errors, omissions, fraud, and abuse.

Part of this rising expectation for compliance professionals is increased accountability to the government and third-party payers, as well as other stakeholders, such as patients and health care professionals. Boards of directors and executive leadership are increasingly looking to compliance programs to evidence a return on investment, as well as reduction in vulnerabilities. Part of the challenge for

compliance professionals is how to develop a culture of compliance within an organization that is efficient, non-intrusive, and cost effective.

The future challenges for compliance professionals will include increased government and other third-party payer oversight. Oversight will not be limited to enforcement bodies such as OIG, FBI, State Medicaid Fraud Control Units, and DOJ. We are in the midst of a "sea change" in enforcement wherein CMS is going to be playing a much larger role through its new contractors, using a veritable alphabet soup of names such as RACs, ZPICs, Medi-Medis, MICs, MACs, etc. These new contractors are obligated to identify fraud and abuse, as well as achieve higher levels of quality and cost savings. Compliance professionals need to recognize these changes and new challenges.

This is further underscored by the fact that the pending health care reform legislation includes mandating compliance programs as a condition of participation in Medicare and Medicaid, along with directions to increase the performance standards for such programs. This will have a major impact upon compliance programs. Many of these new provisions will lead to new and rising expectations for compliance programs and how they will be measured for effectiveness. Compliance professionals must be willing and able to adapt to these changes in expectations and standards in order to be relevant and effective.

One last quick point is that there will continue to be an increased complexity in health care operations, requiring much more sophistication in compliance program oversight and enforcement. Already we are hearing more and more about data mining and analysis as tools for compliance officers.

GI: Can you explain any differences that you have observed in the compliance

Continued on page 38

profession today compared to when you first began addressing compliance issues and matters?

RK: Initially, there was no health care compliance profession. Unlike law or accounting, there was no curriculum leading to a degree in health care compliance. Compliance professionals over the years have had a variety of backgrounds, including law and accounting, as well as health care professions, such as nursing. This continues to be the situation today. However, there has clearly been maturation in the profession. There has been a decade of experience for compliance professionals. That experience has led to a natural evolving of the profession. Over the years there have been seminars, education, and training programs for compliance officers that bring together different people with varied experiences that can be shared with others. Many of these programs have focused on specialized skills needed for the job and understanding of complex legal and regulatory standards. HCCA can take a lot of credit for promoting this movement toward increased professionalism.

One thing, in my opinion, has remained constant in the world of compliance professionals and that relates to how they must go about doing their work. I believe that compliance is 90% sales and 10% compliance. What I mean by that is that compliance professionals must, on a daily basis, sell the concept of compliance as being important to the work of both management and employees. It is critical that everyone buy into the concept that the compliance function is an essential part of the organization, and assists—rather than inhibits—in the mission of the organization. This can be a hard sell, if the compliance professionals see themselves as “in house” enforcers or auditors “second guessing” everyone and playing “gotcha.” I don’t believe it is possible to have an effective compliance program through the use of only

aggressive, internal enforcement activities.

The hardest, but most important, selling effort is convincing all stakeholders in the organization that compliance is a critical core element in the operations of the organization.

GI: What impact do you believe recent DOJ and OIG efforts will have on long-term effective compliance and corporate integrity in the health care industry?

RK: I believe they will continue to be a driver of compliance, simply by the fact that they will act in enforcement when Compliance fails to prevent or properly address wrongful activities. OIG will continue to focus on compliance as a core principle in addressing fraud, waste, and abuse in governmental programs, and seek to educate the health care industry and professionals. OIG will, as part of its mission, continue to alert providers and others in the health care sector of problems and issues they encounter through compliance guidance, fraud alerts, advisory opinions, open letters, and other outlets. They will also continue to meet with the industry in public meetings, seminars, and programs, as they do today with the HCCA. They will continue roundtable discussions between government and health care industry leaders. Also, by the nature of the organization, OIG will also continue to enhance enforcement, using their “Big Stick.”

DOJ will also continue to make known and explain concerns regarding questionable activities it has encountered, through their enforcement initiatives and at public forums.

All of this will have a major impact on what is expected of compliance professionals; however, I would be remiss to not restate and underscore the impact that CMS and their contractors will have on compliance programs. In many ways, CMS will drive compliance program expectations harder and faster than they ever had in the past.

GI: Are you a member of the Health Care Compliance Association? Have you attended any of its numerous educational and networking conferences? If so, has this benefited you and/or Strategic Management?

RK: I have been active with the HCCA since its inception. I have presented at conferences. Our firm has displayed at them as well. I have encouraged all our professionals to work with and take note of what HCCA is bringing to the compliance professional. Needless to add is the fact that participating in these types of programs has allowed us to exchange information and experiences with hundreds of health care professionals. Those exchanges advance our knowledge and expertise. All this interaction has benefited me and our firm by making sure we are staying at the forefront of health care compliance. ■