HCCA HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

January 2016

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

How early childhood experiences shaped a career in Compliance

an interview with Janie McKinney

Compliance Coordinator & IRB Coordinator
Washington Regional Medical Center

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by Roy Snell, CHC, CCEP-F

Where I think the Yates DOJ Memo will take us

Please don't hesitate to call me about anything any time.
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In the past, organizations were able to *privately* discipline leadership, without scrutiny as to the appropriateness of the discipline. But imagine what future DOJ meetings with company leadership will look like…


Snell

On one side of the room will be top leadership; on the other, the lead investigators. The DOJ may ask that the Board Chair be involved. At some point during the meeting, the DOJ will share their recent memo/policy that, paraphrased, states, "If you turn over internal investigations of individuals involved in the alleged wrongdoing, you will get more credit." ("More credit" is a euphemism for, in some cases, millions of dollars in reduced penalties.) But beyond the discussion of credit, leadership will need to be prepared for a discussion of discipline.

Here are some possible responses to the DOJ's offer to "get credit" by disclosing the internal investigations of individuals:

- We have done nothing wrong; there is nothing to share.
- Yes, there was a problem; we respectfully decline to share our investigations.
- Yes, there was a problem; we will share our investigations, *but we have not disciplined the individuals involved*.
- Yes, there was a problem; we would like to get credit and reduce our penalty; here are our investigations, *and we have disciplined the individuals involved in a manner that you will find to be credible and adequate.*

Will it be possible to "get credit" without immediately enacting "adequate" discipline? I don't think so.

What brought me to this observation was recent news about top leadership being fired. (In one case, the CEO, COO, CFO, and head of HR were all fired.) It seems to me that lately, there have been more news stories about leadership discipline, and I wondered if this might be connected to the new DOJ policy. Connected or not, I realized that the new policy could have a profound impact on discipline. Did this cross the DOJ's mind as they were drafting the policy?

> …the new policy could have a profound impact on discipline. Did this cross the DOJ's mind as they were drafting [it]?

When I was a compliance officer, I considered it my job to help leadership when people were pushing them to the edge—or over the edge—of the law. I felt I was effective at keeping them out of trouble. I had specific conversations with them about how questionable decisions would affect them personally. They appreciated it. They respected it.

Is it possible that leadership will now look at their compliance officer in an entirely different way? I think it is inevitable.

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> It's a misperception that the compliance process takes a long time and disrupts financial processes.

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ARTICLES

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VOLUME 18, ISSUE 1

HCCA's Health Care Chief Compliance Officers and Staff Salary Survey report now available

A survey released by the Health Care Compliance Association (HCCA) reveals detailed compensation data for Chief Compliance Officers (CCOs) and their staffs.

"The salary data shows that the compliance profession is strong and growing stronger every year," said HCCA CEO Roy Snell. "Compensation reflects the growing stature of compliance and its importance to the healthcare industry."

The survey breaks down the results by organization size as well as other key metrics. Among other highlights, the data revealed that CCOs at the largest companies (more than $3 billion in annual revenues) earn an average of $297,604 while those at small organizations with revenues of less than $5 million earned $90,487.

The 2015 Health Care Chief Compliance Officers and Staff Salary Survey also yielded a wealth of data about compliance programs. The study found that the typical CCO has managed his or her Compliance department from 6 to 10 years, and more than half of CCOs and Compliance directors hold a Certified in Healthcare Compliance (CHC)® certification. Survey respondents with a certification made significantly more than those without one.

Complete survey report: *http://bit.ly/HCCASurvey*

The Joint Commission sentinel event alert focuses on preventing patient falls

Preventing patient falls and fall-related injuries is the focus of the new Sentinel Event Alert: Issue 55 released by The Joint Commission. According to The Joint Commission, "The alert examines the contributing factors to patient falls and includes suggested solutions to be implemented by health care organizations to help reduce patient falls and falls with injury.

"This topic was chosen for Sentinel Event Alert because patient falls with serious injury are among the top 10 sentinel events reported to The Joint Commission Sentinel Event Database. The Joint Commission has received 465 reports of patient falls with injuries since 2009, and approximately 63 percent of those falls resulted in death. The Joint Commission defines a sentinel event as a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, permanent harm or severe temporary harm where intervention is required to sustain life. Although the majority of falls reported to The Joint Commission occurred in hospitals, the ECRI Institute also reports a significant number of falls occurring in non-hospital settings such as long-term care facilities."

More: *http://bit.ly/1XZZopc*

Read the latest news online ▶ www.hcca-info.org/news

Regulatory news

Meaningful Access final rule

The Centers for Medicare & Medicaid Services (CMS) announced that it "has released a final rule that not only improves our ability to measure and ensure meaningful access to covered services, but also provides greater safeguards for beneficiaries who may otherwise experience great difficulty in receiving needed health care services. The intent of this final rule is to provide a framework for us to use to make better informed, data-driven decisions that support more effective service delivery systems, service rate structures, and provider payment methodologies that reflect our unique and evolving Medicaid population."

According to CMS, "The final rule also strengthens CMS' ability to review and ensure Medicaid payment rates are consistent with efficiency, economy and quality and care. This aligns with the recent Supreme Court *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378 (2015) decision, which concluded that federal administrative agencies are better suited than federal courts to make these determinations. The court ruling placed greater importance on review and enforcement capability at the federal level; thus, improving our ability to monitor, measure, and ensure access to care within fee-for-service payment methodologies.

"The final rule becomes effective on January 4, 2016, at which time states must meet the requirements established through the provisions of the rule. During the 60-day period, CMS will accept comments from the public on the access review requirements. This will enable states to begin preparing their initial review plan analysis and to assess whether adjustments to this provision are warranted."

More: *http://go.cms.gov/1TzyymE*

Discharge planning proposed rule focuses on patient preferences

The Centers for Medicare & Medicaid Services (CMS) recently issued a proposed rule "to revise the discharge planning requirements that hospitals, including long-term care hospitals and inpatient rehabilitation facilities, critical access hospitals, and home health agencies, must meet in order to participate in the Medicare and Medicaid programs. The proposed changes would modernize the discharge planning requirements by: bringing them into closer alignment with current practice; helping to improve patient quality of care and outcomes; and reducing avoidable complications, adverse events, and readmissions.

"The proposed rule would also implement the discharge planning requirements of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), which will improve consumer transparency and beneficiary experience during the discharge planning process. The IMPACT Act requires hospitals, critical access hospitals, and certain post-acute care providers to use data on both quality and resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of care and treatment preferences."

The 60-day comment period closes January 4, 2016.

More: *http://1.usa.gov/1NELNSM*

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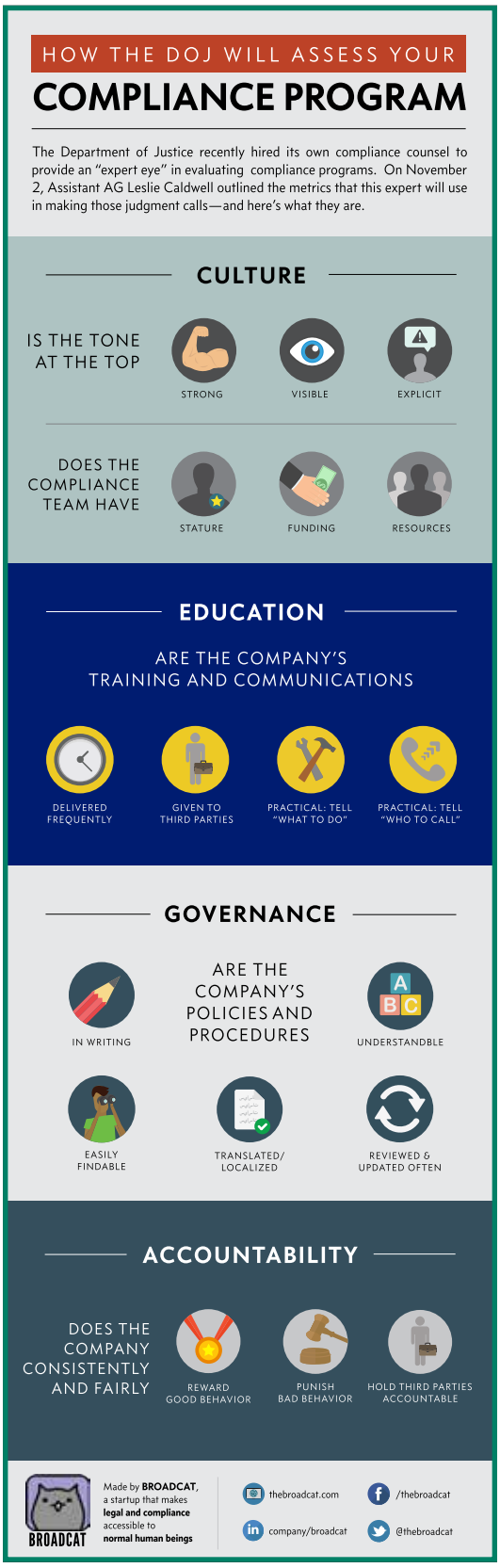
Infographic of the month



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February 29–March 1, 2016

Scottsdale, AZ | FireSky Resort & Spa

Designed for board members and members of a board audit or compliance committee of a not-for-profit healthcare organization. Compliance officers and other senior leaders in the organization are welcome to accompany board members.

Questions? catherine.stollenwerk@corporatecompliance.org

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HCCA *conference news*

Audit & Compliance Committee Conference

February 29–March 1, 2016 | Scottsdale, AZ

www.hcca-info.org/audit

In the current enhanced enforcement environment, a board member's responsibilities don't end with due care. If a compliance failure occurs, the organization's penalties could be substantially higher if the board can't demonstrate that it is knowledgeable about the content and operation of the compliance and ethics program.

Board Members and Compliance Officers are encouraged to attend together…

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Help yourself and your board live up to your compliance oversight obligations…

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Topics Include:

- Introduction to Healthcare Risk Areas & Compliance
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- What It Takes to Be a Good Board Member
- Enterprise Risk Management
- Whistleblower Case Study: Managing the Risk in Healthcare Organizations
- Role and Responsibility of the Audit & Compliance Committee
- Fraud & Abuse and Compliance 2016

"The Audit & Compliance Committee Conference is one of the only educational offerings designed specifically for healthcare organizations' Board members and Audit & Compliance Committee members. Conference attendance continues to grow, and we've crafted educational sessions with valuable takeaways to assist you in your role. Expert speakers will share best practices and their hands-on experiences."

—Gabriel Imperato, Esq.
SCCE/HCCA Immediate Past President,
Audit & Compliance Committee
Conference Chair

Find the latest conference information online ▶ www.hcca-info.org/events

HCCA *website news*

Contact Tracey Page at 952-405-7936 or email her at tracey.page@corporatecompliance.org with any questions about HCCA's website.

Top pages last month

Home Page | Job Board | Events | My Account | Library

Number of website visits last month

59,590

Y-Comply

Check out the "Y-Comply" email newsletter, a quarterly publication dedicated to helping compliance professionals communicate the value and purpose of compliance & ethics to the general workforce.

In it, Deann M. Baker, CHC, CCEP, CHRC, writes about how to motivate the workforce, how to keep lines of communications open, and a many other topics that relate to compliance & ethics.

You can read the current and all past issues and/or subscribe to the newsletter by visting the "Y-Comply" page of our website, at: *www.hcca-info.org/Resources/HCCAPublications/Y-Comply.aspx*.

Video of the Month

What is the first step in conducting a risk assessment?

See this and other videos concerning risk assessments at: *http://bit.ly/votm-ct-2016-01*

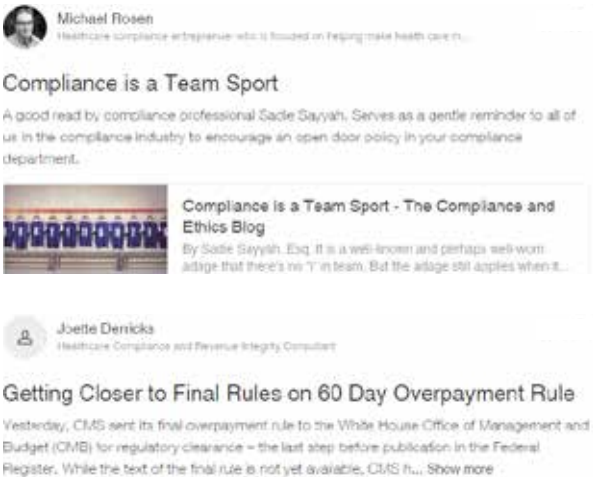
Find the latest HCCA website updates online ▶ www.hcca-info.org

HCCA *social media news*

Contact Stephanie Gallagher at 952-567-6212 or email her at stephanie.gallagher@corporatecompliance.org with any questions about HCCA social media.

LinkedIn — *www.hcca-info.org/Linkedin*

Join us on LinkedIn—a business-oriented network with more than 300 million active users. With more than 22,000 members, our LinkedIn group fosters more than 50 new discussion posts every week. Some recent highlights:



Facebook — *www.facebook.com/hcca*

We're on Facebook, too! Like our page for healthcare compliance news and networking. One recent post:

Pinterest — *www.pinterest.com/theHCCA*

Check out our Pinterest boards for *HIPAA*, *ICD-10*, *ACA*, *Compliance Videos*, and using *Technology & Social Media* in healthcare, as well as map-boards for our major conferences (highlighting local restaurants, sights, and things to do in each of our conference cities). Our "infographics of the month" and much more can all be found on our Pinterest boards.

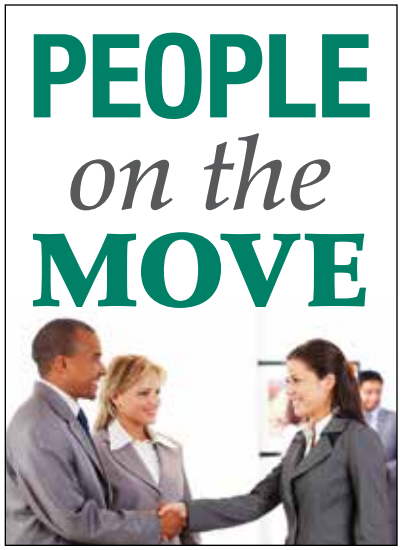
Twitter — *www.twitter.com/theHCCA*

Join 11,000+ others and follow HCCA for breaking news and insights. Some recent favorite tweets:

Find the latest HCCA*net*® updates online ▶ www.hcca-info.org/HCCAnet

▶ Navigant announced the appointment of **Dorothy DeAngelis** as Managing Director of its Healthcare and Life Sciences Disputes, Regulatory, Compliance and Investigations practice. She is located in the Phoenix, AZ office.

▶ The Life Support Technologies group, in Tarrytown, NY, has promoted **Mark Chipps** from Corporate Compliance Officer to Vice President of Corporate Compliance & Safety.



▶ **Christina N. Olson**, RHIT, CHC, CCS, CCSP, CPMA has been named Compliance Education Manager for Baylor College of Medicine in Houston, TX.

▶ Millennium Health, based in San Diego, CA, has appointed **Darrell W. Contreras**, as its new Chief Compliance Officer.

▶ **Tricia Owsley** has been named Director of Compliance for The University of Maryland Medical System in Baltimore, MD.

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"I can't be everywhere,

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Our CFO says, "Our scores are up! Quality Improvement training helped us improve our Medicare incentive payments."

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You can't be everywhere, that's why you need HCCS compliance solutions.

that's why I use HCCS."

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Janie McKinney, CCP-P, CHC
Compliance Coordinator & IRB Coordinator
Washington Regional Medical Center
Fayetteville, AR

an interview by Lori Strauss

Meet Janie McKinney

*This interview with **Janie McKinney**, (jmckinney@wregional.com) was conducted by **Lori Strauss** (LJS6N@hscmail.mcc.virginia.edu), Chief Compliance & Privacy Officer, University of Virginia Health System, in the fall of 2015.*

LS: Thank you, Janie, for your willingness to talk with me today and to share your healthcare compliance work experiences and tips you've learned along the way. Please tell us about your background and how your career path took you to be the Compliance Coordinator & IRB Coordinator for Washington Regional Medical System in Arkansas.

JM: Thank you, Lori, for considering how a once nascent work focus called "compliance" was a direction I chose and where mentors directed me. My father passed away two years ago, and he never quite understood what I did at work, so telling the story—though bittersweet—may help others understand the journey some of us take into Compliance.

Elementary school was when research first entered my life. A classmate's father, a professor of Education, was researching a new theory in young children—if reading quietly to yourself resulted in faster reading and comprehension than reading out loud. Several third-grade classmates and I participated in this study and a demonstration at the University of Arkansas. Grade school is also when researchers propose that kids develop close ties, walking to school every day, standing up for each other. For me, traveling on field trips, participating in sports, and earning Girl Scout badges involved covering two-thirds of 75 counties of Arkansas, and began

my studies of how and where people lived and worked. Later, research—conducting field work, site surveys, and being a study subject in college—helped pay for college and graduate school.

After service in the Army, my mother and father moved our family back to a town where my dad grew up. My parents instilled in our large family that every person who works hard was equally important, which is a message that has stayed with me. I spent hours working and learning, even from grandfathers whom I never knew.

One grandfather was a WWI veteran, a traveling insurance inspector who started his own insurance company, and later served in WWII as a POW farm camp director in a rural Mississippi camp. My maternal grandfather served in the Public Health Service, helping to eradicate diseases in the dense mosquito population of North Carolina. He endured during the Great Depression as a pharmacist and apothecary in Little Rock, Arkansas, helping as many people as he could, even if they were unable to pay for their medications.

Doing land use surveys, parcel by parcel, during graduate work in Memphis …energized my work in how to plan healthcare services.

Doing land use surveys, parcel by parcel, during graduate work in Memphis, Tennessee, observing whether a person drinks aquifer or lake water, the sediment in the air we breathe, energized my work in how to plan healthcare services. In 1993, a friend asked me to work with a state contract developing provider networks, monitoring contract risk, and responding to a challenge of contract compliance, which resulted in a consent decree to expand outreach for children's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services. I presented behavioral healthcare organization contract updates to the Tennessee Department of Health.

Building the provider networks can lead to grueling travel assignments. However, with my groundwork experience with research in the 75 counties of Arkansas, I also quickly learned as much as I could about Tennessee. Our team was now traveling two-thirds of the 99 counties in Tennessee and also contracting with six contiguous states. We would site visit every contracted provider, community mental health center, methadone clinic, mental health institute, and wilderness camp center, to ensure credentialing, contract compliance, patient rights and safety, and appropriate medical care.

You understand your job is not to disrupt the resident's stay, but to guarantee the care received is of the highest quality. You should be in the background unless the location administrator includes you to interact with the program. This contracting position expanded to another company, where I worked to support SoonerCare (Oklahoma Medicaid), and traveling to the company headquarters in Maryland. It's important to listen and learn. My Master's degree research focused on the service and financial structure gaps in the Tennessee Medicaid waiver program.

Like many of our colleagues, I was working in a very culturally diverse office environment in 1995, when an explosion rocked the federal building in Oklahoma City. Suddenly, the provider services and call center where I worked in Brentwood, Tennessee, became a back-up call center for this disaster. Our company held an Oklahoma Employee contract for counseling and

mental health services. With the great training I'd received from Memphis Metropolitan Planning Organization (MPO) and Emergency Management Services, I quickly converted to helping with the disaster-assistance process.

When I first heard about the creation of Health Care Compliance Association, I was building an Access data base of the TennCare contract performance measures with matching liquidated damages and monetary penalties. While deep in the State contract compliance project, I needed to connect with a peer and gauge the measures.

HCCA was one of the groups that identified someone I could discuss this best practice with. Coincidentally, while working for the State of Tennessee in the TennCare offices, I was assigned to cross-walk every section of the TennCare State managed care MCO/BHO contract, line by line; and then I was asked to go back and do the project again, adding liquidated damages for each section of the contract. The value of the time and detail in the previous contract compliance Access database project was not lost on me during this project.

The tenure in Tennessee also included direct or messenger model of contracting for 60 clients and serving as director of hospital compliance. After three years of trying to move closer to family, I was finally able to (with a portfolio of my work) secure my present position in the same hospital system where I was born. If you were born in Washington General Hospital, located at the edge of town in the early 1960s, your birth name was handwritten in a bank-like ledger book. I'd spent my youth volunteering at the hospital sites, and visiting a grandmother after school while she was receiving care at the oldest facility.

LS: What's the favorite part of your job and why?

JM: Several areas are favorite parts of my job. Perceptions of "what is compliance" may be difficult to understand outside our profession.

One is working with a system leadership who understand the compliance process and the importance of a team approach to compliance education for new employees and annual education. We ensure our employees understand they are empowered as part of the compliance process and that we are here for them if they have any questions. I find it helpful in orientation, using parallel examples in daily life for employees (like the example of setting a speed limit for the best interest of the community), that providers participate in Medicare as a "contract" that has set codes, LCDs, and documentation requirements for billing, performance standards, and medical policies; and that there are many agencies which follow this "contract" with regional variations. The goal that all of us set is to achieve "compliance" with that contract. I continue the teachings of my mentors: to provide examples of news stories of the many threats to the compliance regulations and that there are non-healthcare professionals in the world who try to defraud money and services from the governing contracts. By this empowerment of our employees, I also enjoy watching a robust auditing process advance,

We ensure our employees understand they are empowered as part of the compliance process and that we are here for them if they have any questions.

and the departments look forward to learning to improve and expand their knowledge.

Another favorite area is seeing advances in patient electronic health record (EHR) privacy monitoring and security, to further protect a patient's right to privacy and conduct surveillance of our system for an issue, if one occurs.

Auditing is embedded as something good in my area of Compliance, and I've had providers or department directors stop me in my compliance rounds at facilities, and ask me to come audit them, so they can see how their department is doing!

LS: What do you see as the most significant risks in healthcare today?

JM: Many people through their lives understand what a nurse does and why health standards and best practices like hand hygiene, patient care practices, and specific documentation and charting are followed. First, there is not always a clear understanding or clear perception of compliance guidance, and the separation of any financial or revenue-seeking approach from compliance. There cannot be a conflict of interest between a revenue-generating department and true Compliance department. The regulations and the guidance are the focus, and now we are adding IT compliance and security.

I think often of the story told by Debbie Troklus in the preface of the first *Compliance 101* book, when many people in healthcare, medical schools, or universities, didn't clearly define what a compliance program was. It may be focusing on the seven elements of the compliance program from federal guidance. Or in healthcare contracting, conducting contract compliance, and compliance education in the Medicare, Medicaid, provider, or an institution's governing body contract performance standards. The word "compliance" was elevated and evolved into a profession. Oversight of compliance has since grown to more policing agencies, fraud prevention, and into many zone integrity contractors.

Second, growing threats of cyber attacks or hacking, or improper use of social media by our guests or an employee, are demanding ever-increasing attention from IT departments.

Third, letting any kind of "scope creep" occur during a compliance process is a significant risk. Compliance processes may take time; there should be leadership in place that allows adherence to the compliance program over sales or corporate profit.

LS: What should healthcare organizations be doing to stay ahead of the curve and manage the compliance challenges and risks they face?

JM: We should continue to evolve, welcome change, embrace new technology and treatments, and expand our services to treat the life span of a patient.

Years ago, I developed a contract-language requirement grid for our contract staff, which was often adjusted to better position my provider when they negotiated contracts and request liquidated damages in any non-compliance. Providers should demand robust auditing, patient safety compliance, and protection of patient rights, or liquidated damages if there are errors or non-compliance.

Improve your knowledge of the advances in compliance regulation changes and OIG Work Plan mid-year updates, and roll-out that education to your leadership, department leaders, and employees.

Support ICD-10 documentation and coding education for providers, coders, and business office staff. Increase your knowledge of physician advancement in medical care and new advances in devices and procedures. Identify areas of improvement and provide additional training, especially in patient privacy, tagging specific indicators to monitor for patient privacy and security. I work very

closely with a very informed and diligent IT team; and guide proactive prevention of areas that would jeopardize the value-based criteria we are required to follow—which is growing and becoming increasingly challenging.

Coincidentally, for some of us, our healthcare training has evolved from typewriters and carbon paper and forms in triplicate, to punch card computers, reel-to-reel tape computers and handwritten charts, monitored supply dispensing, and now EHR. What amazing advances we've seen in support of medical care and compliance monitoring over 45 years!

LS: What about your job keeps you up at night?

JM: We all should be concerned that any employee may experience bullying in a workplace. I also worry about the growth and burden of growing fraud protection agencies and our response to quickly changing regulations in healthcare; increased threats of information technology hacking; improper use of medical records; the misunderstanding of the importance of auditing, action plans, and identifying risk to a company; and that Compliance departments are fully supported and funded separately from the financial side of a company.

LS: A few years ago, you became certified in healthcare compliance through the Compliance Certification Board. Why did you seek the CHC certification?

JM: I joined HCCA as a member in the early 2000s. I first took the Healthcare Fraud and Abuse Institute (HFAI) exam, because it covered many of the provider system services and services for which, as Director of Compliance, our Compliance Committee would need expertise. Later, that HFAI certification was grandfathered into a company that supported testing for coding compliance. The next step was the compliance certification in CHC, which focuses on all possible regulatory scenarios and the functions of a compliance professional. Although this was a very challenging time for me personally, when my father's health was failing, I was very proud to join this great group of compliance professionals from all backgrounds, and my father was able to know that I'd achieved this advancement and added another certification.

LS: What are some of the professional benefits you've found through having your CHC?

JM: HCCA has added a network of compliance peers who post questions, and HCCA members can all learn together from these posts. HCCA has added many locations for compliance conference training in the basics and advancements in Compliance. Through attending an HCCA conference focusing on areas of study required for the CHC exam, the CHC study process and testing expanded my knowledge and expertise into many day-to-day compliance questions and additional areas of risk. It has helped me to support our compliance officer, leadership, and research IRB. The HCCA re-structured expectations of conference attendance during challenging economic times, and listens to suggestions from members.

…the CHC study process and testing expanded my knowledge and expertise into many day-to-day compliance questions and additional areas of risk.

Learning from the broad spectrum of conference speakers, and how speakers team up

for presentations, helps keep me updated on developing best practices and new technology. Later, sitting with the speakers in another session challenges the rest of the room. The speakers and blogs confirm and affirm that your processes and best practices are functioning appropriately; you may see a colleague you worked with many years ago, or meet a new mentor. You may sit in a conference session and hear a great speaker who brings you back to the days you first learned of sensory responses (including Pavlov's dog), or research in ethical behavior, or the origin of the Nuremberg code. You bring back new energy and creative ideas for education at your facility, and education for leadership and research committees.

The HCCA blog, from an individual or conference perspective, has been valuable and encouraging. I find examples for department staff. Specifically, Adam Turteltaub's great blog post (*www.complianceandethics.org/whats-in-the-job-description*) comparing baseball great Jackie Robinson to what is needed in a compliance professional, based on the risks that employees will encounter, how we are responsible in specific situations to shield employees, pressures that connote when compliance professionals must speak-up, and strictly following data protection procedures. The continuity of this compliance training and monthly quizzes is not often understood by other disciplines—the time we invest to train and maintain competencies, on a weekly and monthly basis.

LS: What value has HCCA membership provided for you?

JM: In a word, a "community." We are on a journey—to which you must adjust to the ever-changing horizon, a community that thinks and speaks a particular language and has a similar background of experiences. I've found value in reassurances, from HCCA peer articles and postings, that our team and company have a good, strong, voluntary compliance program and proper processes in place, and that HCCA supports its members to meet a standard of certification that is at the top of a specialty field. Other areas of certifications do not represent the background that you have from the "origination" of compliance, nor the "regulatory specialists" who truly can discuss any regulation in the same "language" you speak, which many others don't quite understand. In HCCA, I've found a network of consultants and professionals in many disciplines to access as resources for external reviews, to pursue as speakers, or access for study groups. And with the many compliance titles that one may have, I'm reassured that the Compliance industry is strong and supportive, incorporating even government officials as speakers, and focused on all areas of compliance leadership.

LS: What can HCCA do to further facilitate advancement of the Compliance profession in healthcare?

JM: HCCA should continue to focus on all avenues of education; offer re-play of conference sessions so that we may benefit from the conference education, when travel to the conference may not have been possible; and continue HCCA individual applications. Allow us to re-new or re-certify early, as project focus may shift during the year. I hope HCCA will continue the "call for speakers" (as someday I will submit my presentation) and continue to bring us great speakers and regulatory specialists; and provide free guides and reference books for developing proactive and preventative compliance policies. HCCA should focus on reaching out to single providers and small medical practices, expand to those who are multi-lingual—and multi-nationality professionals—not only for compliance coordination, but also in networking.

I learned other languages through traveling with my Dad to the Korean War Memorial

dedication in the late 1990s. We later received a Commanders Award for Excellence for presenting our story of the journey. We learned from being an exchange student host family, and I also learned another language for a friend who was marrying a NATO training Air Force pilot. HCCA and SCCE Conferences are times for some of us to learn best practices and practice our languages, often forming lasting professional bonds. As we continue to support and encourage younger, advancing compliance professionals, we in turn, support new ideas in compliance effectiveness training and compliance education.

LS: With your years of experience as a compliance professional, what do you believe is the greatest misperception about Compliance?

JM: That we are the "bad guys." The opposite is actually true. Our processes should be in place to identify and prevent bad things from happening. We want to be who you can come to if a process is not working, so we can help correct it. It's a misperception that the compliance process takes a long time and disrupts financial processes. Yes, there are times the compliance process must be given time, and often that is not well received. However, this is a time to remember, in comparison, that we may speak another language of regulatory guidance, compliance-speak for example, and yet we are as dedicated to all of the hand washing and clinical processes that are followed for partner departments, because most importantly, it is a "best practice."

Another misperception is that we stay in our offices and don't get involved and are not there to help when needed. Often we can't discuss what we do. And due to regulations, or federal guidelines, we are working on detailed projects and must keep our doors and files, locked and secured for specific reasons.

But, if asked, we often jump in to help. Volunteer when your skills can be used. For example, I was serving on a board of directors of a patient support house near Vanderbilt University Medical Center in Nashville, Tennessee on the day of the September 11th tragedies. I went to work that morning like any other day, as the first planes crashed. While doing compliance rounds, I wanted to assure the patient families in the waiting rooms that our hospital was safe and continuing to operate. The same day, I received a call from the support house that we should all be available on-call to prepare to help families of any burn victims arriving by air ambulance to Vanderbilt's burn unit. I quickly ran my checklists, and waited to help the families. We waited for the call. And we waited. And as the events of the week unfolded, we realized that no patients were coming.

That same week, a few of us rallied to attend an Athena Women's conference. The main speaker asked if we would be able to take in to our homes any of the guests who had traveled to Nashville for the conference. The guests' companies had funded their stay in the hotel for the days of the conference, but they needed to move out of their rooms and find places to stay; with no planes flying to get them home to their families, they were stranded. I happened to live near the airport and a railroad track; for the following week, no planes were flying, no trains were on the rails. There was an eerie sense of quiet.

LS: Why do compliance programs sometimes lose their effectiveness?

JM: I'm very proud that our Washington Regional Medical Center compliance program is continuing to grow, and more employees understand what the program involves and why it is in place. Companies and facilities however, have many priorities which, at times of economic stress, may overshadow the compliance program. It's important that the focus and purpose of the compliance program is maintained to the best of your staff's ability.

Conduct a regular Compliance Program Effectiveness audit; keep education and auditing and monitoring as a top priority, even internal audits for monitoring risk. Watch for "scope creep." Utilize the OIG Work Plan areas of risk, and focus on areas of your hospital that represent changing risk. Instead of asking staff to redo a project, to focus on the risk; if staff have already set a process in place for The Joint Commission or Environment of Care standard, utilize the process that is already in place and coordinate the efforts. Think of the coordination of communication in the seven elements of the compliance program, and maintain work efficiency if your departments seem overburdened with "guidance fatigue."

LS: How can compliance professionals positively impact their organization's corporate culture?

JM: Some of my colleagues will say I'm a bit over-passionate about Compliance. My voice gets loud and I am very excited for our compliance projects, Compliance department, and for our employees.

Ensure you have the buy-in and commitment of your corporate officers and leaders—in support of the program, in budget, and/or cooperation with other department resources. Run comparables of punitive costs as an example for leadership, to support the need for a strong compliance program, including auditing and monitoring. Research and justify the need for compliance activities. Have access to these leaders and the ear of your General Counsel. Our employees' work is very demanding, and they work long hours. Be culturally aware of your employees—what works best for them and for your department leaders; know who learns well in a big group of people and who learns better on their own or in a buddy system.

The providers' time with their patients is very important to them. You may find it works best to be an encourager and avoid criticism. Find a high point that is current and relative to your organization's culture. Have you tried "compliance rounds" to see what your departments need? Have you provided them a list of deadlines for Compliance projects where you need their response, and do you send friendly reminders? Do you have an organized management system which sends the projects electronically, provides the references, and tracks the progress and deadline? Do you announce your deadlines early and make the education and deadlines fun? Do you send quick tips, learning on the go, and hold contests for which department can finish a project first?

Be culturally aware of your employees—what works best for them and for your department leaders.

LS: Based on your role in Arkansas and a prior role you held in Tennessee, you have devoted extensive time to compliance and privacy education and training. What training and education tips can you share with us to help other compliance professionals with education and training responsibilities?

JM: I'd recommend refreshing your own education and presentation skills from time to time. Invest some time in creating new ways to reach your employees. For reading, a good book is *Quiet: The Power of Introverts in a World That Can't Stop Talking*, a 2012 non-fiction book written by Susan Cain. Or watch TED Talks videos for other great ideas. How can you better reach out and ensure your employees

remember when they last had compliance education? At a facility where I was Director of Compliance, we achieved 100% education of all system-wide employees in the roll-out of HIPAA training, with a schedule of classes and in-services over three months. That facility made the top six in its system in the country in effectiveness. Currently, we achieve very close to that percentage.

Set your timetable and stick to it. Seek guidance from your leadership on their goals. Refine the project list and adjust to changes in the company. Remember that Compliance Program Effectiveness assessment/audit project you were going to do? The assessment may show you areas of opportunities, so keep those goals in sight.

Overall, when I sat in HCCA conferences, I'd think we were doing a good job. I jotted down ideas for opportunities or changes to make things more time-efficient or more effective. I thought about what I would do when I had the cooperation of our Education department in planning our annual compliance projects a year ahead. I was surprised how many education systems or other industries didn't know if they had leadership buy-in or support, when they were well aware they had their own regulations expecting deadlines for education and annual reports.

I see what we do in Compliance as proactive, productive, and preventative. I want to have something in a binder or a program to show what we are doing. If your directors need a schedule months ahead for shift coverage for their departments, have your schedule ready before the directors need it.

More than likely, when you leave your office and do any kind of compliance rounds or education, you will see many more employees "interested" in the compliance program than you might think. Keep making the parallel comparisons to an area of work familiar to your employees who may show lack of interest in compliance education. Look to directors and Human Resources to make annual compliance education mandatory as a company standard for annual employee evaluations.

Cheer on the many personalities and levels of your employees for their own successes and in their projects. If you help them become a success, that only strengthens the goals toward success of the company and possibly, your compliance program.

LS: Is there anything else you want to share with your healthcare compliance colleagues?

JM: We are not the bad guys. Our job in Compliance is to look for how we can improve processes. Robust auditing is part of that process.

We should remember what the president of the Dodgers baseball team was looking for when he selected Jackie Robinson to break the color barrier in baseball (from another HCCA blog post). We should not only do our job well, but be dedicated compliance professionals. No matter what comes our way and the challenges we face, we need the guts to do the right thing and support the compliance program passionately and constantly. As the blog post I mentioned earlier said about compliance character, "We must be able to think outside the box." Be diligent. Be creative with communicating your message. Know your employees, and keep up the compliance program work, even when so many other projects at your company may seem to be the top project or require the most focus. Maintain your focus. It's your responsibility to best inform your leadership; continue auditing and improving. Find the opportunities. No matter what their discipline or work title, make all of your employees feel successful in compliance.

LS: Thank you Janie for your time and your valuable insights to our profession.

by Catherine Boerner, JD, CHC

How do you practically define a compliance program?

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Happy New Year! As we begin 2016, I hope it proves to be a good year for our compliance programs to mature and grow. Over the holidays, you may have been asked by family and friends, "What is a compliance program exactly?" Hopefully not, but I know it does happen. What do you say when you are asked that question? What do you say when you are training new employees or explaining it to a new board member? Does the definition depend on your audience? Can you answer the question easily?

Boerner

Corporate Integrity Agreements don't provide a definition of a compliance program in the definition section. The OIG compliance program guidance documents also do not provide a specific definition. There is a listing of the elements of a compliance program, but not really an overall definition. There is a focus on what a compliance program does, but what is it?

I like to define a compliance program as a formal independent infrastructure, separate from normal operations, that is proactive and reactive with oversight to confirm controls are in place to prevent and detect non-compliance with federal and state regulatory risk areas.

When you pull apart this definition, you can think about the following words and ask yourself if your compliance program reflects these words: (1) Formal, (2) Independent, (3) Infrastructure, (4) Separate from normal operations, (5) Proactive, (6) Reactive, (7) Oversight, (8) Confirm, (9) Controls, (10) Prevent, and (11) Detect.

We can look back 18 years to the original OIG Compliance Program Guidance for Hospitals, published on February 23, 1998, which states:

> Fundamentally, compliance efforts are designed to establish a culture within a hospital that promotes prevention, detection, and resolution of instances of conduct that do not conform to Federal and State law, and Federal, State and private payor health care program requirements, as well as the hospital's ethical and business policies. In practice, the compliance program should effectively articulate and demonstrate the organization's commitment to the compliance process. The existence of benchmarks that demonstrate implementation and achievements are essential to any effective compliance program. Eventually, a compliance program should become part of the fabric of routine hospital operations.

So we can add from this: (1) Establish a culture, (2) Promote, (3) Resolution, and (4) Commitment.

It might be good to think about how you are defining the compliance program in your compliance plan, standards of conduct, and training in order to send a clear message what the compliance program is and what it does.

by Vince Farhat, Esq. and David Kirman, Esq.

Current trends in FCPA enforcement in the healthcare industry

» Healthcare companies doing business in foreign countries must comply with the Foreign Corrupt Practices Act (FCPA), which prohibits payments or offers to pay anything of value to a foreign official in order to secure an improper advantage.

» DOJ recently increased the size of its FCPA unit by 50% and FCPA enforcement of healthcare companies is increasing.

» Healthcare companies' frequent interactions with doctors, pharmacists, and administrators from foreign public hospitals expose them to particularly high FCPA risk.

» The Department of Justice recently created a counsel position to evaluate the FCPA compliance programs of companies under investigation.

» Healthcare companies doing business in foreign countries should reexamine their anti-bribery compliance policies to ensure they are doing enough to prevent and minimize FCPA violations.

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Healthcare companies doing business in foreign countries must comply with the Foreign Corrupt Practices Act (FCPA), which prohibits payments or offers to pay anything of value to a foreign official in order to secure an improper advantage. FCPA investigations brought by the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) expose healthcare companies to potentially harsh penalties, including criminal prosecution, disgorgement of profits, fines, interest, legal fees, negative publicity, ongoing governmental scrutiny, and other negative financial consequences. Other countries, such as the United Kingdom, have similar anti-bribery laws.

Farhat

Kirman

FCPA enforcement of healthcare companies—from multi-national pharmaceutical companies, to start-up medical device companies with only minimal international connections—is increasing. Healthcare is already a high-risk FCPA industry and, with increased governmental scrutiny and resources dedicated to FCPA enforcement, robust anti-bribery compliance programs are more critical now than ever before. Companies that invest in FCPA compliance will minimize the likelihood of an FCPA violation, increase the likelihood of finding FCPA issues early, and, with the creation of a DOJ counsel to evaluate compliance programs of companies under FCPA investigation, may also minimize damage if an FCPA allegation or violation occurs. This article summarizes trends and some of the significant

FCPA enforcement actions in the healthcare industry over the previous three years in an effort to highlight healthcare-specific FCPA compliance challenges.

FCPA overview

The FCPA makes it illegal for domestic companies and individuals to make payments to foreign officials to obtain an improper business advantage, such as facilitating the approval of a permit, retaining business, or obtaining new business.[1] The FCPA also prohibits the use of third parties, such as agents, to accomplish the same objective, by prohibiting payments made to any person knowing that all or some of the funds will be offered or paid to foreign government officials. The FCPA broadly defines the term "foreign official" as:

> [A]ny officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality or for or on behalf of any such public international organization.[2]

The FCPA does not define what it means to be an "instrumentality" of a foreign government, and that term has been the subject of recent litigation. On its face, the FCPA applies to "domestic concerns" (i.e., citizens, nationals, and residents of the United States and companies, broadly defined) with principal places of business in the United States or companies organized under US state laws; and to "issuers" (i.e., companies that issue securities registered on US stock exchanges). The FCPA may also apply to foreign individuals and companies with a sufficient jurisdictional connection to the United States. An FCPA violation may occur anywhere in the world.

The DOJ enforces the FCPA's criminal anti-bribery provisions. The SEC may bring civil FCPA charges and also enforces certain accounting and recordkeeping provisions of the FCPA on publicly held companies. The DOJ and SEC frequently work together on FCPA investigations.

The FCPA does not define what it means to be an "instrumentality" of a foreign government…

The US government recovered over $1.56 billion through FCPA enforcement actions in 2014.[3] In November 2015, DOJ announced it would increase the size of its FCPA unit by 50% by adding 10 new prosecutors.[4]

FCPA enforcement in the healthcare industry

Healthcare is a high-risk industry in the FCPA space and FCPA enforcement of healthcare companies is increasing,[5,6] which is not surprising, given the healthcare industry has several features exposing it to more FCPA risk than other industries. For example, representatives from healthcare companies frequently have interactions with doctors, pharmacists, and administrators from public hospitals in foreign countries. These individuals control what foreign hospitals purchase and what doctors who work in these hospitals prescribe. Their decisions have significant fiscal impacts on healthcare companies. Although doctors and pharmacists who work in public hospitals in foreign countries are not typically thought of as "foreign officials," government enforcers view them as foreign officials for purposes of the FCPA. Like other industries, healthcare

companies also have frequent contact with more traditional foreign officials to obtain regulatory approvals and government contracts.

FCPA violations for healthcare companies typically include payments to prescribe, to get on lists of approved drugs or other regulatory approvals, and to get government contracts. Between 2002 and 2015, there have been approximately 19 healthcare companies that have engaged in conduct alleged to have violated the FCPA.[7] In an effort to shed light on the increased enforcement actions of healthcare companies and to discern the types of activities targeted by the SEC and DOJ, six current FCPA actions brought against companies associated with the healthcare industry are examined below.

Pfizer Inc.: August 2012

The SEC charged Pfizer Inc. (Pfizer), a multinational pharmaceutical corporation headquartered in New York, with violating the FCPA, because its subsidiaries allegedly bribed doctors and other healthcare professionals employed by a foreign government. The SEC alleged that the violations occurred in Bulgaria, China, Croatia, Czech Republic, Italy, Kazakhstan, Russia, and Serbia. Pfizer allegedly made the bribes in an effort to obtain regulatory approval, formulary approval, sales, and increased prescriptions for the company's products. According to the government, Pfizer illegally recorded the bribes as expenses for promotional activities, training, travel and entertainment, clinical trials, freight, and conferences, as well as advertising.[8,9]

The SEC also charged Wyeth, a pharmaceutical company acquired by Pfizer, with similar allegations. In an effort to increase sales, Wyeth allegedly created a "points program" for doctors in China. According to the SEC, the points were directly correlated with the number of Pfizer prescriptions written. The SEC claimed that more prescriptions earned more points, and doctors could redeem the points for items such as tea sets, cell phones, reading glasses, and medical books. In Croatia, a similar program was allegedly in place. The doctors in Croatia allegedly would be given a percentage of the value of the products purchased by the doctor's institution, incentivizing the writing of Pfizer prescriptions. Doctors allegedly received this percentage in the form of cash, free products, or international travel. The alleged misconduct was traced as far back as 2001. In 2004, Pfizer made an initial disclosure to both the DOJ and the SEC. Although neither admitting nor denying the allegations, Pfizer paid $16,032,676 in disgorgement and a prejudgment interest of $10,307,268 for a total of $26,339,944, and Wyeth paid a disgorgement of $17,217,831 and a prejudgment interest of $1,658,793 for a total of $18,876,624.

Eli Lilly and Company: December 2012

Eli Lilly and Company, an Indianapolis-based pharmaceutical company, settled an FCPA action brought by the SEC stemming from bribery allegations. The SEC alleged that Eli Lilly subsidiaries made improper payments to foreign government officials in Russia, China, Brazil, and Poland in an effort to win business in their respective countries. According to the SEC's allegations, a Russian subsidiary used offshore marketing agreements to pay millions of dollars to third parties who would then funnel the money to government officials. The SEC alleged that the transactions with offshore or government-affiliated entities did not receive specialized review for FCPA violations. Moreover, the SEC claimed that Eli Lilly failed to curtail the use of "marketing agreements" quickly enough. The SEC claimed that Eli Lilly subsidiaries paid approximately $8.5 million in improper benefits to foreign officials. Eli Lilly, which did not admit or deny the allegations, agreed to pay a disgorgement of $13,955,196, a prejudgment interest of $6,743,538, and a penalty of $8.7 million for a total payment of $29,398,734.

Stryker Corporation: October 2013
The SEC charged Stryker Corporation, a Michigan-based medical technology company, with violating the FCPA in five different countries. Stryker's subsidiaries in Argentina, Greece, Mexico, Poland, and Romania allegedly spent $2.2 million in bribing doctors, healthcare professionals, and other government-employed officials in order to retain or obtain their business.[10] Stryker allegedly recorded bribes as legitimate expenses in its records. The SEC claimed that Stryker profited by approximately $7.5 million through the alleged bribes. The SEC claimed that Stryker failed to have a "robust compliance program" and that this misconduct led to illicit profits.[11]

The alleged bribes dated back as far as 2003. For example, a subsidiary in Mexico is alleged to have had a law firm pay $46,000 to a Mexican government employee to ensure that the subsidiary won a government contract. The subsidiary reimbursed the law firm for the bribe and the subsidiary listed the payment as a legal expense, although, according to the allegations, no legal services were provided. In Greece, another subsidiary allegedly made a donation of $200,000 to a public university to fund a laboratory. A doctor allegedly agreed to provide Stryker with business in exchange for the donation. In the end, Stryker paid disgorgement of $7,502,635, a prejudgment interest of $2,280,888 and a penalty of $3.5 million. Stryker never admitted or denied the allegations.

Bio-Rad Laboratories Inc.: November 2014
Bio-Rad Laboratories Inc., a California-based clinical diagnostic and life science research company, settled SEC enforcement actions after Bio-Rad self-reported misconduct. Bio-Rad reported that its subsidiaries made improper payments to officials in Russia, Vietnam, and Thailand in order to win business. An SEC investigation claimed that Bio-Rad did not have sufficient internal controls to prevent or detect bribes. Furthermore, the SEC claimed that Bio-Rad did not address red flags that a bribing scheme may have existed; instead it "condoned an atmosphere of secrecy."[12] Over a five-year period, $7.5 million in alleged bribes were illegally recorded as legitimate expenses, including commissions, advertising, and training fees. For example, the SEC claimed that a Bio-Rad-acquired company operating in Thailand would inflate the commissions of some of its agents and these agents would then use some of their commission for bribes. Furthermore, Bio-Rad allegedly had foreign agents, with inflated commissions to pay bribes, stationed in Russia. The SEC claimed that the agents had phony Moscow addresses and offshore bank accounts and that Bio-Rad retained the agents primarily to influence Russia's Ministry of Health to award government contracts to Bio-Rad. According to the SEC, to conceal the scheme, the agents had at least 10 personal email addresses with aliases. These bribes resulted in $35 million in alleged illicit profits. Ultimately, Bio-Rad agreed to pay $40.7 million in disgorgement and prejudgment interest to the SEC, as well as a $14.25 million criminal fine to the DOJ.

Bruker Corporation: December 2014
Bruker Corporation is a Massachusetts-based global manufacturer of scientific instruments including x-ray machines and preclinical imaging devices that assist in neurology and cardiology.[13] The SEC charged Bruker with providing improper payments and non-business related travel to government officials to win business. An office in China allegedly paid over $111,000 to Chinese officials and attempted to hide the transaction by calling it a collaboration agreement. In exchange, the officials would allegedly ensure that state-owned entities provided research on Bruker products and would use Bruker products

for laboratory demonstrations. Also, the SEC claimed that Bruker would reimburse Chinese government officials for international leisure travel and that these costs were improperly recorded as legitimate business and marketing expenses. Although Bruker self-reported the misconduct, the SEC faulted the corporation for having "lax internal control" which allowed their offices to enter into sham collaboration agreements to aid in directing money to foreign officials.[14] Furthermore, according to the SEC, Bruker lacked internal controls to prevent and to detect improper payments. Bruker neither admitted nor denied the allegations. In the end, the company agreed to pay $1,714,852 in disgorgement, $310,117 in prejudgment interest, and a $375,000 penalty.

Mead Johnson Nutrition: July 2015

Mead Johnson Nutrition Company manufactures pediatric nutrition products, such as Enfamil. It is headquartered in Glenview, Illinois, with subsidiaries around the world, including in China.[15] In July 2015, Mead Johnson agreed to settle the SEC's allegations that it violated FCPA.[16] The settlement was based on allegations that Mead Johnson China improperly paid healthcare professionals at government-owned hospitals to recommend Mead Johnson's infant formula to new and expectant mothers. According to the SEC, Mead Johnson employees exercised some control over third-party "distributor allowances," which were used to pay healthcare professionals in China hospitals to recommend Mead Johnson Nutrition products. The healthcare professionals also allegedly provided the company with contact information for patients who were new or expectant mothers, so it could market its infant formula to them directly. The SEC claimed that Mead Johnson did not accurately reflect in its books and records the improper payments, which were made during a five-year period. Without admitting or denying the SEC's findings, Mead Johnson agreed to pay $7.77 million in disgorgement, $1.26 million in prejudgment interest, and a $3 million penalty.

FCPA compliance policies and procedures

These enforcement actions show healthcare companies operate in a high-risk FCPA environment and improper payments made to officials or employees of government-owned entities will be subject to prosecution under the FCPA. They also show that FCPA enforcers will look to the substance of a transaction, regardless of whether it is characterized as a charitable contribution, allowance, consulting agreement, business travel, or some other expense that hides the payment's true character. Healthcare companies doing business in foreign countries, therefore, should examine their anti-bribery compliance policies and procedures to ensure that they are doing enough to minimize potential FCPA exposure.

In November 2012, in an effort to describe the FCPA and what a company should do to ensure FCPA compliance, the DOJ and SEC published the *Resource Guide*, which states that there are nine factors considered in conducting an investigation and deciding whether to charge a corporation. A few of the factors are: (1) the nature and seriousness of the offense, (2) the pervasiveness of the wrongdoing within the company, and (3) the existence and effectiveness of the corporation's pre-existing compliance program. Alongside this, the DOJ and SEC place a "high premium on self-reporting, along with cooperation and remedial efforts, in determining the appropriate resolution of FCPA matters."[17]

It is important to have an effective compliance program, because it can be a factor when the DOJ and SEC consider an enforcement action. The DOJ and SEC emphasize that there is no "one-size-fits-all" when it comes to compliance programs. Nevertheless, the *Resource*

Guide lays out the "hallmarks" of an effective compliance program.

A key aspect in an effective compliance program is a clear policy against corruption. Furthermore, there should be a code of conduct that outlines compliance policies and procedures, which should be clear, concise, and accessible to all employees conducting business on the company's behalf. Moreover, there should be periodic training and certification for all directors, officers, relevant employees, and possibly agents and business partners. Inclusively, there should be an assessment of risk with a focus on large government bids, questionable payments to third-party consultants, and excessive discounts to retailers. A company should also incentivize compliance through personnel evaluations and promotions, rewarding those who improve and develop a company's compliance program, as well as those who take a leadership role in ethics and compliance. In sum, these are just a few of the many guidelines the *Resource Guide* provides. These guidelines are meant to provide insight rather than define what an ideal compliance program entails.

In August 2015, the DOJ reemphasized the importance of FCPA compliance with the creation of a counsel position for FCPA matters. According to the chief of the DOJ Fraud Section, the FCPA counsel position exists to assist prosecutors vet companies that are under FCPA investigation. One key aspect of that analysis—which includes whether charges should be brought, and if so, an appropriate disposition—is whether a company "get[s] it and [is] trying to implement a good compliance program from [companies that] have a near-paper program."[18] These comments demonstrate that compliance is not only critical to prevent FCPA violations, but also to mitigate any damage if FCPA violations occur. Additionally, if an FCPA violation occurs, a proactive compliance function will also allow a company the option to seek cooperation credit under DOJ's recently published Yates Memorandum, which requires companies to proactively identify an discovery relevant information about the individuals involved in the misconduct.[19]

The DOJ's recent addition of 10 new prosecutors to the Fraud Section's FCPA unit—increasing its size by 50%—further highlights the importance of FCPA compliance.

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The opinions expressed in this article do not necessarily reflect the views of Holland & Knight LLP or O'Melveny & Myers LLP or their clients, and should not be relied upon as legal advice.

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by Donna Abbondandolo, MBA, CHC, CPHQ, RHIA, CCS, CPC

ICD-10 and quality measures: What are the potential impacts?

Donna Abbondandolo *(donna.abbondandolo@wmchealth.org) is Senior Director, Compliance at Westchester Medical Center Health Network in Valhalla, NY.*

Now that the long-awaited implementation has passed for the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) and the Procedure Coding System (ICD-10-PCS) code sets and the ICD-10 command centers have been dismantled, how do compliance professionals assess the risk to their organization when it comes to the effect that the greater specificity of ICD-10 codes have on quality measure reporting?

Abbondandolo

The use of ICD-10 codes has many benefits. The greater specificity of the codes provides more information and captures a level of detail that may have not been available with the ICD-9-CM and will more accurately reflect the severity of a patient's condition. Better data will help to improve the quality of care delivered and have a positive effect on patient outcomes.

Potential changes with the use of ICD-10-CM:

- Certain populations can be excluded or included in measures based on the change to coding guidelines and conventions. One of the more significant changes is the coding convention for acute myocardial infarction (MI), category I21.[1] The definition for the acute stage of an MI in ICD-9-CM was eight weeks from occurrence. With ICD-10-CM, the acute stage has been shortened to four weeks. This new definition can have an impact on the total patients reported. There is also a new category code, I22, assigned when a patient has another acute MI during the four-week period. This expands the population for the measure.
- Based on the granularity of ICD-10-CM codes, the definition for specific quality measures may change. The definitions for some of the ICD-9-CM codes used to identify cases for quality measure reporting were very general and could be assigned to capture different diagnoses. The translation of ICD-9-CM codes to ICD-10-CM codes is not always a one-to-one match, and the current definition of the quality measure may need to be revised to meet the clinical intent of the measure.
- Comparative and trended data for measures will be impacted. Quality reporting includes comparative data and, depending upon the quality reporting program, the data may include both ICD-9-CM and ICD-10-CM codes.

So where do we start? Identify and monitor the volume of patients reported for measures that may have a change to the population included. Work with your quality improvement team to understand the data reported using both ICD-9-CM and ICD-10-CM codes and how the data may change over the next several years.

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by Joette Derricks, CPC, CHC, FACMPE, CSSGB

Ethics, compliance, and retaliation in healthcare organizations

» One in three people who observe misconduct choose not to report it.
» In 2014, claims alleging retaliation accounted for almost 43% of all claims filed with the EEOC.
» Retaliation action goes beyond termination and can be due to "corporate shunning."
» A survey of compliance officers found that 53% of those who responded had investigated a complaint against senior management.
» Companies that exact retribution or ignore reports of wrongdoing are more likely to be the subject of an outside investigation.

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There are benefits to organizations and the workforce when an ethical culture is promoted. The 2014 Federal Sentencing Guidelines for effective compliance and ethics programs makes that clear in stating that "organizations shall promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law."[1]

Derricks

Studies show that organizations that promote an ethical culture have greater success in meeting their goals and are able to achieve greater customer and employee satisfaction. Workforce members are more productive and are happier when they work for organizations that promote an ethical culture, because it gives everyone confidence in the organization's success and, therefore, their own future success.

Retaliation

The greatest deterrent in creating an ethical culture is when people are not comfortable reporting concerns for fear of retaliation. According to the 2013 National Business Ethics Survey (NBES), there are benefits to an organization that fosters high standards of conduct and honors the rules. However the NBES also reports that more than one out of every three people who observe misconduct choose not to report it and that the rate of retaliation remains alarmingly high at 21%. This results in conflict and confusion as to whether the organization is really creating an "ethical culture or has a commitment to compliance with the law" as defined by the Federal Sentencing Guidelines.[2]

Every employee needs to be familiar with the standards for business conduct, because the standards help employees understand how to raise concerns, define the risks to the organization, and explain how employees are accountable to comply with the laws and the organization's policies. Employees need to realize that they can be held accountable for wrongdoing when they know about it and do not do anything about it. Yet, when many do the right thing, they are retaliated against.

Since 2000, the number of claims alleging unlawful retaliation filed with the U.S. Equal Employment Opportunity Commission (EEOC) each year has roughly doubled—from 19,694

in 2000 to 37,836 in 2012. In fact, in 2014, claims of retaliation were the most frequent charges filed with the EEOC, accounting for almost 43% of all claims filed. Retaliation is now the most common type of discrimination alleged nationally, topping both race and gender.[3]

The NBES has identified the rise in retaliation as a critical warning sign of a possible ethical decline in American business. Although the EEOC and NBES data apply to a broad spectrum of American companies and ethical wrongdoing, many healthcare organizations, including hospitals, nursing homes, and physician groups, have an active compliance program headed by a top executive. A key standard within these compliance programs is a non-retaliation policy. Surprisingly, a survey conducted in 2013 by the Health Ethics Trust of compliance officers who investigated complaints against senior management, found that 33% experienced adverse consequences for doing so. The sizable growth and adoption of compliance programs by healthcare organizations and the corresponding growth in retaliation claims presents a contradiction in the effectiveness of compliance efforts in these organizations.[4]

Compliance programs

The purpose of a compliance program is to detect, prevent, and mitigate practices and behaviors that present regulatory, civil/criminal, financial, or quality risks. Additionally, a well-designed compliance program will foster integrity and serve as a basis for encouraging ethical business practices. Compliance programs were first implemented in response to the Federal Sentencing Guidelines' provisions that allow the presence of a compliance program within an organization to serve as a mitigating factor for determining the penalties for false claims and civil monetary penalty liability.

Today, healthcare compliance is recognized as a distinct profession. Thousands of individuals are certified in healthcare compliance, and schools around the country offer certificate programs in healthcare compliance. HCCA announced in July 2015 that its membership had grown to 15,000. HCCA, along with other professional organizations, including the Medical Group Management Association (MGMA) and the Healthcare Financial Management Association (HFMA), provide a large range of compliance resources (e.g., publications, training programs, and consulting services) to healthcare entities to assist them with creating and implementing an effective compliance program. Nearly every healthcare organization now has some type of a program in place.

The healthcare industry is highly regulated, especially with respect to entities that receive federal and state reimbursement (e.g., Medicare, Medicaid, etc.). A compliance program that effectively implements the seven elements can mitigate risks that result from fraud, waste, and abuse; regulatory noncompliance; substandard quality of care; and unethical business practices.

Whistleblowers

The False Claims Act (FCA) *qui tam* or whistleblower actions are a unique mechanism that allows persons and entities with evidence of fraud against federal programs to sue the wrongdoer on behalf of the government. Currently, *qui tam* provisions include strong financial incentives to file a lawsuit on behalf of the federal government. Healthcare fraud cases, including coding false claims, Prospective Payment System (PPS) false claims, outpatient PPS false claims, kickbacks, Stark Law violations, Durable Medical Equipment (DME) fraud, and Diagnosis Related Group (DRG) fraud (DRG creep) now comprise the majority of all FCA cases. As a percentage of the total FCA lawsuits filed each year, *qui tam* lawsuits have steadily increased from 12% in Fiscal Year 1987, to more than 45% in 2007, and to 66% in 2013.[5]

An "adverse employment action" goes beyond termination. In the context of employment discrimination (generally considered applicable to the whistleblower context) the Supreme Court has said that "corporate shunning," including changing an employee's schedule, or even excluding the employee from an important business meeting or activity, could potentially constitute retaliation.[6] The 2012 Whistleblower Protection Enhancement Act, which protects federal agency whistleblowers, includes in its definition of prohibited retaliation an agency's reassignment, adverse pay decisions, or a significant change in duties, responsibilities, or working conditions.[7]

…"corporate shunning," including changing an employee's schedule, or even excluding the employee from an important business meeting or activity, could potentially constitute retaliation.

Under the FCA, the whistleblower is entitled to reinstatement with seniority, double back pay, interest, special damages sustained as a result of discriminatory treatment, and attorneys' fees and costs. To establish a claim for retaliation, the whistleblower must engage in conduct protected by the FCA. Second, the courts require a showing that the defendant had some notice of the protected conduct—that the whistleblower was either taking action in furtherance of a *qui tam* action, or assisting in an investigation or actions brought by the government. The protection against retaliation extends to whistleblowers whose allegations could legitimately support an FCA case, even if the case is never filed. Finally, the whistleblower must show that the suspension, firing, demotion, harassment, or threat was in retaliation for the protected activities. An FCA retaliation case can include whistleblower claims and other legal claims based upon other state and federal laws, and a claim for retaliation may be brought in federal court.

A complainant regarding a retaliation claim can prevail merely by showing by a preponderance of the evidence that his/her protected activity was a contributing factor in the unfavorable action. A contributing factor is "any factor which, alone or in connection with other factors, tends to affect in any way the outcome of the decision." Once a complainant meets his/her burden of proof by a preponderance of the evidence, the employer can avoid liability only if it proves by clear and convincing evidence that it would have taken the same action in the absence of the employee engaging in protected conduct, an onerous burden.[8]

A closer look

In March 2013, Mark Pastin released the results of a survey of compliance officers who subscribe to the *Ethics Whisperer* blog. More than half of the site's members who opened the survey responded. The results were very interesting. A few key findings relative to retaliation are:

- Fifteen percent (15%) of the responding compliance professionals had left a position at their organizations under adverse circumstances of being fired or forced out.
- Thirteen percent (13%) of respondents thought their job was insecure, with 67% believing that there is at least some level of insecurity in their positions. Some

respondents in the "somewhat secure" category noted that there is a certain amount of job insecurity in general, but most comments pointed to specific reasons for the perceived insecurity.

- Fifty-three percent (53%) of the compliance professional respondents said they have investigated complaints against senior management. Of those who investigated complaints against senior management, 33% experienced adverse consequences for doing so.
- A surprisingly high 21% of responding compliance professionals have considered becoming whistleblowers.[9]

A broader study, beyond healthcare compliance professionals, is "Inside the Mind of a Whistleblower." This study attempts to determine why certain employees will and others will not report activities they perceived to be misconduct. Most of the report focuses on factors influencing employees to report misconduct and how they do it. The first major factor depends on whether the employee felt that the report would make a difference. If the employee believed that no one would listen or care, then he/she was less likely to take action. The second factor is the employee's sense that the employer would retaliate for the report. Employees who felt more financially secure and who believe that they will not suffer retaliation are more likely to report misconduct. The third influence is the whistleblower's level of support, both within and outside of the job. Not only does this affect an employee's confidence in doing the right thing, but it is also likely to make the employee understand the best place to report. Most workers would rather report to a supervisor, if they had a good relationship, than to an anonymous tip line. This is true, of course, only if the employee regards the supervisor as an ethical person.[10]

Conclusion

The biggest conclusion from this report seems to be that the corporate culture is critical. A workplace that is perceived to be healthy, interested in what its employees have to say, and likely to make changes when needed will find its employees speaking up. Companies that exact retribution, or ignore reports of wrongdoing, are more likely to find themselves the subject of some outside investigation.

Employers that ignore reports of wrongdoing not only do the organization a disservice, but also lose certain defenses for charges of wrongdoing. Research and anecdotal evidence show most whistleblowers brought problems to their companies' attention and only became whistleblowers when problems weren't fixed. The organization's lack of response may be the organizational chaos resulting from claiming to have open-door policies when they actually restrict discussion and dissent, even at the board level. They rationalize their behavior and avoid self-examination. Their executives may use fear to control employees, so there are no safe places within the company for honest people to ask questions or report problems. Most often the whistleblower is categorized as a rouge employee, a non-team player. Many can never find employment again. In short, those who should be applauded as truth bearers often are scorned as turncoats.

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by Frank Ruelas

Save time by using the taskbar

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One of the many advantages of a Windows environment is how people can customize their desktops. Setting up your desktop to fit your personal preferences allows you personalize your workstation. It can also be a primary factor in how efficiently you use your computer.

Ruelas

This month's tip introduces the taskbar that appears along the bottom of the desktop. This is an area that, for the most part, goes unnoticed and is often underused.

Opening programs

One of the most frequent tasks that computer users perform in a Windows environment throughout the day is launching or opening programs. Most folks do this in one of two ways. One way is to double click the program's icon located on the desktop. The second is to click on the "Start" button and select the desired program from the subsequent menus that appear. There is nothing wrong with either way, because they both accomplish the same thing. However, here's another option that you may find useful. It launches a program in just one click.

Launching programs from the taskbar

The next time you have a program open that you use often, notice that its icon appears in the taskbar (the long horizontal border located on the bottom of the screen) after it starts. When you see the icon on the taskbar, you can "pin" or place a copy of the icon on the taskbar by right clicking on the icon and selecting the "pin this program to the taskbar" option. The icon will remain on the taskbar whether or not its associated program is open.

Setting up your desktop to fit your personal preferences allows you personalize your workstation. It can also be a primary factor in how efficiently you use your computer.

The next time you want to launch the same program, a single right click on the icon pinned to the taskbar does the trick. This also comes in very handy when you want to launch multiple sessions of the same program. As mentioned in an earlier computer tip, multiple sessions are useful in helping you view more than one file side by side.

Save space on the desktop

Placing commonly used icons on the taskbar also has an additional benefit. By launching programs from the taskbar, you can remove the shortcuts for these programs from your desktop. Now you have even more room for a few more icons to fit onto your screen.

by Laura E. Hutchinson, Richard E. Moses, DO, JD; and D. Scott Jones, CHC

Vicarious liability: Frustrating the major policy goals of the Affordable Care Act

» PPACA was intended to improve the quality of medical care and decrease the cost.
» The face of the health system is changing as a result of PPACA.
» PPACA provisions expose hospitals and healthcare institutions to greater liability.
» The theory of "vicarious liability" will be applied to hospitals and healthcare institutions.
» Compliance and quality are intersecting, offering an opportunity to avert litigation.

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It is well known from the results of multiple studies that medical error is a prevalent and serious problem that makes medical care more expensive. The federal government passed the Patient Protection and Affordable Care Act of 2010 (PPACA) to increase the quality of care patients receive and decrease the cost of medical care. Several of the key PPACA provisions have exposed hospitals and healthcare institutions to greater liability under the theory of "vicarious liability," which actually may result in increased medical costs to patients seeking care.

This article provides a brief history of the medical error crisis and the steps federal and state governments have taken to address this pervasive issue, and then explains how the passage of PPACA has affected institutional liability. The goal of this article is to help compliance officers understand the significance of how PPACA has exposed the healthcare system to more vicarious liability claims.

The medical error crisis

As many as one in three hospitalized patients may be harmed or die as a result of "medical error," which is defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."[1] Medical errors cost $19.5 billion dollars in 2008 in the United States.[2] A recent study suggests that each year between 210,000 and 440,000 patients who go to the hospital for care may suffer some type of preventable harm that contributes to their deaths.[3]

The severity of the medical error crisis was brought to the forefront of legislative reform by studies that were conducted in the 1980s and 1990s. Congress first responded with the Health Care Quality Improvement Act of 1986 (HCQIA) to promote higher quality of care by holding physicians responsible for adverse events. More recently, Congress passed PPACA


Hutchinson


Moses


Jones

when further evaluation of the medical error rate suggested that the problem was far from resolved. States have responded by imposing certification requirements, damage caps, and funds that function as a secondary insurance provider for physicians and healthcare institutions. Despite federal and state legislative efforts, medical errors remain a persistent problem in the United States.

Background of the current medical error crisis

Studies throughout the past 30 years demonstrate that medical errors are increasing, not decreasing.[4] This does not mean that quality of care has decreased. Rather, more people are choosing to seek medical treatment through individual providers as well as hospitals. Data from the Kaiser Family Foundation (the Foundation) indicates that 49,435,610 individuals are currently Medicare beneficiaries (2012 data). The Foundation also records that almost 70 million Americans are enrolled in the Medicaid program, which was significantly expanded by PPACA.[5] Demand for medical services is proportionately significant. Additionally, the increased complexity of medical practice and technology, increased incidence of antibiotic-resistant bacteria, and overuse/misuse of medications contribute to higher rates of adverse events.[4]

The movement of the medical industry toward higher productivity and expensive technology encourages rapid patient flow and overuse of risky and invasive medical procedures, all factor into these staggering statistics.[6–8] Physicians are more likely to be looking at the computer screen, entering a patient's medical information, than looking at the patient's face for telltale signs of medical problems. As more individuals become insured, they will seek medical attention, which increases a physician's exposure to being involved in an adverse event. The Pew Charitable Trust notes that 10,000 Baby Boomers turn 65 every day, and that this will continue until the year 2030, when fully 18% of the U.S. population will be Medicare-eligible, joining a population that uses a large proportion of medical services.

Physician competence

HCQIA established the National Practitioner Data Bank (NPDB). Physicians must report all payments made in the settlement of adverse incidents, and healthcare entities are required to request information from the NPDB for all physicians who apply for appointment to the medical staff or staff privileges. The goal was to improve medical care quality and safety by providing information to assess the professional's competence.

The NPDB is a repository for information regarding adverse professional review actions brought by state boards, adverse professional review actions taken by healthcare entities, and medical malpractice settlements and judgments. There is no minimum dollar threshold for medical malpractice payments and the report remains on physicians' records for the rest of their careers. Failure to report subjects the physician to civil money penalties of up to $10,000 per violation.[9] Although employers are permitted to access a physician's NPDB record every two years, the NPDB records are explicitly not available to the public. Studies suggest that the NPDB information is accurate and fairly complete.[10] Critics of data banking argue that the NPDB has resulted in an increase in use of defensive medicine, in an effort to avoid medical malpractice liability, rather than treating the patient in accordance with the standard of care.

The NPDB provides a uniform platform for shared information regarding a physician's competence. Healthcare organizations are responsible for providing appropriate care to patients both directly as a corporation and indirectly as a principal of employed or contracted

physicians. Therefore, they have a vested interest in identifying "problem" doctors, both before hiring them and while they continue to render treatment within their facilities.

PPACA

As noted earlier, PPACA was enacted to increase the quality of provided care and decrease the cost of health insurance for the consumers and the government. Its mandates, subsidies, and incentives aim to boost the number of insured individuals and to force healthcare providers to strive for better quality and more efficient inter-provider communication.[11]

PPACA was created to promote uniformity in medical practices through well-funded research and widespread guidelines. It created more requirements for disclosing adverse events, such as reporting to The Joint Commission, an independent standard-setting and accrediting body in healthcare. Public disclosure is also provided through the creation of the Physician Compare and Hospital Compare performance websites.

PPACA intended to streamline provider integration by creating incentives to coordinate care systems such as Accountable Care Organizations (ACOs), performance-based care coordination, and payment bundling. Some provisions, such as mandatory electronic health record (EHR) systems, also indirectly forced consolidation or coordination of providers for financial reasons.[12]

As of May 2014, about 20 million Americans gained health insurance coverage under PPACA. The percentage of uninsured persons decreased from 18% in 2013 to 13.4% in 2014. The Congressional Budget Office and the U.S. Congress Joint Committee on Taxation project the following data for each year, 2017 through 2024:

- About 24 to 25 million people will obtain health insurance each year through exchanges;
- About 12 to 13 million people will be added to the Medicaid and CHIP rolls;
- About 6 to 7 million fewer people will obtain insurance through their employers;
- About 5 million fewer people will have no group or other coverage; and
- About 25 million fewer people will be uninsured.[13]

These statistics show a positive trend in enrollment, but they also demonstrate the dramatic increase in exposure for liability that institutions and physicians will face resulting from medial errors.

Vicarious liability in the medical malpractice context

Vicarious liability of an employer is rooted in the legal doctrine "*respondeat superior*," which makes a principal or employer liable for the actions of its agent or employee. Courts have identified three main objectives for upholding the doctrine: (1) to prevent recurrence of the harmful conduct; (2) to assure compensation for the victim; and (3) to hold accountable those who benefit from the enterprise giving rise to the injurious conduct.[14] However, courts have yet to unify a definitive test to be applied to cases involving vicarious liability.

Vicarious liability is established through two basic theories: apparent agency and ostensible agency. A person filing the lawsuit, the plaintiff, can prove apparent agency by first showing that the hospital "holds out" the physician as its employee, when the hospital acts or fails to act in some way, which leads the patient to a reasonable belief that he/she is being treated by the hospital or one of its employees.[15] The plaintiff must show that the patient looked to the institution, not to the individual physician, for care.

Ostensible agency is seen when a reasonably prudent person would be justified in the belief that the care in question was being

rendered by the hospital or its agents or the care in question was advertised or otherwise represented to the patient as care being rendered by the hospital or its agents.[16] If a physician is held out as an independent contractor, the institution is usually not held to be responsible for the physician's actions.

With the growth of healthcare systems and ACOs under PPACA, an institution's liability will likely begin to cross state lines, but there is no national standard for state-based medical malpractice cases.

Expanding liability for healthcare organizations

PPACA reform has caused many solo and small-group practices to become salaried employee-agents of healthcare organizations (HCOs) and hospitals in order to comply with the new and expensive requirements. PPACA's reforms have shifted the power towards enterprises that can buy and coordinate technologies, such as EHRs and case management strategies to meet the demands of the federal government. Increasingly, medical providers are employee-agents of institutional providers instead of independent contractors, which in turn creates agency liability for those institutions.

Apparent agency theory applies to hospitals and other HCOs under vicarious liability for the alleged malpractice of an employee-agent. Principal providers have also been held liable for the actions of independent contractor physicians where the principal has not made it overtly known that the physician is not an employee of the institution. The determinative factor is whether it was reasonable for the patient to believe the care was being received from the institution, not a particular physician.

Under the various PPACA reforms, incentives and forces converge; institutional providers will become directly liable for patient injury as well as vicariously liable for injuries caused by physicians, because agency law will carry liability upstream from agent to principal. With more physicians working for the principal institution, there will be a staggering increase in principal liability for these institutions, whether the physicians are salaried employees or not. The integrated systems will likely blur the lines of the employment-agent relationship and disclosures may not be enough to insulate hospitals from the legal reach of vicarious liability. Across the United States, healthcare systems are branding themselves, thereby creating the impression that all physicians—employees or not—"work" for the healthcare system.

PPACA's effect on vicarious liability

As more physicians become "employees" of the hospital and other healthcare organizations, those institutions will not be able to declare that the physicians were "independent contractors." Institutional vicarious liability is a growing concern because the increased institutional exposure and frequency of liability will likely result in higher insurance premiums for the institution, which will in turn increase patient medical costs.

Conclusion

PPACA has changed the face of the healthcare system in many ways; of particular concern are its effects on the medical malpractice field. Under current federal and state legislation, hospitals and other healthcare institutions are coming under a greater risk of liability than the care providers who actually cause the adverse event, given the increasing employment models and branding as a result of PPACA.

In a hospital setting, it may be difficult for a plaintiff to determine which provider is at fault or there may be several providers whose negligence contributed to the injury. Malpractice law allows plaintiffs to sue the agent, the employer, or both, and it is sometimes more efficient for plaintiffs to solely name the hospital as a defendant. However, this practice puts an unjustly disproportionate

burden on the hospital. Without physicians or other employees joined as defendants, institutions are on the hook for the entirety of any settlement or judgment payouts to the plaintiff. Plaintiff verdicts can quickly reach millions of dollars in absence of damages caps. The hospital must pay out of its business revenue, once it has gone through its insurance ceiling. Placing more of the compensation burden on hospitals increases costs of insurance premiums and business costs. These financial burdens will eventually be carried downstream to the consumer patients, which is the opposite effect that PPACA intended.

This paints an alarming picture for future medical care and frustrates the primary goal of legislative reform over the past 30 years. As is clear from the discussion of vicarious liability, health systems as employers are at an increased risk for potential errors of their healthcare providers. The reality is that compliance and quality of care are intersecting, thereby offering an opportunity to avert potential vicarious liability situations through enforcement of compliance plans.

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by D. Wayne Little

Cracking the ICD-10 code to stay compliant: Meeting the challenge

» Forecast the top ICD-10 concerns pertinent to your organization and how you can effectively monitor them.

» Evaluate how your organization is performing with the ICD-10 transition.

» A large backlog of bills or bill holds, decreased provider productivity, and a queue of discharges waiting to be billed are warning signs of ICD-10 non-compliance.

» Most will not know how well their organization or practice is complying with ICD-10 until several months down the road.

» Until October 1, 2016, Medicare review contractors will not deny valid claims billed under the Part B physician fee schedule, as long as they are submitted with a valid ICD-10 code from the right family.

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The International Classification of Diseases (ICD)-10 coding system went into effect October 1, 2015, replacing the decades-old ICD-9 coding system with 141,000 new diagnosis and procedure codes and definitions. After several postponements, the new clinical diagnostic and procedural codes are in place and the question now becomes, "How are we doing?"

Little

Are we compliant?

For the most part, providers and other key stakeholders have continued to move along without too much anxiety or disruption post ICD-10 conversion. With such a significant change, some might wonder if there should be more concern. Others just assume organizations did such a great job of preparing for the ICD-10 challenges that most providers are compliant.

Unfortunately, while some providers may be at a different level of preparedness and acceptance than their peers, the reality is most will not know how well their organization or practice is complying with ICD-10 until several months down the road.

What are the top compliance issues likely to be?

As the last developed nation to adopt ICD-10, and the only one in the world that relies on these codes for reimbursement, the U.S. is implementing a modification that is vastly more granular and specific than any of our contemporaries. Just as you have probably spent the last year educating, training, and testing your staff and systems for the transition, the next six months will be crucial to meeting compliance milestones by closely monitoring your providers, coders, billing services, claims scrubbers, and clearinghouses. Here is what you need to know:

- **Finding the appropriate ICD-10 code can be difficult if search tools are not logical or as intuitive as busy providers may need.** Additional education post ICD-10 may be needed for your providers, sooner than later, before issues escalate.

- **Lack of code specificity may result in claims rejections.** The new ICD-10 coding convention has gone from a 3-5 character composition to 3-7 characters. Because of the changes in the ICD-10 code structure and definitions, the new level of detail will require greater specificity and, in some cases, different documentation for care provided. You need a good internal edit resolution and denial management process in place.
- **Coders will need greater connectivity with physician resources.** As coders learn the new ICD-10 language, they will need greater access to and alignment with physician resources and clinical documentation processes.
- **Erroneously entered codes can slip through the cracks.** In some environments, professional coding resources may not code or review all codes assigned by providers. Unless your EMR and/or billing systems have the sophistication and functionality to trigger an edit following a physician entry, you will run the risk that a coding resource may never touch the claim. Batten down the hatch with the proper investment in software and technology upgrades.
- **There's no magic right answer or right code**. Payers may follow the Centers for Medicare and Medicaid Services (CMS) closely, but not completely. Because payers are not bound to adopt a universal set of edits, each may have their own unique edits and authorizations that may not map with those of your organization. With the vast number of codes at play, be prepared for a greater chance for variances.
- **CMS will not penalize, hold a claim, or authorize audits for the next 12 months as long as your coding is in the correct family.** According to CMS guidelines, "For 12 months after ICD-10 implementation, Medicare review contractors will not deny physician or other practitioner claims billed under the Part B physician fee schedule through either automated medical review or complex medical record review based solely on the specificity of the ICD-10 diagnosis code as long as the physician/practitioner used a valid code from the right family."[1] Remember, this is not a blanket of freedom—you still need to get the code right so that you don't delay or lose reimbursement in the future. Specificity required for medical necessity or authorizations as well as in National or Local Coverage Determinations will still need to be met.
- **There will be difficulty calculating PQRS quality scores, but penalties will be suspended for twelve months.** According to CMS, "For all quality reporting completed for program year 2015 Medicare clinical quality data review contractors will not subject physicians or other Eligible Professionals (EP) to the Physician Quality Reporting System (PQRS), Value Based Modifier (VBM) or Meaningful Use (MU) penalty during primary source verification or auditing relating to the additional specificity of the ICD-10 diagnosis code, as long as the physician/EP used a code from the correct family of codes."[2]

Be vigilant post ICD-10

As most professionals understand, ICD-10 requires a different structure and logic to comprehend and implement. Intuitively we all understand what needs to be done; however, people can quickly fall back into old patterns once they return from training and are taking care of patients. Keeping watch over the ICD-10 transition will be an important part to achieving compliance. For the most

part, experienced healthcare professionals will know that some risks are imminent. The key is to keep watch and be ready to identify the early warning signs that may lie ahead.

Three common warning signs:

1. Your organization has a large back log of bills or bill holds, because they are stuck in the queue awaiting proper coding, increased specificity, or require other edits.
2. Provider productivity levels have decreased.
3. "Discharged not final billed" levels are increasing.

What you already know is still important

Fortunately, there are several facts regarding the imminent impacts of ICD-10 that you can expect. For instance, we know that everyone covered by the Health Insurance Portability and Accountability Act (HIPAA) is affected by ICD-10, including providers and payers who do not deal with Medicare claims. And for better or worse, we know that we have the same compliance risks after October 1 that we had before September 30. It won't change that much; it will just be wearing a new set of codes and the climb to compliance will be steeper.

Mitigating the risks and minimizing disruption to your claims and reimbursement process will most likely require more time for providers to adequately document care provided, and coders and billers are going to need more time for verifying and processing.

Success in making the transition will likely be in direct proportion to the amount of "connectivity" you have embedded in your organization. It will require improved technological connectivity and interfacing between your electronic medical records and claims editing systems. It will require increased human connectivity between coders and providers, and providers and patients, none of which will achieve much if you haven't already established the underlying clinical documentation excellence needed to avoid errors from code ambiguity and outdated terminology usage.

Conclusion

Only history will tell how quickly and adeptly our industry will adapt to and comply with the massive changes ICD-10 presents. It may well turn out to be our industry's Y2-K. But one thing is certain—the tools that you will use to "crack the code" will benefit your organization and the populations you manage in the long-term. In our quest to get it right, the greater connectivity and specificity it will require may very well lead us into a world where we will welcome improved outcomes, reduced compliance issues, and appropriate reimbursements as "the new normal."

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by Kelly M. Willenberg, MBA, BSN, CCRP, CHRC, CHC

The ABCs of AEs

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Clinical drug and device trials depend upon nurse and study coordinators to report complications or adverse events (AEs) once a patient begins receiving active treatment. The FDA's MedWatch program monitors drug safety with accurate reporting by the frontline healthcare providers. This process demands diligence in capturing the information in a timely manner.

Willenberg

When recording the adverse event, is it imperative that detailed, specific information is reported. Reporting events that occur under an Investigational New Drug (IND) application is mandatory and reports are submitted separately to the FDA as specified in the regulations. These are required to be submitted to the Institutional Review Board as well. The key is to specify the timing of the problem, lab values, and all signs and symptoms the patient has during the episode.

The other piece that should be considered by the study team is the cost of treating an adverse event. If the sponsor agrees to cover the cost of treating adverse events, these must be tracked, and many times, they can be invoiced after the event occurs. Many sites fail to report these to government payers, as billable with codes and modifiers, if the Sponsor is not paying the charges. The site may be pulling the charges from the claim for the patient and moving it to a research account, but never recouping the cost.

An open line of communication can enhance this process. Whether you rely on a clinical trial management system (CTMS), a flag when patients are admitted, or old-fashioned word of mouth, these must be not only tracked for regulatory purposes, but also for billing compliance purposes and contractual obligations.

If the sponsor agrees to cover the cost of treating adverse events, these must be tracked, and many times, they can be invoiced after the event occurs.

Some sites use an alert when patients are treated in an Emergency Room. This can help to identify the adverse events. Conveying this to patients and their families during an informed consent process can aid in making sure that the study team knows when a patient receives treatment anywhere, that may or may not be study-related, even if it is not at their facility or by their doctor.

An operational framework will help establish a process flow for reporting these events to MedWatch, the IRB, and the billing team. Above all, remember that if you tell a patient in a consent form that the sponsor covers adverse events, you cannot bill a payer for those services. The costs of tracking these events to ensure that they are not billed can be time-consuming and difficult.

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by Peggy Beat, Esq. and Tracy Shenk, RN, CCRC

Research compliance and the due-diligence process

» A compliance program risk assessment is essential during a merger and acquisition.
» Clinical research is an area that may be overlooked during the due-diligence process.
» Each study must be reviewed and prioritized according to risks.
» All agreements relating to research must be reviewed.
» Research compliance program due diligence provides an understanding of potential risks.

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Mergers and acquisitions have been defined as "a combination of two companies where one corporation is completely absorbed by another corporation. A merger extinguishes the merged corporation, and the surviving corporation assumes all the rights, privileges, and liabilities of the merged corporation."[1] In today's climate of healthcare reform, it has become exceedingly common for healthcare organizations to acquire physician practices or hospitals. Undoubtedly these trends will grow as predicted by healthcare analysts.

Due diligence is a necessary stage involved with any merger or acquisition. The due-diligence process is a lengthy, complicated, and multidisciplinary-approached practice of reviewing the business to be acquired to identify potential risks in the purchase. As Compliance departments take on a larger role in healthcare organizations, so should their involvement with mergers and acquisitions.

Background

In 1998, the Office of Inspector General (OIG) published a Compliance Program Guidance for Hospitals and then a Supplement seven years later.[2,3] The Compliance Program Guidance for Hospitals outlined the elements of a compliance program, the benefits of a compliance program, its application, and how to measure the effectiveness of a compliance program. The compliance program guidances were developed to detect and reduce the risk of non-compliant behavior. Despite the first release of the compliance program guidance 17 years ago, the growth and awareness of Compliance departments have been on the rise over the past several years.


Beat


Shenk

Compliance program due diligence is the evaluation of compliance risks and determining the effectiveness of the compliance program of the business to be acquired. If the compliance program is deemed as effective, then it is a great defense to any exposures inherited by the merger or acquisition.[4] However, if the compliance program is not effective, then it is crucial to assess compliance risk areas and determine if the identified risks may impact the merger or acquisition.

Merger and acquisition risks

When merging or acquiring another healthcare entity, whether a physician practice or

a hospital, many potential risks need to be assessed. It will often depend upon the size and reach of the business to be acquired. Compliance-related risks may include false claims, Stark Law violations, kickbacks, Health Insurance Portability and Accountability Act (HIPAA) breaches, Emergency Medical Treatment and Active Labor Act (EMTALA) violations, non-compliance with Joint Commission standards, non-compliance with Centers for Medicare and Medicaid Services (CMS) regulations, tax violations, bribery, and countless others. A risk area that may be overlooked and that requires a specific degree of expertise is that of conducting research, especially involving human subjects.

The Department of Health and Human Services (DHHS) defines a human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information." DHHS defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[5] In some instances, human subject research can also be known as clinical trials. There may be a number of general compliance-related due-diligence checklists available, but we determined during a recent acquisition that we needed a checklist specifically focused on research. As a result, a Research Compliance Due-Diligence Checklist was subsequently drafted.

A risk area that may be overlooked and that requires a specific degree of expertise is that of conducting research, especially involving human subjects.

Potential risk considerations

The following broadly summarizes various research areas and the potential risk considerations covered by the checklist.

Study inventory

To initiate the research compliance due-diligence process, we obtained an inventory of all active and ongoing clinical trial studies (see Table 1). This list must be complete and accurate, because it is the foundation for assessing and prioritizing levels of risks throughout the research compliance program due-diligence process. Looking at just a subset of studies will provide a microscopic view of the effectiveness of the practice's or hospital's research compliance program. One of the highest areas of risk is study sponsorship or funding source (e.g. National Institutes of Health [NIH], industry, etc.). The studies with government funding are of the highest risk. Not only is the spending of federal funds highly regulated, but if they are misspent, you may face federal prosecution for fraud.

We also considered knowing and understanding each study type as an important risk area. For studies involving a drug, device, or biologic, the Food and Drug Administration (FDA) regulations must be followed. If the study is observational or perhaps a registry or biorepository, the risks can often involve loss of confidentiality or privacy. Each study is then categorized as "enrolling, or enrollment complete and in followup." It is important to know how many study participants have been enrolled to date, how many are yet to be enrolled, as well as the

Table 1: Inventory of all active and ongoing clinical trial studies

Sponsor or funding source (e.g. NIH, industry, foundation, society)	Study Type (FDA-regulated, registry, etc.)	Status (Enrolling or Enrollment Complete and in Follow-up)	Number of Study Participants Enrolled	Number of Study Participants to be Enrolled	Study Name/ Protocol Title	IRB Expiration Date
Foundation ABC	Registry	Enrolling	1	20	XYZ	12/31/15
Company XYZ	Device	Follow-up	5	5	ABC	12/31/15

Institutional Review Board (IRB) expiration date. Knowing where enrollment numbers are for each study can indicate whether the study just started or how close it is to being completed. All of these factors help in prioritizing which study(ies) to review first and foremost. If constructed well, this table will continue to expand with other essential factors while proceeding through the research compliance due-diligence process.

Contracts and awards

Beginning with the highest-risk study, the clinical trial agreement (CTA) or terms and conditions of the award requires consideration. A clinical trial agreement is a legally enforceable and binding written agreement between the sponsoring organization and the research entity. CTAs outline arrangements between the two parties and set forth all rights and responsibilities for the performance of a research activity or project. Some of the material terms to include in the review are data ownership, intellectual property rights, rights to publish, indemnification, research-related injury, and payment terms.

Data ownership and intellectual property rights

A key concern in CTAs is data ownership and intellectual property. If the study sponsor wrote the protocol, provided the case report form, and reimburses study-related expenses, then typically the study sponsor will own the data. The study sponsor has intellectual property rights vested in the study product and/or the results of the research study, but the practice or hospital has a legitimate right to protect the inventions and other intellectual property developed by an employee during the study. It is important to know whether these rights were preserved.

Publications

Typically, research and education is part of the mission of a non-profit or tax-exempt organization. If the organization acquiring a physician practice or hospital has a non-profit or tax-exempt status, then it is essential that the CTA allows for publication of study results in order to maintain that status. Further, the study sponsor should not be permitted to censor any adverse medical findings or any other portion of the study.

Indemnification

Indemnification refers to third-party recovery. The CTA should provide for mutual indemnification and should not offer more than what the study sponsor is providing. Generally, there should not be indemnification of a contract research organization that is working on behalf of a study sponsor.

Research-related injury

Recovering the costs for adverse events and research-related injuries that occur during the

course of the study is a hot topic. Many study sponsors try to carve this out, setting provisions for subject conduct under which they will not pay or reimburse for research-related injuries. When reviewing this section of the CTA, it is important to assess if there have been any subject injuries, and how were they handled.

Payment terms

Review of the payment terms of the CTA can uncover potential legal issues. Physician practices and hospitals must charge the study sponsor fair market value for the services and procedures provided as part of a research study. Incentives and bonus payments for meeting study targets or accelerated enrollment are not acceptable.

Although a CTA is one of the more common contracts, a CTA may not be the only contract required for conducting research. It is important to inquire if there are other types of contracts or third-party arrangements for research-specific activities, such as service agreements for labs or imaging. These types of arrangements need to be carefully reviewed for possible Stark or anti-kickback situations. Other contracts may include data use agreements, business associate agreements, or consulting agreements.

If there is study sponsorship from federal or state governments, those awards need to be carefully reviewed to ensure that the practice or hospital to be acquired was compliant with their terms and conditions. Some examples on the federal side might be the NIH, Department of Defense (DOD), FDA, or the Veterans Administration (VA), just to name a few. With those awards come very stringent rules and methods that specify how a researcher can spend the funds awarded as well as the means for cost accounting.

Clinical research billing

From beginning to end, clinical research billing is a cumbersome and arduous process. CMS's Clinical Trials Policy allows for payment of routine services provided as a part of a clinical trial.[6] Of course, that policy comes along with several criteria and caveats. Nevertheless, it allows for Medicare beneficiaries to participate in clinical trials. Due to fraud and abuse concerns, it is vital that a coverage analysis is performed prior to commencing a clinical trial. A coverage analysis helps to distinguish between the items and services which are allowed to be billed to Medicare (or any insurance), based on national and local coverage determinations. Hence, reviewing the practice's or hospital's process for conducting a coverage analysis is crucial. If no coverage analyses were conducted, it is necessary to understand and evaluate the potential risks of each study, taking into consideration charges to and payments from Medicare for standard of care vs. research-related charges.

Further, the Medicare Claims Processing Manual mandates that claims for clinical trials and registries have the appropriate modifiers (Q0/Q1), condition codes (30 or 53) and/or revenue codes (0624) applied in certain instances.[7] Most recently, CMS began to require the National Clinical Trial (NCT) number be included on the claim. If the NCT is not appropriately attached, then denial of the claim is highly possible. The acquiring healthcare organization would need to be aware if there is a risk for potential false claims.

Finances

Obtaining a full understanding of the current financial records for each research project as well as the process of credit/debits for research expenses is important for assessing related risks that would be acquired. One item that can assist in this review is obtaining a statement from the practice or hospital regarding their current accounting methods. If the entity has received federal funding or grants, determine whether government A-133 audits are required.

The Office of Management and Budget (OMB) Circular A-133 is a single audit, organization-wide examination of an entity that expends $750,000 or more of federal assistance received for its operations.[8] If the entity has received an audit, request a review of the findings; or access government websites to see if an audit has been filed, because these are public documents. Ensuring that the funds have been spent in accordance with the terms of the contract or award is an essential piece of the research compliance due-diligence process and should not be overlooked.

Conflicts of interest

In an age of transparency, there is an expectation that a healthcare organization will disclose relationships between physicians and industry. Over the past several years, these relationships have been scrutinized by the public and government entities. Conflict of interest is a relationship between the private interests and the official responsibilities of a person in a position of trust. In addition to federal regulations regarding conflicts of interest in research regarding disclosure and management, conflicts of interest could prejudice an individual's ability to perform his/her research duties and responsibilities objectively. Larger healthcare organizations generally have a *de minimus* threshold coupled with a process to review and manage these types of relationships. The risks relating to unmanaged relationships in research can be very high. If it appears that the practice, hospital, or research investigator has an apparent conflict, then the conflict should be evaluated prior to the completion of the acquisition.

Audits and inspections

Any time a clinical trial involves an FDA-regulated product, such as a drug or device, it can open the door to a FDA audit. Therefore, it is reasonable to inquire about any FDA inspections and whether any have any resulted in the issuance of a FDA Form 483 and/or a warning letter. If a FDA Form 483 and/or warning letter has been received, it is important to assess any corrective action plans to ensure that they have been implemented along with measures to prevent future recurrence.

Although allegations and/or findings of research misconduct do not frequently occur, it remains a valid question during the research compliance due-diligence process.

Although allegations and/or findings of research misconduct do not frequently occur, it remains a valid question during the research compliance due-diligence process. The DHHS Office of Research Integrity defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."[9] If there has been an allegation or finding, then a deeper review of the details needs to occur in order to understand any potential sanctions for participating in research.

Sampling and study review

Following the risk model previously suggested, a sampling of studies should be reviewed for indications of non-compliance. Those items reviewed should include any protocol waivers or violations, unanticipated problems, subject death or injury, and serious adverse events, as well as the signed research Informed Consent forms. When reviewing the consent forms, ensure that all of the required elements (in accordance with federal

regulations) are included in the consent; likewise when reviewing the HIPAA authorization, which can be included within the research consent or be a separate stand-alone document. The HIPAA authorization must contain the elements for permitting a valid authorization or documentation of an alteration or waiver approved by an IRB.

Conclusion

Performing a merger or acquisition due-diligence process of a practice's or hospital's research program can be easily overlooked. Although the Research Compliance Due Diligence Checklist may not be an exhaustive list of items to review, it does provide a means to start understanding the risks that a healthcare organization may inherit with a merger or acquisition. We have focused on the higher-risk areas and there are certainly more than what we have discussed.

A serious, meaningful, and effective research compliance program, implemented by the practice or hospital being acquired, can reduce the risk of research compliance surprises after the merger or acquisition is finalized. A research compliance due-diligence process will provide an understanding of the effectiveness of the research compliance program and shed light on the many risks that may be acquired.

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by Harry R. Silver

The *Kane* decision: A flawed interpretation of the 60-day rule

» *Kane v. Healthfirst, Inc.* is the first decision by any court to interpret the meaning of the word "identified" as used in the 60-day rule.

» In *Kane*, the court ruled that the 60-day clock starts ticking when a provider receives notice of a possible overpayment.

» The decision was a ruling on a procedural motion, not on the merits.

» The court's analysis of the issue is flawed and its definition of "identified" is by no means definitive and should not be treated as the final word on the issue.

» In reaching its decision, the court ignored CMS's proposed regulations, which provide the only guidance from the government on the meaning of the word "identified" in the 60-day rule.

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As anyone involved in healthcare compliance is undoubtedly aware, the Affordable Care Act (ACA) requires providers (and suppliers) to report and return any overcharges to Medicare or Medicaid within 60 days after such overpayments have been "identified." Because the ACA does not define "identified," it is far from clear exactly when this 60-day time period commences. Because a failure to meet the 60-day deadline constitutes a violation of the federal False Claims Act, a wrong guess about when the 60 days begins can have severe consequences. As anyone who has grappled with the identification and quantification of overcharges knows, this is not a simple matter.

Silver

First, every regulatory violation does not necessarily result in an overpayment. More to the point, however, when confronted with a credit balance, a provider must determine the source or sources of the credit balance and the amount attributable to each payer, including whether Medicare was primary, secondary, or tertiary. In many cases, this task is virtually impossible to complete within 60 days. That is why a definition of the term "identify," which marks the beginning of the 60-day period, is so badly needed.

On August 3, 2015, the United States District Court for the Southern District of New York became the first court to attempt to define "identify." In *Kane v. Healthfirst, Inc.*,[1] the court acknowledged the practical problems inherent in identifying and quantifying an overpayment. Nevertheless, the court determined that an overpayment has been identified when a provider receives information indicating that there is the possibility of an overpayment. The government and whistleblowers are likely to view the *Kane* decision as the definitive interpretation of the meaning of the word "identified." For the reasons discussed in this article, the court's analysis of the issue is flawed and its definition of "identified" is by no means definitive and should not be treated as the final word on the issue.

Because the 60-day rule is part of a series of amendments to the False Claims Act (FCA), most recently by the ACA, any discussion of the *Kane* decision should begin with a brief summary of the FCA and its various amendments.

The False Claims Act

A violation of the FCA typically consists of "knowingly" presenting a false or fraudulent claim for payment or approval.[2] Any person who is found to have violated the FCA is liable for a civil penalty of $5,500–$11,000 per claim, plus treble damages. This can result in healthcare providers facing potential liability in the hundreds of millions of dollars.

The terms "knowing" and "knowingly" are defined as "actual knowledge" that a false claim has been submitted, "deliberate ignorance" of the truth or falsity of the claim, or "reckless disregard" of the truth or falsity of the claim.

The FCA allows an action to be initiated by either the United States or by a private citizen, who is entitled to up to 30% of any recovery.[3] Actions initiated by private citizens (relators) are called *qui tam* actions.

The FCA was initially enacted in 1863, and was substantially amended in 1943, and in 1986. Although the FCA had been aimed at fraud by government contractors, it increasingly focused on healthcare fraud after the 1986 amendments.

The FERA and ACA amendments to the FCA

In May 2009, the FCA was amended as part of the Fraud Enforcement and Recovery Act of 2009 (FERA) in an effort to prevent fraud in connection with federal stimulus funds. The FCA was amended again in 2010 as part of the ACA.

One of the 2009 FERA amendments to the FCA was the expansion of the so-called "reverse false claims" provision, which made the avoidance of an "obligation" to pay money to the government an FCA violation.[4] The 2009 amendment made the avoidance of an obligation to pay the government a violation of the FCA, even if the avoidance of the obligation did not result from the submission of a false record or statement.

Following up on the FERA amendment, in 2010 the ACA made additional substantive changes to the reverse false claims provision by (1) requiring any person who has received an overpayment to return it, and report the reason for the overpayment to the payer within 60 days after the overpayment has been identified; and (2) defining the retention of an overpayment after 60 days as an obligation for purposes of the reverse false claims provision.[5]

Because the ACA failed to define several critical terms, such as "identified," it is far from clear when the 60 days start running. In what was hoped to be a clarification of the statutory language, on February 14, 2012, the Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare and Medicaid programs, published proposed regulations. CMS proposed to define an overpayment as being identified when a person has "actual knowledge of the existence of an overpayment, or acts in reckless disregard or deliberate ignorance of the overpayment." The 60-day clock does not start running (i.e., an overpayment is not identified) until after the provider has an opportunity to undertake a "reasonable inquiry" into the basis of a suspected overpayment. The receipt of information, by a provider or supplier, about a possible overcharge creates a duty to conduct this reasonable inquiry promptly ("with all deliberate speed"). A failure to do so may be found to constitute reckless disregard or deliberate ignorance of the overpayment under the FCA.[6]

Although the proposed regulations remain just that, and CMS has deferred the issuance of final regulations until February 16, 2016,[7] the statutory duty to report and refund overpayments within 60 days remains in effect and exposes providers and suppliers to civil false claims liability.

Factual background

This recitation of the facts is taken from the court's decision. Because the court was ruling on a motion to dismiss, the court relied largely on the allegations of the plaintiffs.

The *Kane* case involved three hospitals in New York City (the hospitals), which were members of a hospital network operated by Continuum Health Partners Inc. (Continuum). The hospitals belonged to the Healthfirst Medicaid managed care network. Under its contract with New York Medicaid, Healthfirst provides covered services to enrollees in its Medicaid managed care program in exchange for a monthly payment from the New York Department of Health (DOH). Healthfirst is limited to this monthly payment and may not bill for any additional amount.

Healthfirst issues computer-generated electronic remittance statements to its participating providers indicating the amount of payment due for services rendered by the provider. The remittance statements contain codes indicating whether the provider can seek additional payment from any secondary payer. Beginning in 2009, an error in the software that generates the remittance statements resulted in remittances that erroneously contained the code authorizing providers to seek payment from secondary payers. As a result, claims were submitted to DOH on behalf of the hospitals for additional payment to which the hospitals were not entitled. DOH compounded the error by paying many of these claims.

In September 2010, state auditors raised questions regarding these erroneously paid claims and the software error was soon discovered. The software vendor furnished a corrective patch within three months.

Continuum assigned one of its employees, Robert Kane, to identify the claims containing the erroneous billing code. In February 2011, Kane sent an email to Continuum management, attaching a spreadsheet that identified more than 900 claims that contained the erroneous billing code, and advising management that further analysis was required to confirm that the 900 claims were, in fact, improper. Four days after sending the email, Kane's employment was terminated by Continuum. It was subsequently determined that approximately 50% of the claims identified by Kane did not result in an overpayment. Shortly after his termination, Kane initiated a *qui tam* action under the FCA. After investigating, both the United States and New York State intervened in the action, and the United States took over its prosecution. (For the sake of simplicity, Kane, DOH, and the United States shall collectively be referred to as "the government.")

The government alleged that, while Continuum commenced repayment of the overcharges in April 2011, the overpayments were not repaid in full until March 2013, thus demonstrating that Continuum fraudulently delayed repayment for two years after knowing the extent of the overpayments. Indeed, the government alleged that Kane's email and spreadsheet identified overpayments within the meaning of the 60-day rule, thus triggering the duty to report and return them within 60 days. The government further alleged that, rather than fulfilling its obligation, Continuum never even advised the New York State auditors of the existence and the content of Kane's analysis. Thus, according to the government, the hospitals, Healthfirst, and Continuum (the defendants) violated the FCA by "intentionally or recklessly" failing to take the necessary steps to identify the claims erroneously filed and to repay the overpayments in a timely manner.

The court's ruling

The defendants filed a motion to dismiss the complaint, contending that Kane's email and spreadsheet only provided notice of *potential* overpayments, and that this alone is not sufficient to trigger the commencement of the 60-day clock. The defendants argued that "identified" means "classified with certainty," while the government contended that "identified" means being put on notice that a claim *may* have been overpaid.

Because the term "identified" had not been defined in the ACA, and because *Kane* was the first case to raise the issue of the meaning of "identified," the court examined the "plain meaning" of the ACA, the legislative history of the ACA and the FCA, the policies underlying the 60-day rule, and the manner in which CMS has interpreted "identified" for purposes of the 60-day rule. The court did not consider the agency's interpretation to be worth much, if any, weight, but it did mention that CMS's regulations interpreting the 60-day rule for purposes of Medicare Parts C and D supported the government. While noting the existence of the more relevant proposed regulations interpreting the 60-day rule for purposes of Medicare Parts A and B, the court simply concluded that they contemplated the adoption of "the same definition of 'identified' that was adopted for Medicare Parts C and D."[8] In so doing, the court failed to recognize that the definition of "identified" in the adopted regulations for Parts C and D is not the same as the proposed definition for Parts A and B. The court also failed to recognize that the reimbursement mechanisms for Part C organizations and Part D sponsors are not the same as those for Part A and B providers.[9] Thus, contrary to the proposed regulations, the court concluded:

> To define "identified" such that the 60-day clock begins ticking when a provider is put on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained, is compatible with the legislative history of the FCA [as amended by FERA].[10]

The court acknowledged that this interpretation can impose a demanding, or even unworkable, burden on providers. According to the court, even if a provider undertook an internal audit immediately upon receiving notice of a possible overpayment, advised the government on the 60th day that it had not yet identified and returned every overpayment, on the 61st day that provider would be in violation of the 60-day rule and the FCA because "[t]he ACA itself contains no language to temper or qualify this unforgiving rule; it nowhere requires the Government to grant more leeway or more time to a provider who fails timely to return an overpayment but acts with reasonable diligence in an attempt to do so." To ameliorate this harsh result, the court would rely on "prosecutorial discretion" to preclude the initiation of an enforcement action "[w]hich would be inconsistent with the spirit of the law and would be unlikely to succeed."[11] Of course, such prosecutorial discretion would not inhibit a *qui tam* relator, such as Kane, from initiating an action.

On the other hand, the court stated that if Kane's email did not "identify" overpayments, the government would have no recourse if a provider did nothing to investigate information about possible overpayments, such as the information provided by Kane. The court stated:

> It would be an absurd result to construe this robust anti-fraud scheme as permitting willful ignorance to delay the formulation of an obligation to repay the government money that it is due.… Therefore, while the Government's interpretation would impose a stringent—and, in certain cases, potentially unworkable—burden on providers, Defendants' interpretation would produce absurd results.[12]

Implications of the *Kane* Decision

In *Kane,* the court defined the identification of an overpayment, for purposes of commencing the 60-day clock, as the time a provider is put on notice of a *potential* overpayment. This should not be taken as the final, definitive word on the subject for several reasons.

First, the court was deciding a motion to dismiss, which is a procedural pretrial ruling—not

a decision on the merits of the case. As such, it is not the court's final ruling on the issue, and is certainly not binding precedent in any court.

Second, to the extent the court's ruling is governing law anywhere, it is limited to the Southern District of New York, the federal judicial district in which it was decided, which covers Manhattan, the Bronx, and six upstate counties in New York State (i.e., Westchester, Rockland, Orange, Putnam, Sullivan, and Dutchess).

Finally, and perhaps most importantly, CMS's proposed regulations applicable to Medicare Parts A and B, state that a provider's receipt of information concerning a potential overpayment creates a duty to undertake a reasonable inquiry, "with all deliberate speed," to determine whether an overpayment has, in fact, been received. An overpayment has not been identified unless and until the reasonable inquiry has determined that an overpayment has been received. It is only then that the 60-day clock starts to run. The final regulations applicable to Parts C and D are not inconsistent with this.[13] In ruling that the language of the ACA does not permit the extension of the deadline for reporting and returning overpayments beyond 60 days after the receipt of information about a possible overpayment, the court unnecessarily rejected CMS's interpretation.

Conclusion

To violate the FCA, a defendant must be found to have acted with actual knowledge, reckless disregard, or deliberate ignorance of a false claim. A provider that, in good faith, conducts a prompt and thorough examination of a possible overpayment, but does complete it within 60 days, simply cannot be acting with the requisite knowledge, reckless disregard, or deliberate ignorance for FCA liability. The proposed regulations provide the only guidance from the government on the meaning of "identified" for purposes of determining when the 60-day clock starts to run.

The definition of "identified" in the *Kane* decision is an unworkable one because, in many cases, it is virtually impossible report and return overpayments within 60 days of receiving information that there *may* be overpayments. Because it is just this sort of situation that the proposed regulations were intended to address, the court did not have to interpret the meaning of "identified" in a manner that can leave many well-meaning providers subject to FCA liability. It certainly did not have to issue such a harsh ruling in order to decide the case because, if the allegations made by the government in the *Kane* case are proven, the defendants would be liable under the standard set forth in the proposed regulations.

The inevitable question remains: How can a provider protect itself given the absence of a clear definition of "identified." Although this should not, under any circumstance, be considered legal advice, I have advised clients who have been notified of possible overcharges to immediately undertake an investigation as contemplated by the proposed regulations. This investigation can involve legal counsel and/or accountants. A memo to file should then be prepared specifying the date on which the information was initially received, the nature of the information, the steps undertaken to initiate an investigation, and the date on which the steps were taken. The memo should also include a notation that these actions have been taken in reliance on the guidance provided in the proposed regulations. The progress made, and the status of the investigation, should be documented in a monthly updated memo to file.

1. 2015 WL 4619686
2. 31 U.S.C. §729 (a).
3. 31 U.S.C. §3730 (b), (d).
4. 31 U.S.C. §3729 (g).
5. 42 U.S.C. §1320a-7k (d)(3).
6. 77 Fed. Reg. 9179,9182 (Feb. 16, 2012).
7. 80 Fed. Reg. 8247 (Feb. 17, 2015).
8. 2015 WL 4619686 at *15-16.
9. 79 Fed. Reg. 29844, 29920-29924 (May 23, 2014).
10. 2015 WL 4619686. at *11.
11. *Id.* at *13 (emphasis added).
12. *Id.* at 13-14.
13. See 42 C.F.R. §422.326

by Maggie Perritt, BS, RPh, MBA, CHC

"Who am I?"—Branding your compliance program

» A compliance program provides critical support to a company's reputation.
» Having a strong compliance program shows that you take "doing the right thing" seriously.
» Developing a strong positive brand reinforces a strong culture of compliance.
» Developing a brand doesn't happen overnight. It takes time and thought.
» Once established, your brand is your reputation. Take care of it.

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What do you think of when you hear the word "brand"? For most people, they think of an image similar to the golden arches of McDonalds or the Nike swoosh. Branding is the use of a logo, an image, or a feeling that is conveyed when the image is seen or the name is heard. Branding and maintaining a positive image are associated with that.

Perritt

Although most people don't automatically associate compliance with a positive image, they should. Most people may associate compliance with something bad, because it could involve a negative situation. At WellCare Health Plans, we have discovered that the right branding can change the image of a Compliance department.

A compliance program is actually something good, because it provides critical support to a company's reputation. Instead of looking at a Compliance department as a type of police effort, it's better for organizations to focus on the value it provides to ensure compliance with requirements. Developing a strong positive brand for your Compliance department reinforces a strong culture of compliance and facilitates a strong collaborative relationship between your Compliance department and other departments within your organization.

Where do you start?

Developing a brand isn't easy. It takes time and thought. Some key questions to ask as you develop the components of your own compliance brand include:

- Who is your customer?
- What are your department's competencies?
- What value do you bring to your organization?
- What characteristics distinguish your department, and how does it do business?
- What message do you want to convey?

You can begin to build your brand concept once you've answered those questions. This too is not an easy task and takes time. Ultimately, you want your brand to convey some or all of the answers to those questions in just a few words.

HCCA's Corporate Compliance & Ethics (CC&E) Week is another great place to start. During CC&E Week, you have an opportunity to educate and celebrate compliance in your organization. HCCA has a number of marketing tools available to assist Compliance departments of any size. And if you have already established your brand, you can capitalize on CC&E Week to promote and reinforce it.

Our path to branding

Four years ago, we set out to establish our Compliance department brand at WellCare Health Plans. We started by positioning the department as a resource whose function was to help associates and encourage them to take an active role in the compliance of our company. It became clear that our associates were the key, so we developed the tagline "Key to Compliance," and our brand was born.

Initially, we hosted an event and encouraged associates to socialize with the compliance team. As part of our celebration, we developed a keychain with a plastic key to promote our compliance hotline phone number. We distributed keychains among associates to remind them that they are the "key to compliance." Also, our internal creative team created a cartoon character incorporating a key. We call the character KC (as in the Key to Compliance). We used KC on collateral and posters promoting the event.

Over the years, we've continued to build our brand. Each year as we launch CC&E Week activities, we create events using our brand and the compliance message we want to convey. We tie every event component, statement, piece of literature, or activity to our concept and brand.

In the program's second year, we introduced a baseball-themed event that featured KC as a baseball player. In our marketing materials, we focused on the compliance team and what we do for the organization. At the same time, we encouraged associates to step up to the plate. We introduced additional signage around HIPAA, compliance and ethics topics, as well as other tools that continued to reinforce our branding.

During the third year, we introduced a superhero-themed celebration and encouraged each associate to be a superhero and identify potential fraud, waste, or abuse. Our very own KC morphed into Kaptain Compliance as part of the branding effort.

In 2015, our fourth year, we took a different approach and developed the MOCHA—The Museum of Compliance, HIPAA, and Audit. We developed our own art gallery using our beloved KC and showed how compliance has evolved through the ages. In an effort to reinforce the message that associates need to be engaged in compliance, we encouraged associates to show us what compliance means to them. The collateral we developed was tremendous, but nothing is more powerful than having an associate demonstrate what compliance means to them through art.

In addition to CC&E Week activities, we have distributed quarterly compliance newsletters, computer messages, telephone enhancements, and training activities to continue to build on our brand and reinforce our message.

Parting thoughts

Having a strong compliance program shows others that you take "doing the right thing" seriously. Branding your compliance program clearly indicates the impact your compliance team has on an organization. The branding process is best when it is controlled and deliberate. Think of the brand examples mentioned at the start of this article. They didn't happen overnight. It has taken most companies years, sometimes decades, to fully develop their brand.

Lastly, it's important to remember that once you establish your brand, it is associated with your reputation. Be as cautious with your brand as you are with your reputation. As hard as you worked to build it, it only takes one bad interaction to destroy it. Maintain your brand image and what you stand for. Be cautious in how you use your brand. Consider what might occur if it's misused. And carefully plan and weigh the best time and place to use your brand.

by Robert Foster, CCCO

Staying compliant while navigating the new world of self-pay collections

» Listen to the consumer's needs.
» Learn from the information obtained.
» Lead them down a path that helps them.
» Consult your Compliance department.
» Talk with your peers.

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We all know the Affordable Care Act (ACA) in itself leaves several unanswered questions to the future of self-pay collections. In short, the ACA is a game changer. Many hospitals are asking how they can prepare for dealing with a new class of insured patients and plans, while keeping a customer service mind set and a strong Compliance presence.

Foster

With the rollout of the ACA, millions of previously uninsured people are now insured through public exchanges. It can be said that people with insurance are more likely to pay than those who are not insured. That in itself brings up two interesting points. First, what is the scale we are talking about? Second, what is the Compliance and customer service impact to those new patients who are now insured?

In terms of sheer volume, more than 910,000 people enrolled during the ACA 2014 open enrollment period (Oct. 1, 2013–April 15, 2014). Of those, nearly 50% were uninsured. Those newly insured are taking full advantage of this newly acquired coverage as well. A large national healthcare system with 160+ hospitals experienced a 20% increase in ER visits and a 23% increase on the inpatient side between January 2013 and January 2015.[1]

However, this new insurance coverage from the ACA comes at a greater price. The same healthcare system between 2013 and 2015 experienced a 57% increase in ER visit balances as well as a 37% increase in inpatient balances after insurance had processed.

Hospitals are faced with dealing with patients who now owe a debt that they are not used to seeing. It's not as simple as using a local business office to place calls to the patient and ask for payment. State laws, federal restrictions, and customer service issues make it almost impossible to keep up with this new market of patients. It's also not just those restrictions that hamper collections. A large percentage of these new patients come from a generation that is more educated and knowledgeable as well as tech savvy. They have higher expectations and lower tolerance for inefficiency and poor service.

Taking these facts into consideration, you are now faced with the problem of how to collect from the consumer/patient while providing excellent customer service and staying compliant in a highly litigious environment driven by oversight of the Telephone Consumer Protection Act (TCPA), Fair Debt Collection Practices Act (FDCPA), and the Consumer Financial Protection Bureau (CFPB).

The best way to stay in compliance can go hand in hand with giving the best customer service. You can focus your staff to turn any uncomfortable situation into a positive outcome by using the following three Ls:

- Listen to the consumers' needs
- Learn from the information obtained
- Lead them down a path that helps them

It's paramount to keep in mind that these patients are using a new service. The fact of the matter is that some believed all services are covered at a 100% rate. When contacting them for payment, difficult conversations will usually follow. However, it's how you help guide the operations staff in dealing with those consumers that will lead to a reduction in complaints to state agencies.

1. Statistics are from a proprietary Parallon client survey.

by Cindy Hart, LPN, CPA, CPC, CHC; Walter E. Johnson, MSA, CHC, CCEP-I, CHPC; and Adam K. Weinstein, MBA, MPA, FACHE

Compliance 101

The seven essential elements, Part 7: Response & prevention

- Failure to demonstrate effective response and prevention might discredit the compliance program.
- The success of a compliance program depends on the skills of the compliance officer.
- Act immediately to avoid a potential *qui tam* lawsuit.
- The compliance officer should maintain detailed notes of the investigation.
- The 4th Amendment of the U.S. Constitution guarantees people the right to be secure in their persons, papers, and effects against unreasonable searches and seizures.

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As the recently appointed compliance officer (CO), you have done your due diligence to establish a compliance infrastructure that reflects the recommendations outlined in the Federal Sentencing Guidelines. Since your appointment, you have been establishing rapport throughout the organization, obtaining support from the board of directors and senior management, and receiving accolades for the compliance activities implemented thus far. Failure to demonstrate the implementation and a working process for this final element (Response and prevention) has tremendous potential to discredit the compliance program and worse, damage the organization's public image and weaken its financial stability.

Overview of Response and prevention

As the CO, you are expected to be independent, conservative, and fair in your dealings. At first glance, you might think "fair" means that everyone and everything is treated exactly the same way. However, your response to alleged violations depends on the situation. For example, overpayments would be handled differently than employee theft and differently than harassment.

In *The Characteristics of a Great Compliance Officer*, Nicole H. Waid describes a good compliance officer as one who is fair and who assesses all the facts and circumstances before reaching a conclusion. "The success of a corporation's compliance program is dependent on the success and skill set of the compliance officer."[1]

To conduct a thorough investigation, a CO may decide to involve directors from other departments, such as Health Information Management, Information Technology Security,


Hart


Johnson


Weinstein

Audit, Risk Management, or Human Resources. The CO may subsequently involve Legal if the circumstances found during the investigation warrant a legal opinion.

Fortunately, the CO can rely on guidance documents to help steer actions and decisions. The Office of the Inspector General (OIG) developed a series of voluntary compliance program guidance documents directed at various segments of the healthcare industry (e.g., hospitals, nursing homes, durable medical equipment suppliers, third-party billers) to encourage development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirments.[2] Your first step might be to involve legal counsel, especially in the event of overpayments or employee theft.

Act immediately to avoid a potential *qui tam* lawsuit. Ignoring or delaying your response can alienate staff, especially the individual who reported the claim. If you deem it necessary, notify legal counsel and develop an investigation plan. Depending on the situation, you might decide to engage external counsel. With the advice of counsel, you should decide whether to conduct the investigation under attorney-client privilege. In any event, a thorough, objective investigation should be conducted. (See our article on Element 5, Reporting & investigation, in the July 2015 issue of *Compliance Today*). The OIG requires prompt reporting to government authorities within a reasonable period. The reasonable period is defined as not more than 60 days after credible evidence is found; to avoid stricter fines, you should report within 30 days of the discovery of credible evidence.[3]

Detailed documentation is critical. The CO should maintain detailed notes of the investigation, including the nature of the allegation, who was interviewed, interviewee responses, when and where the investigation took place, location of any supporting documents or other evidence, the actions taken, and any other outcomes of the investigation.

The role of the CO during a government investigation is to protect the organization while cooperating with and monitoring the actions of the government investigators.

Sometimes the government notifies the organization of an alleged violation, such as a *qui tam* allegation. In this situation, the government conducts the investigation. The role of the CO during a government investigation is to protect the organization while cooperating with and monitoring the actions of the government investigators. In *Compliance 101*, Troklus and Warner suggest the following when dealing with a government investigation:

- Policies and procedures should explain how to handle contact from the government.
- Policies and procedures should spell out who is responsible in the event of a search warrant or subpoena (usually the CO).
- Notify legal counsel immediately.
- All nonessential staff should be sent home or relocated during the search.
- Only identified documents can be searched. The CO must be present and keep a detailed account of all activities and an itemized inventory of documents inspected and documents removed from the premises.[4]

The 4th Amendment of the U.S. Constitution guarantees people the right to be secure in their persons, papers, and effects against unreasonable searches and seizures. A search requires probable cause, which exists when a reasonable person has an honest belief that the objects sought are linked to the commission of a crime, and that those objects will be found in the place to be searched and the items to be seized. The investigating officer has no discretion; the investigating officer must follow the description on the face of the search warrant.[5]

Impact on program elements

A summary of the other six elements follows, with examples showing how an effective compliance program would impact each scenario.

Standards of conduct

Response and prevention contributes to the determination of whether an organization's Standards of Conduct (SOC, also called a code of conduct) are words on paper or words in action. Remember, a key aspect of the SOC is that they apply to everyone within the organization. Using the working assumption that everyone has developed an understanding of what is expected under the SOC (through the application of an effective training and education program), people know essentially what is allowed and what is not allowed in terms of behavior. In addition, these same people also understand what to expect if they or others demonstrate non-compliant behavior. This is where the response and prevention element provides a tangible illustration as to how committed an organization is in its implementation of its compliance program. If people witness non-compliance followed by a non-response by the organization, what is the basis for anyone to make the connection that the organization is serious about maintaining an effective compliance program? The answer is simple. There is no basis. In fact, it would not be unreasonable to make the assumption that the lack of response to detected non-compliance actually promotes the idea that the compliance program is ineffective or that the behavior is condoned.

> ***Example of non-compliance:***
> An employee reports seeing pictures on social media of a hospital vendor and other hospital employees at a dinner party. An investigation ensues. After interviewing all parties, it is determined that the vendor paid for the dinner party for the participating employees, and that no other gifts or money were received by the employees. To resolve these issues, the employees are re-educated and provided with a reminder of the gifts and entertainment policy and its meaning.

Additionally, members of the organization begin to realize that the organization's actions in cases like this speak volumes to its commitment in upholding the values and expectations codified in the SOC. People are going to formulate and own their perspectives about the organization's SOC based on what they see or experience, whether directly or indirectly. Certainly the SOC clearly describe what is also considered compliant behavior. However, most people would likely agree that organizations are probably more known by their employees

People are going to formulate and own their perspectives about the organization's SOC based on what they see or experience…

for how they respond to transgressions versus how expected behavior is acknowledged and recognized. This may be one area that is ripe for development. If the CO can build and promote activities that bring positive attention to those who support the SOC through their actions, it will help drive the point that the organization is totally committed to its SOC, rather than the impression that the organization and, just as importantly, the CO are just focused on non-compliance.

Compliance Officer and Compliance Committee

Hiring the right person as the compliance officer epitomizes response and prevention. An experienced CO performs risk assessments, conducts audits, monitors adherence to policies, and provides education to the organization. A skilled CO is visible and makes himself/herself available to all within the organization. The CO responds in a timely manner to all reports of non-compliance and establishes procedures to prevent non-compliance. The CO does not just report to the Compliance Committee. The CO develops a rapport based on trust and action. The CO and the Compliance Committee work together to reduce risk to the organization.

Responding promptly and fairly to reports of non-compliance is essential to the success of the organization. Fair responses result in higher morale and engaged, motivated employees. As the saying goes, an ounce of prevention is worth a pound of cure. That is certainly true when it comes to the CO's role of preventing risk to the organization.

Responding promptly and fairly to reports of non-compliance is essential to the success of the organization. Fair responses result in higher morale and engaged, motivated employees.

Example of Compliance teamwork:

An organization allows employees to partake in social media activities during their breaks. The organization's IT department has established controls that disable access to identified social media sites after 30 minutes of daily accumulative use. The CO receives notification that employees are using their 30 minutes to share work-related activities. After conducting an investigation, the CO determines next steps to update the social media policy and conduct training. The CO shares the issue with the Compliance Committee. As representatives of the operational areas, they provide feedback to the proposed social media policy revisions. Additionally, they share the best time and location to conduct training with minimal interruption to the continuity of care.

The Compliance Committee may also provide an effective forum for its members to regularly review and assess the organization's efforts related to its prevention and response-related activities. This is more than just formulating or displaying a chart or graph that shows how many reports were received, which of these reports translated into investigations, the status and number of investigations that are open or closed, and their respective outcomes. The Compliance Committee is uniquely qualified by virtue of its membership to engage in meaningful discussions on whether the prevention and response-related activities taken by the compliance program are positively received by its employees. Do employees think

the organization responds too harshly? Does the organization respond in a timely manner? Do employees feel that sanctions are applied consistently with well-publicized policies and procedures? These are a few of many important questions that the Compliance Committee can consider as an ongoing, practical assessment of whether the prevention and response-related activities are contributing to the effectiveness of a compliance program.

Education and training

Education and training is often attributed to efforts to get new members of the workforce on board through new employee orientation or in response to the need to re-educate or re-train workforce members when issues are detected and mitigating action is needed. However, response and detection can play a vital role in promoting the education and training element during other critically important times as well.

An organization might identify through its policy and procedure management process that certain updated policies are not accessed by staff. This may indicate that the employee base is not aware of important process changes or industry updates relative to that policy. The organization may see an increase in the number of incidents that border between non-compliance and compliance. This could indicate a potential risk of non-compliance. By reintroducing related education and training, the CO could reduce that risk. Education and training also help people realize what adjustments they need to make to keep their actions in alignment with expectations.

> By reintroducing related education and training, the CO could reduce that risk. Education and training also help people realize what adjustments they need to make to keep their actions in alignment with expectations.

Example of non-compliance:

A hospital employee does not observe the HIPAA minimum necessary requirements when leaving a telephone message with the daughter of a patient, detailing both her medical condition and treatment plan. The ensuing investigation also indicates that confidential communication requirements were not followed. The employee left the message at the patient's home telephone number, despite the patient's instructions to contact her through her work number.

To resolve the issues in this case, the hospital develops and implements several new procedures. One addresses the issue of minimum necessary information in telephone messages. Employees are re-educated to provide only the minimum necessary information in messages, and are given specific direction as to the content of that information. Employees are also trained to review registration information for patient contact directives regarding leaving messages. The new procedures are incorporated into the standard staff privacy training, both as part of a refresher series and mandatory yearly compliance training. To prevent recurrence of this issue, the organization schedules periodic audits and monitors staff responsible for followup with patients via telephone.

Auditing and monitoring

The OIG states: "The best evidence that a provider's compliance program is operating effectively occurs when the provider, through its compliance program, identifies problematic conduct, takes appropriate steps to remedy the conduct and prevent it from recurring, and makes a full and timely disclosure of the misconduct to appropriate authorities." To identify the problem areas, utilization of internal and external audits is the key. A good compliance plan that utilizes both internal and external auditors shows the facility's desire to operate within the guidelines.[6] The OIG strongly recommends that hospitals conduct an external compliance effectiveness review of its compliance program at least every three years.[7] If the organization does not have a strong history or track record of auditing and monitoring, it can develop one moving forward. Organizations in such a position may benefit by starting on a very small and selective scale in defining and conducting auditing and monitoring-related activities. As internal experience and expertise develops, the organization can advance to identifying more activity within those identified risk areas that lead to auditing and monitoring.

> ***Example of auditing and monitoring:***
> As part of the audit plan for 2015, the CO audits medical plans for appropriate dependency claims. The audit reveals that several employees have included former spouses, close friends, deceased family members, and adult children over the age of 26. The inappropriate dependents have cost the organization over a million dollars in premiums. The insurer has paid several million dollars in claims for the inappropriate dependents.

All employees were required to confirm dependents, and all records were updated. The insurer was notified and a restitution plan was created. Continued monitoring now occurs annually during the enrollment period.

Reporting and investigating

Reporting can take several forms. First is organizational level reporting where each individual is responsible for reporting misconduct or wrongdoing within the organization. Most organizations are best situated when multiple methods of reporting are offered, such as a confidential hotline, suggestion or message box, and of course, the open door policy of the CO. The next level of reporting occurs when an organization voluntarily reports misconduct or wrongdoing to an authority or government agency. Voluntary reporting is a mitigating factor in the event of a government investigation.

> ***Example of reporting and investigating:***
> An employee reports via the hotline that another employee is soliciting his own personal business during working hours. He is involved in a multi-level marketing company and is pressuring others to join. He is also selling his products during work hours. Company policy clearly prohibits selling products and soliciting personal business. The CO starts the investigation by interviewing employees within the same department where the subject works. After ascertaining that the activity is occurring, the CO involves the department manager and Human Resources. The subject is reeducated regarding the policy.

Investigation is imperative for all claims of misconduct. An organization is best served by developing and utilizing a standard investigation process (e.g., a questionnaire template to be used during interviews, a check box form for documentation reviews, and a policy that dictates when an external party should be involved in the investigation).

Enforcement and discipline

Enforcement and discipline are at the core of establishing the validity of a compliance program. A clear message is communicated to members of the workforce with endorsement by the organization's uppermost levels of management. Demonstrating support for the compliance program via genuine efforts to enforce adherence and mete out consistent discipline assures that the compliance program will meet its objectives. Support from leadership encourages employees to abide by the objectives of the compliance program. (See our article on Element 6, Enforcement & discipline, in the September 2015 issue of *Compliance Today*).

> ***Example of enforcement and discipline:***
> The CO receives an anonymous tip through the compliance hotline that an employee is not complying with their assigned work schedule. According to the anonymous statement, the alleged employee is arriving late, taking extended lunch periods, and leaving early. After conducting an investigation, evidence supports the allegations. The CO meets with the employee's supervisor and Human Resources. It is determined that the employee will be placed on suspension, which includes three days leave without pay. A few months later, the CO receives notification of a similar violation involving a different employee.

Investigating the new violation requires consistency, regardless of the rank or position that the employee holds. Although the details vary by violation, the CO adheres to the same investigation process to determine whether or not a violation exists and recommends disciplinary action based on the severity of the violation.

Conclusion

As CO, you are an invaluable component of the organization. As the delegated individual responsible for day-to-day operations of the compliance program, you determine the magnitude of the program.[8] Your ability to implement the compliance program elements and demonstrate the organization is doing its due diligence is essential. Failure to demonstrate these actions may discredit the compliance program.

The success of the organization relies on the collaborative efforts of all employees. Compliance is not the sole responsibility of the CO. By incorporating colleagues early, compliance initiatives will be easier to implement. Show gratitude, publicly acknowledge contributions, and authentically support incentives for colleagues who promote the program. By participating in operational initiatives and intentionally adding value, responding to and preventing potential compliance deficiencies may be less taxing on organizational resources and long-term initiatives. Commitment from all levels may lead to a program that exceeds regulatory requirements and meets public expectations.

The authors express their gratitude to Frank Ruelas, Facility Compliance Professional with Dignity Health in Phoenix, for his contributions to this article.

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by Sergio Sztajnbok, MD, MsC, OAB-SP, CCEP-I

CREMESP Resolution No. 273/2015: First step to Brazilian Sunshine Act?

» Brazil is a country of continental dimensions, with more than 400,000 practicing physicians concentrated in large urban centers.

» So far, there are few rules that seek to regulate the relationship between Brazilian physicians and the pharmaceutical industry.

» Recently, the Regional Council of Medicine of the State of São Paulo, released a standard that seeks to make more transparent the relationship between physicians and pharmaceutical industries.

» Unfortunately, the rule only makes it obligatory for the doctor to disclose interactions with pharmaceutical companies, but not the monetary amount involved.

» This standard is a breakthrough and the first step towards complete transparency in the close relationship between doctors and the pharmaceutical industry in Brazil.

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Brazil has a large territory. With an area of 8,515,767.049 km^2 and estimated population of 204,818,249 inhabitants,[1,2] it is the fifth largest country in the world, behind only Russia, Canada, China, and the U.S. in territory, and behind China, India, the U.S., and Indonesia in population.

Sztajnbok

The current Constitution of Brazil is dated 1988 and defines the country as a Federal Republic, ruled by the president, composed by inseparable union of the Federal District and its 26 States, divided into 5,570 cities.

World Health Organization establishes 2.3 health professionals (physicians and nurses) per 1,000 inhabitants as a minimal acceptable number to meet primary health needs of a certain community.[3]

With an estimated number of acting physicians of 409,235,[4] Brazil has an approximate ratio of two physicians/1,000 inhabitants, irregularly distributed throughout its territory. The Federal District has an approximate ratio of 4.09 physicians/1,000 inhabitants, but the State of Maranhão has only 0.71 physicians/1,000 inhabitants.[5] The Federal State with the highest income and population is São Paulo, which has an estimated population of 44,490,747[2] and 123,205 acting physicians,[4] for a ratio of 2.77 physicians/1,000 inhabitants.

Regulation of medical professional activity

Brazil has 257 medical schools, where approximately 23,441 students graduate every year. Of the higher degree courses, 56.81% are provided by private universities, and 43.19% are offered by public universities.[6]

Medical course duration is six years, and after graduation, the student has to be enrolled in the Regional Council of Medicine of his/her State to be able to practice medicine professionally. Only after this enrollment will the physician be allowed to act as a medical professional, being limited to the State where he/she was enrolled. Besides being responsible for the enrollment of physicians acting in their respective States, the Regional Councils of Medicine (RCM), present in all the 26 States of Brazil, also have the functions of inspecting health institutions. RCMs are responsible for receiving,

investigating, and judging accusations related to professional misconduct. Medical practice regulation is based upon the publication of opinions and resolutions with mandatory power on medical professionals. Above the Regional Councils is the Federal Council of Medicine (CFM), located in the national capital, Brasília. The CFM is responsible for inspection and normalization of medical practice, besides functioning as a type of court of appeals in the event of physicians convicted of unethical professional practice by their respective RCM.

In addition to the organizations mentioned above, medical practice is ruled by laws set forth by legislative power (federal, state, or municipal), as well as by Executive power (Department of Health and internal organizations, State Departments of Health, and Municipal Departments of Health).

Transparency between physicians and the pharmaceutical industry

There is a strong relationship between physicians and the pharmaceutical industry. The relationship is vast and goes from the pre-launch of a product (i.e., clinical research) to actual promotional activities, in additional to educational support, institutional sponsorship, hiring of opinion leaders for the disclosure of clinical results, advisory activities, etc. From the perspective of Compliance, these are high-risk relationships, because other factors, such as the inadequate and improper treatment of patients, may become primary for the existence of these relationships.

Aiming at protecting patients' interests, some laws have been created to make those relationships more transparent. That is the case with the Physician Payments Sunshine Act in the United States. Since 2013, drug and device manufacturers and group purchasing organizations (GPOs) on a yearly basis must report payments or gifts of $10 or more made to physicians, hospitals, and other providers.[7,8]

On the other hand, Brazil still does not have any rule obligating physicians to disclose their income (whether direct or indirect) from the pharmaceutical industry. Similarly, the country also does not have any rule obliging the pharmaceutical industry to disclose their expenses with physicians.

CREMESP Resolution No. 273/2015

In April 2015, Resolution 273/2015 from the Regional Council of Medicine of the State of São Paulo (CREMESP) became effective. This Resolution in Article 2 obliges physicians acting as opinion leaders in the State of São Paulo, when hired as advisors or speakers, to inform in writing the RCM of the State of São Paulo for how long they will act in this capacity, as well as the name(s) of the company(ies) they will be working for.[9] Article 2 states:

> Whenever s/he is invited to give a lecture, the physician shall explain who is sponsoring such activity, expressly declaring conflicts of interest, if any, especially when dealing with therapeutic or diagnostic efficacy of the product or drug.

Unlike the Sunshine Act, the Resolution creates an obligation for physicians, but not for the companies and, especially, it does not create the obligation of disclosure of monetary amounts involved in the service agreements.

Discussion

Resolutions from Regional Councils of Medicine are normative for physicians (whether individuals or legal entities) only, and even so, exclusively for those enrolled with the Council creating the rule. Therefore, such resolutions have no normative power on the pharmaceutical industries, even on those acting in the respective State. As mentioned before, CREMESP Resolution No. 273/2015 obligates the physicians of the State of São Paulo to

inform in writing their roles as advisors and/or speakers when hired by pharmaceutical companies. We emphasize that such resolution does not obligate them to disclose their fees. The creation of the resolution shows clearly an increasing concern of CREMESP regarding making the physician-pharmaceutical industry relationship more transparent, in line with the civil society mobilization.

For the relationship between physicians and the pharmaceutical industry in Brazil to reach the level of transparency achieved with the Sunshine Act, some steps need to be taken:

- Rule from the Brazilian Association of Research Companies (Interfarma)—a fragile option, since association with Interfarma is optional;
- Resolution from the Federal Council of Medicine obliging all physicians to fully disclose their interaction with the pharmaceutical industry, including a clear provision of fees involved—however, this option is also fragile, because it could easily give rise to constitutional issues;
- Resolution from the Brazilian Agency for Health Surveillance (ANVISA—the Federal regulating organization); and finally,
- Rule from the legislature with clear and evident mandatory power. The enactment of laws such as the Sunshine Act maybe is the best way, since this type of law is the most powerful and has the most coercive force to make financial disclosure mandatory.

Conclusion

We have a long way ahead until the enactment of laws that require mandatory disclosure of amounts paid by the pharmaceutical industry to physicians for services provided. Several conflicts of interests still embarrass and prevent such discussions, but, on the other hand, it is undeniable that civil society is willing and mobilized to make all relationships, whether in the private or public sphere, more and more transparent. Maybe CREMESP Resolution No. 273/2015 is our first step in this long and important way.

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- Tiffany Roen, Regional Health

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- Elizabeth Delahoussaye, IOD Incorporated
- Ann Olsen, Vanderbilt Health Affiliated Network
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- Katherine Dixon, Mentis Neuro Rehabilitation, LLC
- Mary Duffy, Bluebonnet Trails Community Services
- Donna Garrett, Legend Healthcare
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- Leah Montez, Children's Medical Center
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- Art Muela
- Mike Mumma
- Maulik Parikh, Atlas Anesthesia Associates, PA
- Jamey Phillips, Centene Corporation
- Courtney Rose, Atlas Anesthesia Associates, PA
- Saroeun Svay, Metrocare Services
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- Steve Oroho, PwC
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- Melanie Guenther, Aurora Health Care
- Jon Kammerzelt, Quarles & Brady

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- Maame Gyamfi
- M Hazelyn Martin-Henry, Loyola University Chicago
- Chris Williams, TRUSTED Health Plan

PUERTO RICO
- Gisselle Benitez, Clinical Medical Services
- Ibis Rodríguez-Longo, Super Farmacia Nelia
- Sandra Ruiz-Torres, Triple-S Advantage

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Current trends in FCPA enforcement in the healthcare industry

Vince Farhat and David Kirman (page 28)

- Healthcare companies doing business in foreign countries must comply with the Foreign Corrupt Practices Act (FCPA), which prohibits payments or offers to pay anything of value to a foreign official in order to secure an improper advantage.
- DOJ recently increased the size of its FCPA unit by 50% and FCPA enforcement of healthcare companies is increasing.
- Healthcare companies' frequent interactions with doctors, pharmacists, and administrators from foreign public hospitals expose them to particularly high FCPA risk.
- The Department of Justice recently created a counsel position to evaluate the FCPA compliance programs of companies under investigation.
- Healthcare companies doing business in foreign countries should reexamine their anti-bribery compliance policies to ensure they are doing enough to prevent and minimize FCPA violations.

Ethics, compliance, and retaliation in healthcare organizations

Joette Derricks (page 36)

- One in three people who observe misconduct choose not to report it.
- In 2014, claims alleging retaliation accounted for almost 43% of all claims filed with the EEOC.
- Retaliation action goes beyond termination and can be due to "corporate shunning."
- A survey of compliance officers found that 53% of those who responded had investigated a complaint against senior management.
- Companies that exact retribution or ignore reports of wrongdoing are more likely to be the subject of an outside investigation.

Vicarious liability: Frustrating the major policy goals of the Affordable Care Act

Laura E. Hutchinson, Richard E. Moses, and D. Scott Jones (page 42)

- PPACA was intended to improve the quality of medical care and decrease the cost.
- The face of the health system is changing as a result of PPACA.
- PPACA provisions expose hospitals and healthcare institutions to greater liability.
- The theory of "vicarious liability" will be applied to hospitals and healthcare institutions.
- Compliance and quality are intersecting, offering an opportunity to avert litigation.

Cracking the ICD-10 code to stay compliant: Meeting the challenge

D. Wayne Little (page 47)

- Forecast the top ICD-10 concerns pertinent to your organization and how you can effectively monitor them.
- Evaluate how your organization is performing with the ICD-10 transition.
- A large backlog of bills or bill holds, decreased provider productivity, and a queue of discharges waiting to be billed are warning signs of ICD-10 non-compliance.
- Most will not know how well their organization or practice is complying with ICD-10 until several months down the road.
- Until October 1, 2016, Medicare review contractors will not deny valid claims billed under the Part B physician fee schedule, as long as they are submitted with a valid ICD-10 code from the right family.

Research compliance and the due-diligence process

Peggy Beat and Tracy Shenk (page 53)

- A compliance program risk assessment is essential during a merger and acquisition.
- Clinical research is an area that may be overlooked during the due-diligence process.
- Each study must be reviewed and prioritized according to risks.
- All agreements relating to research must be reviewed.
- Research compliance program due diligence provides an understanding of potential risks.

The *Kane* decision: A flawed interpretation of the 60-day rule

Harry R. Silver (page 59)

- *Kane v. Healthfirst, Inc.* is the first decision by any court to interpret the meaning of the word "identified" as used in the 60-day rule.
- In *Kane*, the court ruled that the 60-day clock starts ticking when a provider receives notice of a possible overpayment.
- The decision was a ruling on a procedural motion, not on the merits.
- The court's analysis of the issue is flawed and its definition of "identified" is by no means definitive and should not be treated as the final word on the issue.
- In reaching its decision, the court ignored CMS's proposed regulations, which provide the only guidance from the government on the meaning of the word "identified" in the 60-day rule.

"Who am I?"—Branding your compliance program

Maggie Perritt (page 64)

- A compliance program provides critical support to a company's reputation.
- Having a strong compliance program shows that you take "doing the right thing" seriously.
- Developing a strong positive brand reinforces a strong culture of compliance.
- Developing a brand doesn't happen overnight. It takes time and thought.
- Once established, your brand is your reputation. Take care of it.

Staying compliant while navigating the new world of self-pay collections

Robert Foster (page 66)

- Listen to the consumer's needs.
- Learn from the information obtained.
- Lead them down a path that helps them.
- Consult your Compliance department.
- Talk with your peers.

Compliance 101: The seven essential elements, Part 7: Response & prevention

Cindy Hart, Walter E. Johnson, and Adam K. Weinstein (page 68)

- Failure to demonstrate effective response and prevention might discredit the compliance program.
- The success of a compliance program depends on the skills of the compliance officer.
- Act immediately to avoid a potential *qui tam* lawsuit.
- The compliance officer should maintain detailed notes of the investigation.
- The 4th Amendment of the U.S. Constitution guarantees people the right to be secure in their persons, papers, and effects against unreasonable searches and seizures.

CREMESP Resolution No. 273/2015: First step to Brazilian Sunshine Act?

Sergio Sztajnbok (page 75)

- Brazil is a country of continental dimensions, with more than 400,000 practicing physicians concentrated in large urban centers.
- So far, there are few rules that seek to regulate the relationship between Brazilian physicians and the pharmaceutical industry.
- Recently, the Regional Council of Medicine of the State of São Paulo, released a standard that seeks to make more transparent the relationship between physicians and pharmaceutical industries.
- Unfortunately, the rule only makes it obligatory for the doctor to disclose interactions with pharmaceutical companies, but not the monetary amount involved.
- This standard is a breakthrough and the first step towards complete transparency in the close relationship between doctors and the pharmaceutical industry in Brazil.

HCCA's Upcoming Events

Learn more about HCCA's educational opportunities at www.hcca-info.org/events

January 2016

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
27	28	29	30	31	1 HCCA OFFICE CLOSED *New Years Day*	2
3	4	5	6 *Epiphany*	7 WEB CONFERENCE *Provider Credentialing and Privileging: A Strategic Role for the Compliance Officer*	8	9
10	11	12	13 WEB CONFERENCE *Stark Law Update: 2016 Stark Rule Changes Stark Self-Referral Disclosure Protocol (SRDP)*	14	15	16
17	18 **Basic Compliance Academy** **New York, NY** HCCA OFFICE CLOSED *Martin Luther King Jr Day*	19	20	21 WEB CONFERENCE *Fraud and Abuse: Year in Review* **CHC Exam**	22 **Regional Conference** **Atlanta, GA**	23
24 **Managed Care Compliance Conference** (1/31–2/3) **Las Vegas, NV**	25 WEB CONFERENCE *Everything You Always Wanted to Know About Exclusions But Were Afraid to Ask* **Basic Compliance Academy** **San Juan, PR**	26 WEB CONFERENCE *Leveraging Agility in Governing Health IT Compliance*	27 WEB CONFERENCE *Why Comply? Addressing the Non-N egotiables in Clinical Research Compliance*	28 **CHC Exam**	29	30
31 **Managed Care Compliance Conference** (1/31–2/3) **Las Vegas, NV**						

February 2016

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
31 **Managed Care Compliance Conference** **Las Vegas, NV**	1	2 WEB CONFERENCE *The ABCs of Professional Development for Compliance Practitioners* *Groundhog Day*	3 **CHC Exam**	4	5 **Regional Conference** **Orlando, FL**	6
7	8 **Basic Compliance Academy** **Scottsdale, AZ** *Chinese New Year*	9 *Mardi Gras*	10 *Ash Wednesday*	11 **CHC Exam**	12 **Regional Conference** **Portland, OR** *Lincoln's Birthday*	13
14 *Valentine's Day*	15 *Presidents' Day*	16	17	18	19 **Regional Conference** **Dallas, TX**	20
21	22 *Washington's Birthday*	23	24	25 **Regional Conference** **Anchorage, AK**	26	27
28	29 **Audit & Compliance Committee Conference** **Scottsdale, AZ** *Leap Day*	1 **CHC Exam**	2	3	4	5

Dates and locations are subject to change.

Managed Care Compliance Conference
January 31–February 3 • Las Vegas, NV

Audit & Compliance Committee Conference
February 29–March 1 • Scottsdale, AZ

20th Annual Compliance Institute
April 17–20 • Las Vegas, NV

Research Compliance Conference
June 5–8 • Baltimore, MD

Clinical Practice Compliance Conference
October 23–25 • Scottsdale, AZ

Healthcare Enforcement Compliance Institute
October 23–26 • Washington, DC

Regional Conferences
January 22 • Atlanta, GA
February 5 • Orlando, FL
February 12 • Portland, OR
February 19 • Dallas, TX
February 25–26 • Anchorage, AK
March 4 • St Louis, MO
March 11 • Washington, DC
March 18 • Charlotte, NC
April 28–29 • San Juan, PR
May 6 • Columbus, OH
May 13 • New York, NY
June 3 • Philadelphia, PA
June 10 • Seattle, WA
June 17 • Santa Ana, CA
September 9 • Boston, MA
September 16 • Minneapolis, MN
September 23 • Kansas City, MO
September 30 • Indianapolis, IN
October 7 • Pittsburgh, PA
October 13–14 • Honolulu, HI
October 21 • Denver, CO
November 4 • Louisville, KY
November 11 • Phoenix, AZ
November 18 • Nashville, TN
December 2 • San Francisco, CA
December 9 • Houston, TX

Basic Compliance Academies
January 18–21 • New York, NY — **SOLD OUT**
January 25–28 • San Juan, PR
February 8–11 • Scottsdale, AZ — **LIMITED SEATS**
March 7–10 • New Orleans, LA
April 25–28 • Boston, MA
June 13–16 • San Francisco, CA
June 20–23 • Scottsdale, AZ
July 25–28 • Honolulu, HI — **JUST ADDED**
August 8–11 • New York, NY
September 12–15 • Chicago, IL
October 3–6 • Las Vegas, NV
October 24–27 • Nashville, TN
November 14–17 • Orlando, FL
December 5–8 • San Diego, CA

Healthcare Privacy Basic Compliance Academies
March 14–17 • Orlando, FL
June 20–23 • Scottsdale, AZ
October 24–27 • Nashville, TN
November 7–10 • San Diego, CA

Research Basic Compliance Academies
March 14–17 • Orlando, FL
November 7–10 • San Diego, CA

HCCA Training Resources

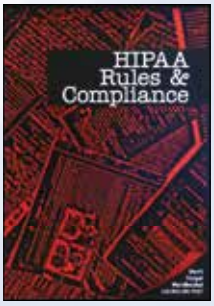
GUIDEBOOKS & VIDEOS TO TRAIN YOUR HEALTH CARE WORKFORCE

Compliance and Ethics: An Introduction for Health Care Professionals

HCCA's top-rated DVD covers 7 key compliance areas in a 23-minute program split into 7 dramatized scenarios. Includes a trainer's guide with suggested agendas and discussion outlines.

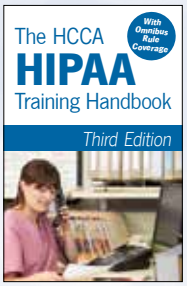
Compliance, Conscience and Conduct

HCCA's classic compliance training DVD is still available! The 17-minute video overviews what compliance means and walks viewers through seven common case studies. Includes session leader guide and reproducible participant worksheets.



HIPAA Rules & Compliance

This 15-minute video reviews basic, unchanged requirements and the latest, critical changes, including the Omnibus Rule.



The HCCA HIPAA Training Handbook, Third Edition

The new, third edition of this handbook covers the privacy and security regulations that frontline health care workers need. This 40-page primer clearly explains the essential, basic workings of HIPAA, HITECH, and the Omnibus Rule.

A Supplement to Your Deficit Reduction Act Compliance Training Program

This 13-page handbook offers an easy way to educate your employees about the basics of Medicare and Medicaid, the Federal False Claims Act, and the whistleblower protections that help health care workers fight fraud.

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General Compliance/Hot Topics

Here's the track for everything from the basics of Compliance 101 to hot topics like healthcare reform. Learn what you need to know from compliance officers, regulators, outside counsel, in-house counsel, auditors, providers, and industry experts.

Long-Term Care

Keep abreast of the changing regulations for skilled nursing facilities, including best practices for developing an effective compliance program, and the latest information on auditing and monitoring compliance programs now regulated by the Patient Protection and Affordable Care Act.

Privacy & Security

Understand the privacy and information security compliance issues that continue to emerge, and learn how to integrate privacy and security issues into your overall compliance program.

Physician Compliance

You'll learn vital information related to small and large physician practices, research billing for physicians, academic medical centers, hospitals, and health systems.

Compliance Lawyer

Learn the legal basis for the compliance issues you manage. The compliance lawyer track sessions will be presented by experienced and knowledgeable lawyers from inside and outside the government. They understand the law and can make it more understandable.

Auditing & Monitoring

How do you know your compliance program is working? Auditing and monitoring is key to measuring effectiveness and improvement. Learn the practices that you need to read the vital signs of your compliance program.

Internal Audit

Increase your understanding and approach to healthcare internal audit. Designed to increase awareness of audit opportunities in the healthcare compliance arena as well as provide tools and techniques to aid you in your audits, this track is loaded with useful information to jump-start your audit efforts. Experienced professionals will present their approach to address key audit areas in the healthcare industry.

How to Succeed as a Compliance Professional

The more effective your leadership, the more effective your compliance program. The sessions in this track will help you develop your skills and increase your value to the compliance program and the organization for which you work.

Quality of Care

Quality of care is one of the newest compliance challenges. Hear from compliance officers, doctors, nurses, and other healthcare providers as they provide you with the information, tools, and processes needed to help you do quality work on quality of care.

Advanced Discussion Groups

If you're an experienced compliance professional, or if you're looking for a more interactive program, this track is for you. Each session is designed to involve everyone in the room. There are no formal presentations, just discussion facilitated by industry experts.

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