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Jim shares his thoughts on the board’s role in the oversight of compliance programs.

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Feature Focus: Managing security risks in business associate relationships

Three tools providers can use to reduce the risk of security breaches, protect assets, and create contractual remedies.

CEU: Research compliance: PhRMA guidance on professional conduct in clinical trials

New guidance for evaluating the effectiveness of internal systems and for ensuring objectivity in clinical trials.

Beyond the basics: Medical necessity issues in home health care

Nurses act as patient advocates and are key to setting realistic goals in home health care.

The Stark Law and the “group practice” requirement

Neither the HCCA nor the Stark Law are engaged in rendering legal or other professional services. If such assistance is needed, readers should consult professional counsel or other professional advisors for specific legal or ethical questions.
How are ethics and regulations connected in the hospital setting?

By William C. Moran

Editor's note: William C. Moran is Senior Vice President in Strategic Management's Chicago Office. He may be reached by telephone at 847/828-3515 or by e-mail at wmoran@strategiccm.com.

If we are to understand how ethics and regulations are connected, we have to first have a common understanding of how we define each of them. According to Webster, "ethics" is the study of standards of conduct and moral judgment, and "regulations" are rules, ordinances or laws by which conduct is regulated. Thus, ethics gives us underlying principles by which we judge human behavior, and regulations carry out those principles by saying how a designated group of people should act. Ethics tells us what is right and what is wrong, and laws and regulations apply what is right and wrong for society.

The study of ethics and regulations, and the connection between the two, has been going on at least since the time of the Greek philosophers. One of those philosophers, Aristotle, wrote a treatise, Nicomachean Ethics, to help sort through what is good and what is bad. He followed with a treatise, Politics, to apply the good and the bad to societal issues by discussing legislation and regulations.

In this article, I will address three questions: What are the ethical principles behind the ten major hospital regulatory categories? Can ethics and regulations be at odds with each other? What will the future bring for ethics and regulations?

What are the ethical principles behind the ten major hospital regulatory categories?

In the hospital setting, there are ten major categories of regulations based on ethical principles. Some hospitals do not provide services in a few of these areas, but most hospitals would be governed by the vast majority of these regulations. These ten categories are:

- **Anti-kickback regulations** are premised on the ethic that public money (namely Medicare and Medicaid) will be used in the best interest of the patient, without regard to the financial interests of the physician and hospital.
- **Clinical research** regulations are based on ethical considerations for the human subject who is involved in that research, as well as the ethical considerations that exclude conflict of interest between the researcher and the pharmaceutical or medical device company that sponsors the research.
- **Emergency Medical Treatment and Active Labor Act (EMTALA)** regulations try to ensure that no one will be turned away from a hospital and sent somewhere else unless they first receive a medical exam and, if necessary, are stabilized prior to being transferred. The ethical premise here is to ensure the patient’s safety before considering financial implications.
- **Health Insurance Portability and Accountability Act (HIPAA)** regulations address the privacy and security of patient information, based on the ethical principle that only certain people have a right to know the personal medical facts involved.
- **Quality of care** regulations deal with the evidence-based standards of good health care, including the quantity of services provided. The ethical underpinning here is that payment should be for generally accepted good performance by the clinicians involved.
- **Corporate governance and compliance** regulations address the structure and process used to ensure that regulatory issues are appropriately addressed. This follows the ethical principle that laws and regulations need to be properly enforced at the local level.
- **Cost reports** regulations address efforts including the collection of bad debts, failure to return credit balances, and miscalculating wage indices.
- **Claims development and submission** regulations cover all the individual claims submitted to receive reimbursement.
- **Laboratory services** regulations address the bundling of claims and assurance of medical necessity.
- **Physicians at Teaching Hospitals (PATH)** regulations deal with ensuring that services provided are not duplicately billed.

The last four categories have regulations that are based on the ethical principle that hospitals should accurately and honestly bill for services that are allowed by Medicare and Medicaid.

Can ethics and regulations be at odds with each other?

The short answer is Yes. Let me give you two examples, the first of which is the seminal case
for ethical consideration in human subject research. The Tuskegee experiment is the most obvious example of the ethics of a situation being at odds with the regulations. As you probably know, the U.S. Public Health Service recruited 399 impoverished African-American sharecroppers who had syphilis for research related to the natural progression of the untreated disease. The study began in 1932. In 1947, penicillin became the standard treatment for syphilis, but the research continued until 1972. The control group continued to receive placebos, not penicillin. As Dr. John Heller, the head of the study stated, “The men's status did not warrant ethical debate. They were subjects, not patients; clinical material, not sick people.” This was in 1972. Finally, a whistleblower within the Public Health Service went public, Congressional hearings were held, and the experiment was immediately stopped. The creation of Institutional Review Boards and other human subject mechanisms are partly a result of the Tuskegee experiment. In this case, all the Public Health Service regulations were followed, but the ethical underpinning was faulty.

One other example took place in 1998 on the sidewalk outside Ravenswood Hospital in Chicago. A man with a gunshot wound lay bleeding on the public sidewalk outside the hospital. The legal policy of the hospital stated that Emergency Room personnel could not leave the department. When the hospital was told about the man on the sidewalk, the hospital called 911. The ambulance took longer than usual. A police sergeant finally brought the man inside the hospital. The man subsequently died. Later, a jury awarded the man’s family $12.5 million dollars. In this case, the legal policy did not allow for the situation that occurred. This prompts the question of whether ethical matters should be considered primarily by legal considerations or by other factors.

What will the future bring for ethics and regulations?
I suggest three trends: More transparency, more quality-of-care “Pay for Performance,” and more questions about the end of life.

Transparency
There are currently two bills in the Congress, one in the Senate and the other in the House, that address transparency in money paid by pharmaceutical and medical device companies to hospitals and physicians. The “Sunshine Laws” would make these monetary contributions public by posting them on the Internet. By the way, this is something the Cleveland Clinic already does. And some states, such as Minnesota, Maine, and California, have passed laws that require this type of information. The other area of transparency will focus on consumer involvement, making more information available to consumers so they can make better decisions about their health needs and how and where they want to be treated.

Quality of care
The government's push for Pay for Performance would contribute both to better quality care and to cost savings. Pay for Performance will include an increasing numbers of items every year, and along with cutting fraud, waste, and abuse, will result in significant cost savings for taxpayers. How to decide and quantify quality of care and who will pay for it will be a major battleground between payers and providers.

End of life
Questions about care at the end of life will multiply, and ethicists will try to make reasoned decisions, in the midst of technological advances and family anxiety. A recent case in Belgium provides a good example. A man was in an auto accident 23 years ago and was thought to be in a coma all that time. A year ago, his physician decided to conduct a test of his brain by using a new CAT-scan. They found he was not in a coma, but was totally paralyzed. He had been able to hear people discuss his medical condition for some part of those 23 years. I am sure there will be other families who will want their loved ones to be re-tested. Decisions about when and under what circumstances loved ones should be tested and kept alive will occur more frequently.

Conclusion
As I mentioned in the beginning, the discussion of ethics and regulations has been occurring for centuries, and will continue to occur as long as people want to distinguish right from wrong. Let's keep the conversation flowing.

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Conflicts of interest: The new frontier in health care risk

By William Sacks, MBA

Editor’s note: William Sacks has over thirty years experience in health care management as a consultant, medical practice manager, and faculty practice plan director. Mr. Sacks has consulted to hospitals, medical groups, and academic medical centers on compliance training and education. In 1998 he established Health Care Compliance Strategies, Inc. (HCCS), which develops computer-based training and management tools for hospitals, Medical Schools, physician groups, and payers. HCCS offers a tool to help organizations manage conflicts of interest. Bill may be reached at bsacks@hccs.com.

This article will provide insight into the evolution of thought on conflicts of interest in health care, and will discuss the significant shift in perceptions, policies, and practices over the last several years. It will discuss efforts by academic associations, government, and professional societies to bring about a wholesale change in the attitudes and behavior of physicians and the industry at large. It will discuss actions in Congress that will mandate transparency in payments to physicians, as well as the efforts being undertaken by institutions to require disclosure of potential conflicts, and to manage any that are uncovered. These efforts to uncover and manage conflicts of interest will have a profound effect on the ability of a typical organization to manage risk.

Introduction

As the Director of an Academic Faculty Practice Plan in the mid 1980s, I was well aware of the close and mutually beneficial relationships between faculty members and the medical industry. Pharmaceutical and other companies contributed to medical education, funded clinical trials, and provided free product samples to support the teaching, research and clinical practice missions of the organization. In those days, any suggestion that such relationships were improper, or that they might influence decision making in a way that could conflict with the best interests of patients, was met with indignation and dismissive denial. How things have changed.

Background

A conflict of interest occurs when an individual or organization has a financial or other interest that has the potential to interfere with their professional judgment, objectivity, or ethical responsibilities. Conflicts of interest are difficult, if not impossible, to avoid in medicine. Indeed, fee-for-service medicine, where physicians are paid more for doing more, has inherent conflicts. For most of modern history, however, health care practitioners have held positions of such high status and regard that they have benefited from a presumption of good and ethical behavior.

Things began to change in the late 1980s. Astute observers noticed that physician referrals to ancillary facilities would tend to increase if the physician had a financial interest in the facility. In response, Congressman Pete Stark of California introduced legislation, which took effect in January 1992, prohibiting self referrals. Unlike the federal anti-kickback statutes, which were on the books since 1972 and prohibited providers from taking outright bribes, the Stark laws represented a tacit admission that medical decisions could be influenced by financial considerations.

In the early 1990s, concerns began to grow that research funded by the Public Health Service (PHS) could be biased by “conflicting financial interest of those investigators responsible for the research.” In 1995, the PHS and the Office of the Secretary of Health and Human Services promulgated the first federal regulations, quite weak in retrospect, requiring investigators to “disclose to an official(s) designated by the institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by the research proposed for funding by the PHS.” (Italics added). The regulations required institutions to create and maintain a written policy on financial conflicts of interest, communicate that policy to investigators, identify and manage potential conflicts, and report that information to the government.

The Gelsinger case

In 1999, a young man by the name of Jesse Gelsinger died from an immune reaction during a clinical trial at the University of Pennsylvania. While essentially healthy, he suffered from a rare metabolic disorder, and had volunteered for an experiment to test gene therapy for babies with a fatal form of the disease. After his death, his family learned that the principal investigator and treating physician had a financial interest in the success of the therapy being tested. The FDA found “serious deficiencies” in the informed consent process, which, the family claimed, did not include a discussion of potential conflicts of interest.

The Gelsinger case was a wake-up call for Academic Medicine. Even so, when the NIH reiterated concerns about “Financial Conflicts of Interest and Research Objectivity” in a June 5, 2000 memorandum, it did little more than make suggestions to the Institutional Review Boards (IRB’s) responsible for overseeing research at the nation’s medical centers:

Continued on page 8
“While there is no regulatory requirement for IRB’s to consider investigators’ financial conflicts of interest,” the memorandum stated, “the protection of human subjects requires objectivity…” and “IRB’s should refer to their institution’s policies and procedures for identifying and managing conflicts of interest.”

Without detailed and specific guidance from the government it was left to hundreds of separate institutions and thousands of providers to define, assess and manage their own conflicts of interest.

**Attitudes begin to change**

Two articles published in the Journal of the American Medical Association (JAMA) had an impact on the ongoing discussion about conflicts of interest. The first was published in the January 19, 2000 issue, and was titled “Physicians and the Pharmaceutical Industry/Is a Gift Ever Just a Gift?” The author analyzed 29 separate studies, which provided data on physician interactions with the pharmaceutical industry and the attitudes toward those physician-pharmaceutical industry interactions. The interactions ranged from industry-sponsored meals and samples, to honoraria, conference travel, and research funding. Both residents and practicing physicians expressed the belief that pharmaceutical representatives prioritize product promotion above patient welfare, yet each group denied that gifts and other perks could affect their behavior.

Regression analysis, however, demonstrated that interactions with pharmaceutical representatives had an impact on “the prescribing practice of residents and physicians in terms of prescribing cost, nonrational prescribing, awareness, preference, and rapid prescribing of new drugs, and decreased prescribing of generic drugs.” Furthermore, the study continued, “…receiving a gift and the number of gifts received correlated with the belief that pharmaceutical representatives have no impact on prescribing behavior.” So not only did industry contacts influence prescribing behavior, but gifts made physicians less likely to think they had been influenced!

The second JAMA article, published in July, 2003, was a commentary offering “A Social Science Perspective on Gifts to Physicians From Industry.” This article took on the common belief that while large gifts or significant financial support (conference travel, CME support) might influence behavior, smaller gifts (meals, note pads, even pens) were not likely to do so. The authors used both medical and non-medical social science research to demonstrate that “…by subtly affecting the way the receiver evaluates claims made by the gift giver, small gifts may be surprisingly influential. Furthermore, individuals are generally unaware of the bias, so they do not make efforts to correct for it or to avoid conflicts of interest in the first place.”

These articles, and others that preceded and followed them, began to shift the conventional wisdom about the effect of conflicts of interest in medicine. Still, it took several very high profile cases to push the issue into public consciousness, and to the front page of the New York Times.

**High profile cases**

On June 8, 2008 the New York Times published a story about Dr. Joseph Biederman, a prominent Harvard psychiatrist who had failed to report at least $1.6 million in consulting fees from drug makers, while publishing research and giving scholarly talks which may have served to promote drugs from those companies.

In October of 2008, the Times reported that another leading psychiatrist, Dr. Charles Nemeroff, had accepted more than $2.8 million in payments from drug makers over a period of several years, failing to report at least $1.2 million to his employer, Emory University.

The facts surrounding these cases are beyond the scope of this article, but the publicity surrounding these cases and others that followed have created a sense of urgency on the part of organized medicine, academia, and government to define, identify, and manage conflicts that interfere with the delivery of cost effective, evidence-based medicine. The remainder of this article will discuss efforts being undertaken to eliminate conflicts in medical research, medical education, and clinical practice.

**Professional associations get involved**

The Association of American Medical Colleges (AAMC) represents all 131 accredited U.S. and 17 accredited Canadian medical schools, approximately 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies. The AAMC has taken a lead role in addressing conflicts of interest in its constituent organizations. In the absence of specific direction from the federal government, the AAMC, together with the Association of American Universities, issued recommendations in 2001 and 2002 addressing individual and institutional financial conflicts of interest in research.

In 2006, an Advisory Committee was formed to review and revise those guidelines, and in February 2008, they published their recommendations, describing and urging the adoption of consistent COI policies and advocating quick action on the part of its membership. Recommendations addressed disclosure, analysis, and management of conflicts in clinical research. This was followed in June 2008 by a similar report addressing industry funding of Medical Education. These reports significantly strengthened earlier recommendations, suggesting that member
institutions prohibit gifts of any size, ban food provided by industry, restrict industry access to physicians, and distribute free product samples through a central repository.

Dozens of Medical Schools and health systems have taken these recommendations, built on earlier progress, and, in very short order transformed the culture of their organizations. Boston University, University of Massachusetts, Yale, University of Pennsylvania, the Universities of Michigan, Wisconsin, Chicago, and the entire University of California system all have strong COI programs in place.10 Stanford has limited CME funding by drug makers.11 The Cleveland Clinic decided to publicly report the business relationships that any of its 1,800 staff doctors and scientists have with drug and device makers.12 Harvard, Columbia, and New York University have all worked to strengthen their COI policies.13,14

An interesting player in the conversation about COI has been the American Medical Students Association (AMSA) which ranked all United States Medical Schools on the basis of their conflicts of interest policies. Of approximately 130 schools, only nine earned an “A” and 36 a “B”.15 This gives some indication of the progress that still needs to be made.

State and federal legislation
A number of individual states and the federal government are hoping to accelerate that progress by mandating disclosure of payments to physicians from pharmaceutical companies and device manufacturers. Legislators in Massachusetts, Maine and Vermont have passed strict disclosure requirements and more than a dozen other states are discussing such legislation. Senator Charles Grassley of Iowa has been at the forefront of the effort to increase oversight of physician-industry ties. He was responsible for uncovering the Biederman and Nemeroff stories, and shedding light on numerous other questionable relationships through his Senate Committee hearings.

In January 2009 Grassley introduced the Physician Payments Sunshine Act (S.301) requiring drug, biologic and medical device manufacturers to report certain gifts and payments made to physicians. A record of these payments would be maintained in a national database so medical and academic organizations and the public could see if their physicians had received financial support, or gifts, from industry. The proposed legislation includes fines of up to $10,000 for each “transfer of value” that is not reported, and up to $100,000 for knowingly failing to report.

Industry efforts
In January 2009, The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents leading pharmaceutical and biotech companies, released the newest version of its voluntary “Code on Interactions with Healthcare Professionals”. The code went further than ever before in instructing its member companies to prohibit the giving of gifts, entertainment, even pens and other small promotional items, to physicians.

Also in 2009, the industry group AdvaMed, which represents medical device manufacturers, implemented a “Code of Ethics” with similar prohibitions. While some see these industry efforts as a cynical attempt to forestall government intervention, others interpret these guidelines as sincere efforts to be part of the solution to a very real problem.

Conclusion
The most recent organization to weigh in on the topic of conflict of interest was the respected Institute of Medicine (IOM), of the National Academies of Science. In April, 2009 the IOM published a comprehensive analysis titled “Conflict of Interest in Medical Research, Education and Practice.”16 The 392 page report provides sixteen recommendations, some aimed at providers, some at industry and some at government. These recommendations, if enacted, would go a long way toward creating policies and systems to manage conflicts of interest in medicine, enabling physicians, other providers, and the institutions that carry out medical research, education and clinical care to maintain public trust.

In difficult economic times, hospitals, medical schools, and physicians rely on the good will and trust of the public more than ever, as they make the case for resources in the political arena. Organizations that ignore the potential damage that conflicts of interest can do to their reputations do so at their own risk. Compliance Officers, Risk Managers and Internal Auditors should study the issues discussed here, and take measures to protect their institutions and the industry as a whole.

This article was first printed in the December, 2009 issue of New Perspectives on Healthcare Risk Management, Control and Governance, journal of the Association of Healthcare Internal Auditors, Vol. 28 #4. Reprinted with permission.

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7 www.AAMC.com
8 Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subject Research; AAMC, February 2008
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Interview with James G. Sheehan, New York State Medicaid Inspector General

Introduction by Health Care Compliance Association CEO Roy Snell:

The Board’s role in regulatory and compliance oversight is coming under scrutiny more than any other time in our history. This role is important and can’t be taken lightly. It weighs heavily on the minds of countless board members. Many board members are looking for guidance on how to fulfill this obligation and to do so efficiently. James G. Sheehan is one of the most knowledgeable leaders in this field. In the following interview, Jim shares his thoughts and ideas regarding the board’s role in the oversight of compliance programs.

HCCA NOTE: Jim and other experts will be covering this topic at the Audit & Compliance Committee Conference, May 20-21 in New York. For more information, see http://www.hcca-info.org/StaticContent/2010MayNY_AuditComp_brochure.pdf.

RS: Why should board members be concerned with the activities of a compliance program?
JS: In my view, there are five reasons:
1. It is the right thing to do to protect the interests of the non-profit and its beneficiaries, and to assure the implementation of its mission.
2. The members of the board in a non-profit organization have a fiduciary and legal duty to determine that systems and procedures are in place to provide reasonable assurance of compliance with governing law. The exposure for the organization without such systems and procedures can be substantial, including both economic recoveries and exclusion from Medicare and Medicaid-even where the problem was an imprudent acquisition or a failure of oversight rather than intentional conduct.
3. For non-profits, the IRS 990 informational return (particularly for hospitals) makes specific representations about compliance activities, and factual representations about non-profits operations and activities which are unlikely to be reliable in the absence of an effective compliance program. The 990 contains specific representations about board members’ reviews of that document.
4. State statutes and regulations in New York require that every Medicaid provider which receives more than $500,000 per year have an effective compliance program, including board oversight. The Patient Protection and Affordable Care Act will impose similar obligations on certain health care providers.
5. Non-profit board members can face personal financial and professional exposure and embarrassment from membership on a board which fails in its oversight responsibilities.

RS: What is the board’s role in the oversight of compliance programs?
JS: The most significant role is becoming sufficiently educated about the topic to ask appropriate questions and determine whether management has the expertise, the will, and the metrics to provide a reasonable assurance of compliance, and for the board members to review intelligently the responses and submissions of management.

RS: Are boards being held responsible for organizations’ non-compliance?
JS: Generally they are not held responsible for the organizations’ non-compliance unless they have personal involvement. However, they can be held responsible for neglecting their duty of oversight where non-compliance occurs and there were either significant warning signs that the compliance program was not effective, or a failure to undertake oversight.

RS: Can the board delegate oversight of a compliance program to a subcommittee of the board?
JS: Yes, a significant portion of oversight responsibilities may be delegated to a subcommittee. In fact, a Compliance and Audit Committee is often better equipped by background and by time to undertake this responsibility. The scope of the charge to the subcommittee should be clear from the minutes and from the subcommittee’s charter and reporting. Care should be taken to assure that independent directors are a majority of the Compliance subcommittee. Delegation must be accompanied by periodic reporting of significant compliance issues to the whole board.

Even where responsibility has been delegated, education of new board members should include a compliance component.

RS: How many times a year do you recommend reporting to the full board?
JS: In the absence of a specific, major compliance issue, I would recommend a quarterly report, in writing with an opportunity for questions, to the full board by the subcommittee, and at least an annual in-person presentation by the compliance officer to the full board.
RS: Some object to having the board held accountable for fraud committed by employees.  
JS: Board members are not accountable when they have no knowledge of fraud that is committed by employees, although the corporation is accountable, since the corporation is the employer. Board members are accountable for failing to undertake their duty of oversight where fraud or abuse occurs and there were either significant warning signs that the compliance program was not effective, or a failure to undertake oversight at all. These duties are defined by law, and board members must carry out these duties.

RS: How much training should the whole board receive, if any, on an annual basis?  
JS: Every new member of a board should receive adequate training in compliance issues and their compliance oversight responsibilities as part of their initial introduction to the board. In my view, boards should consider brainstorming sessions annually similar to SAS 99 (See http://fvs.aicpa.org/Resources/Antifraud+Forensic+Accounting/Educators+and+Students/Regulatory+Considerations/SAS+No.+99+Guidance/).

RS: Do you feel boards are vulnerable to having important information filtered by management or the General Counsel? And is there anything that can be done to stop this?  
JS: There is a risk in any organization that senior managers will provide filtered and emphasize positive information to the board. This is true whether the senior manager is the CEO or the General Counsel, or in some other position. The best response to this concern is a culture of transparency that is embraced by the CEO and emphasized by the board, and inviting other managers to present at board meetings.

However, if the board feels that the CEO or the General Counsel are not providing accurate information, it is time to consider either replacing these individuals, or leaving the board.

RS: What is the biggest problem you see with regard to the board’s involvement in the oversight of compliance programs?  
JS: In my opinion, it is board members who fail to ask the tough questions of management, do not require and review compliance metrics, and do not require compliance education for the board itself and for senior managers.

RS: Do you think the board should ask one board member to focus their time on compliance, as they do with finance or audit?  
JS: No.
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Meet Miaja Cassidy
Director of Healthcare Compliance, Target

Editor’s note: This interview with Miaja Cassidy was conducted in the first quarter of 2010 by Jacqueline M. Darrah, Shareholder, with the law firm of Nilan Johnson Lewis PA. Ms. Darrah may be contacted by telephone at 612/305-7562 or by e-mail at jdarrah@nilanjohnson.com. Ms. Cassidy may be contacted by e-mail at Miaja.Cassidy@target.com.

JD: Tell us a little bit about Target and the scope of your responsibilities as Director of Healthcare Compliance?

MC: Target’s first store with a pharmacy in opened 1962. Today, Target’s health care business includes in-store Optical and Clinics as well. As Director of Healthcare Compliance, I am responsible for developing and maintaining a robust health care compliance program that maintains guest expectations of Target and reduces enterprise risk by implementing and operationalizing legal and regulatory requirements that affect Target’s health care business. In fact, that is our mission.

We know that our critical success factors are structure, tools and measurements, and people and partnerships. For structure, that means building the compliance program based on the seven core elements. The tools and measurements include the processes, tools, and measurements needed to drive the program performance. Finally, the people that help us succeed are both the team we built and the internal and external relationships needed to deliver results.

JD: Tell us a little about your background and whether you set out to take on the compliance role at Target or whether the role found you.

MC: Both. My career began leading towards compliance about 10–12 years ago. I am an attorney, and when I left private practice to go in-house at a health care company, my role was largely a compliance support function. That continued to evolve as HIPAA rolled out, and I supported the implementation of those requirements in two separate organizations. I became passionate about being a strategic thought partner and how the organization was going to do its business. This was different than being a pure legal advisor, where you analyze the law, talk about what may or may not work, and your service is complete.

In my last role before coming to Target to lead the Healthcare Compliance program, I worked with a brilliant woman who was a vice president and compliance officer for that organization. She gave me an opportunity to be an integral part of leadership on her compliance team. She allowed me to participate in the development of the strategy as well as the day-to-day compliance matters. It was a world-class compliance program. That experience energized me and allowed me to use the skills that I had developed as a lawyer in a more strategic way.

When I learned about the opportunity at Target, I couldn’t pass it up. Target is an outstanding company with a great reputation for integrity and quality. I applied for the position, and after a very thorough interview process (on the part of both Target and me), I began working here in 2008.

JD: Can you share with us your compliance structure and how you are able to manage the compliance challenges in the retail space of health care?

MC: Target’s health care compliance program is part of and aligns with Target’s overall corporate compliance structure. The corporate compliance program has multiple functional compliance areas in a

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Retail business with multiple products and services. Health care compliance is one of the functional areas. The corporate compliance program is governed at the highest level within the organization.

Speaking specifically about the health care compliance structure, we have developed the program on the seven core elements established in the Federal Sentencing Guidelines. Each year, we create our strategic plan focused on the highest risk areas and implement the plan, ensuring that our compliance building and remediation activities fall within those core compliance element areas.

As far as managing compliance challenges in the retail space, the most surprising thing to me is how seamless the effort has been. We have an Oversight Committee that is wholly vested in the outcome of our compliance efforts. We regularly seek their guidance and direction in key compliance initiatives. The Oversight Committee stays informed about the activities of the Compliance Team and they review reports and recommendations that we provide. Every meeting is a lively and healthy discussion. Because they remain well informed and because they see it as their responsibility, they promote the importance of compliance across the health care division and throughout the company. That high level buy-in is, without question, a key to our success.

**JD:** What do you see as the regulatory focus and the top two or three emerging compliance challenges for retail health care?

**MC:** The regulatory focus and emerging challenges for retail health care are the same for the health care industry as a whole. We are facing unprecedented economic conditions, while at the same time working to deliver the highest quality with the newest innovations at the lowest costs. We all want and expect access to health care and information in record time. As the deliverers of health care services, the industry is trying to make the balance of immediacy versus privacy and security—which often are in direct conflict with each other. The more secure you make information, the longer it takes to unlock and share it. Congress at the state and federal level is dealing with that same concern, so we are seeing legislation like HITECH.

Another emerging challenge is in the area of “cost containment” regulatory efforts, particularly in reimbursements. Health care costs are on the rise, year over year. States are looking at ways to save on costs wherever possible, but the costs can only be cut so much before the costs to deliver are greater than the reimbursement. Typically, the very populations that need access the most are the ones that are impacted to the greatest extent.

**JD:** What tools do you have in place to measure the ongoing effectiveness of your compliance program? What do you find as the single biggest challenge in your compliance function?

**MC:** We measure our effectiveness using the same standards as regulators (i.e. using the seven core areas), plus we add in a risk management planning process as an “eighth” element. Our risk management planning process is a consolidated approach to identifying, addressing, monitoring, and auditing the most significant risks. The health care division pulls in key stakeholders who are asked to identify and prioritize risks using multiple inputs for the coming year. The proposed risk management plan is then brought before the Oversight Committee for their review and approval.

The greatest challenges we face are likely the number of obligations and certainly figuring out solutions to conflicting requirements while delivering a service that meets guest expectations without exception.

**JD:** What do you find to be the most exciting or energizing part of your role for Target?

**MG:** I am thoroughly energized by the passion of the team members I work with at Target as well as their willingness to problem solve and innovate in the most complex of situations. The positive environment that I work in makes me realize how much can be accomplished when everyone is vested in an outcome that is best for guests and best for Target.

**JD:** What advice do you have for organizations struggling to create a strong culture around compliance and ethics?

**MG:** I would advise that they get the high-level oversight structure in place as soon as possible. If you have that support, the partners you ask to make a change or impose on their already-too-long list of priorities will find it much easier to reprioritize their list. If you don’t have that, you will be more frustrated and accomplish much less.

**JD:** There is increased focus on governance and board engagement. Can you share some effective methods you use with your senior leadership to ensure your board understands their role in providing reasonable oversight regarding your program’s effectiveness?

**MG:** Creating metrics that identify risk in a relative way to other risks or within the industry, for example, can help a board understand their responsibility and help them make good decisions. Effective communication with the board means providing the appropriate level of detail so the members can ask questions and make decisions or provide recommendations. The Healthcare Compliance Team provides its leadership with relevant information about the key risk areas, which allows those leaders to probe and discuss and feel well informed about the issues that affect their business.

**JD:** How do you keep compliance education and training valuable and interesting to Target employees (and “fast, fun, and friendly”)?

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Meet Miaja Cassidy ...continued from page 15

MC: Target has an outstanding team specifically devoted to training and education of team members. We work closely to provide that team with specifics of the training and the requirements. The team then puts together professional quality training, using innovative techniques and methods. It is collaborative, but the creativity is really that of our training team.

JD: You are an experienced compliance officer. Why should someone choose a Compliance career and what recommendations do you have for individuals interested in focusing their career in Compliance?

MC: First, the area of Compliance is growing. Companies everywhere see the benefits of having a compliance program in place and understand that the investment pays off. Now is a great time to get into a Compliance career. A compliance professional gets to use both one’s analytical and strategic thinking skills. You get to be innovative and creative in solving complex problems that can give you visibility in the company early in your career. Compliance careers allow you to work with multiple functional areas within your organization.

If you have decided you want to focus your career in Compliance, look for opportunities within companies that give you exposure to compliance functions. Get connected in the industry through organizations like HCCA, SCCE, or other similar organizations. If your company is large enough, you can get connected to the compliance areas and others who have compliance-related roles. The opportunities are boundless, and while the profession continues to grow, so will the availability of positions.

JD: How does HCCA best support the work you are doing and in the alternative, what can HCCA be doing to support your work and the profession even more?

MC: HCCA provides great networks of compliance professionals. It has great resources and information. I also think one of the most important things that HCCA provides its membership is the opportunity to become certified in health care compliance. Having a recognized national standard of requisite knowledge allows others to adequately assess the profession as a whole. It also allows us to grow in the practice of health care compliance.

JD: Target has an outstanding team specifically devoted to training and education of team members. We work closely to provide that team with specifics of the training and the requirements. The team then puts together professional quality training, using innovative techniques and methods. It is collaborative, but the creativity is really that of our training team.

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Proactive data analysis with the One Program Integrity System

By Leigh R. Adams, MS, CHC

Editor's note: Leigh R. Adams is Compliance Data Analyst with Erlanger Health System, located in Chattanooga, TN. Leigh may be contacted by telephone at 423/778-5272 or by e-mail at Leigh.Adams@erlanger.org.

Unlike the Centers for Medicare and Medicaid Services (CMS) contracted programs, such as Recovery Audit Contractors (RACs), Medicaid Integrity Program (MIP), Zone Program Integrity Contractors (ZPICs), and Medicare Administrative Contractors (MACs), CMS-contracted tools receive very little publicity. The CMS One Program Integrity (One PI) System is a perfect case in point. The most comprehensive public document explaining One PI (as of this writing) is Exhibit 300 for Budget Year 2010 of the Department of Health and Human Services’ Office of the CIO’s Capital Planning and Budgeting website (http://www.hhs.gov/ocio/capitalplan ning/exhibit300/FY10Exhibit300/cmsmipmodernizationonepisystem.html).

The project summary outlines plans for a centralized source of data for Medicare and Medicaid beneficiaries, providers, and claims. Data for Medicare Parts A, B and D will be merged with multiple state Medicaid data sets. The system allows direct access by government employees, including law enforcement, as well as a host of assorted government contractors. Reducing fraud, waste, and abuse is the ultimate mission of the system. The reason that this tool is noteworthy is that previous CMS data systems segregated data into different reporting tools. Within these legacy systems, connections across government payers and between providers (e.g., skilled nursing facilities and hospitals, physicians and hospitals, durable medical equipment companies and physicians) could not easily be examined.

There are too many combinations of providers with shared beneficiaries to name within the limits of this article; however, providers should use this opportunity to examine their relationships with other providers. These relationships appear one way when examined on paper or from a legal perspective, but relationship software may show contractors a different picture. The new integrated system allows for mapping of these and other relationships with speed and ease previously unavailable to contractors and other users.

The One PI contract was awarded to SafeGuard Services LLC on September 30, 2006 to establish the system. Unknown system variables regarding the project include a realistic completion/implementation date and the projected look-back period. A seven-year historical look back period would offer a larger base for potential extrapolations and would increase financial incentives for any contractors paid on percentages of recoupments.

Although that estimate is purely speculative, additional, some contractor-published analyses lend themselves to examination at the point of billing (pre-payment), but others are better examined post-payment. The exercise of answering these questions may provide insight into areas of potential vulnerability within an organization or health system. In fact, providers who adopt a conservative approach to a full scale attempt to replicate will provide insight into contractor trends and enable providers to more readily identify internal focus areas. This identification of internal trends may be at the anecdotal level, but with study of contractor activities and tools the interpretation will be more meaningful.

With limited concrete information to study, it is difficult for providers of Medicare and Medicaid services to formulate opinions and/or response plans for the One PI System.

Providers have a range of potential courses of action, from the extremes of a wait-and-see approach to a full scale attempt to replicate the One PI system at the provider level to perform comprehensive proactive data analysis. A conservative approach might include an initial assessment of internal data systems to determine whether proactive analysis could be developed in a manner replicating what contractors will be creating through One PI.

Gathering of the data into a useable format may be more of a challenge for organizations new to proactive data mining. Other questions to consider include:

- what software tools to utilize for data analysis and reporting,
- who in the organization is best suited to perform the analysis, and
- whether vendor options would offer a better solution.

Additionally, some contractor-published analyses lend themselves to examination at the point of billing (pre-payment), but others are better examined post-payment. The exercise of answering these questions may provide insight into areas of potential vulnerability within an organization or health system.

In fact, providers who adopt a conservative approach can still benefit from studying contractor data analysis systems, because this will provide insight into contractor trends and enable providers to more readily identify internal focus areas. This identification of internal trends may be at the anecdotal level, but with study of contractor activities and tools the interpretation will be more meaningful.

Another important consideration is the relative lack of benchmarking data available.

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Jury duty, the Rule of Law, and Compliance

I am sitting in the basement of the Minnesota Hennepin County Court House. No, I haven’t been arrested, although some would believe I have met with a worse fate. I am on jury duty, for two weeks. Most people don’t want to be here. Most want to get out of it. I was asked to testify this week in front of the US Sentencing Commission. I might have used this as an excuse to try to get out of jury duty this time, but I didn’t do it for two reasons. I want to be part of the process, and there are better people than me for the USSC testimony (we asked Joe Murphy).

There is a new problem I am facing. I don’t think most defense attorneys would want a compliance professional on the jury. I have been told that CEOs are highly undesirable. I have been told by lawyers that I have no hope of being picked. The first group was pulled this morning, and I am still here writing. True to form, I still have never been in the front lines of the legal process.

It’s lunch break now. I just got back from Burger King® and saw a line formed at some department with the name Fines and Penalties. There were so many people in line, their lobby was full and the line stretched into the hallway. I thought about those people in that line and had a judgmental moment. They looked like a bunch of ne’er-do-wells to me. They looked like people who couldn’t be bothered with rules. Apparently, they found out that our society had a different view of the world. It brings me back to the big picture. We compliance types can, like anyone, get lost in the weeds. Who are compliance professionals? What is our purpose? Why do we exist? I think we are here for the same reason the people behind the desk of the Fines and Penalties department are here. We are part of a system that is here to create a civil society.

Think about, for a moment, countries without the rule of law. Those rules and sent them a letter fining them. Then, you set up a desk downtown and waited for them to come pay their fines. You better bring a lunch. You better bring about 99 lunches. You will be there a long time. I have no idea what they have for rules, but I know what they have for enforcement and respect for the rules. That would be zero. And what follows, my friend, is chaos.

On the other hand, you can’t say they have too many lawyers. You can’t say that they have too many regulations. And, if you don’t have regulations, the regulations certainly can’t be too vague. They don’t have any of the problems with regulations that we have. Man, come to think of it, Somalia must be the place to live right now.

I am sure there is a country that survived without the rule of law. But the fact that it happened once doesn’t mean it’s a reasonable expectation.

What we have here in this country, as far as the rule of law, is infuriating. In fact, I would go so far as to say that any country with any form of the rule of law and enforcement is infuriating. There is no rule of law system that is not infuriating. It is an infuriating process to maintain a civil society. There are too many lawyers, too many laws, and too little flexibility. There is too much and too little of everything related to our legal system. Our system stinks, of that I have no doubt, but there is no better system to maintain the rule of law than what we have in the United States of America. The fact that the US system is infuriating is irrelevant. What is infuriating is that we need a system.

You can blame you for the rule of law. Apparently, left unchecked, we humans are unruly. Just look at Somalia or one of a number of other countries that do not have a rule of law that measures up to ours. History is replete with examples of what happens without the rule of law.

This point is where some people jump in with anecdotal stories. They share one example and make broad sweeping generalizations based on the one example. They add a heavy dose of how things should be or how they want things to be. I am sure there is a country that survived without the rule of law. But the fact that it happened once doesn’t mean it’s a reasonable expectation.

Then there are the theorists. Theorists believe that we should be able to buy a bucket of carrots and pass them out. Everyone will know how to

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behave and will behave that way all the time. There are also those who say that a rule-based system is not as effective as one guided by principles or values. For the most part they would be correct. The problem is that ethical behavior is on level two of our game of life. You can't even begin to reach level two (ethical behavior) until you follow some simple rules, like don't kill people. We need rules, and we need to enforce them. Take, once again, Somalia. How do you think someone with a bucket of carrots and no rules would do there? Before Somali can behave ethically, they have to stop breaking basic rules, and for that, you (unfortunately) will need a stick.

Some countries have no government and therefore can't implement the rule of law. Some countries have a corrupt government and can't implement a rule of law. Some countries have people who believe humans can be left to their own devices, and don't think they need the rule of law. A majority of those countries are on fire.

I am sorry that humans can't create a civil society without a rule of law. But, given that we will face abject failure without the rule of law, I am glad to be a small part of it as a compliance guy. Since I started this article I have been called to a court room three times. Twice they settled while we stood outside the court room. We were that good. The third case was a woman who was accused of settling a dispute by running over someone with her car; apparently, that is against the law. Alas, I was not picked for that jury. This is like a lottery within a lottery within a lottery. It got picked for jury duty. Then, I had to be picked to be in a jury pool (about 35 people). Then, I would have to be picked to be on a jury. I think I would have better odds creating a civil society without the rule of law.

One PI reports will likely be driven by benchmarking data. As PEPPER (Program for Evaluating Payment Patterns Electronic Report) reporting resumes in 2010, the process of benchmarking may become more feasible for providers at the Medicare level. It will remain difficult to comprehensively predict comparative values for other providers in the respective peer groups. Absence of comprehensive benchmarking data should not dissuade organizations from attempting proactive data analysis, but rather is an important element to consider when evaluating internal reports.

For those purchasing data, it is wise to consider that the comparative base is potentially not as comprehensive as what will be available through the One PI tool. Purchased benchmarking data has its value; however, awareness of the comparative base used by contractors is an important consideration to maintain.

Many compliance conferences and educational opportunities have offered a wealth of information regarding all of the emerging government contractors and the probability of related recoupment(s). In addition to continuing with traditional educational opportunities, providers should also monitor for news regarding One PI and any other developing technologies that utilize claims data to stay fully aware of trends in compliance and ultimately gain further understanding of internal patterns at the organizational level.

1. Available at http://www.hhs.gov/ocio/capitalplanning/exhibit300/FY10Exhibit300/cmsmipmodernizationonepisystem.html
2. See http://www.edssafeguardservices.eds-gov.com/onePI.asp

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You are a relatively new compliance officer at Ozymandias Memorial Hospital, responsible for administering its fraud and abuse compliance program, which includes following up on complaints on the compliance program hotline. After a few somnolent months on the job, you are awakened by an alarming voicemail from an anonymous hotline caller who asserts that Oz (a hospital nickname) has been submitting false claims to Medicare and other federal health care programs for a number of years. The claims are for medically unnecessary angioplasty, elective angioplasty, and elective stenting procedures. According to the caller, these procedures were performed by Dr. Greedly. You happen to know quite well one of the nurses named and decide to talk to her. She unloads on Dr. Greedly and states that her complaints and other complaints to the Head of Cardiology and your predecessor were simply ignored.

The anonymous caller’s allegations are that Dr. Greedly falsely diagnosed the existence of coronary artery disease, falsely identified coronary blockages, recorded false diagnoses in patients’ charts, and put patients at risk by performing these medically unnecessary procedures. The anonymous caller’s voicemail names four patients as examples of instances where Dr. Greedly caused Oz to submit false claims to Medicare.

The caller also provides names of a number of Oz nurses and medical technicians who allegedly have complained to their superiors after witnessing unnecessary angioplasty procedures by Dr. Greedly. You happen to know quite well one of the nurses named and decide to talk to her. She unloads on Dr. Greedly and states that her complaints and other complaints to the Head of Cardiology and your predecessor were simply ignored.

You wrestle with the following questions:

■ Are the anonymous caller’s allegations true or is this a “gray” area where medical opinions about the necessity of the services provided will differ?

■ If the allegations are true, is Dr. Greedly’s conduct endangering the health of Oz patients?

■ If true, how many nurses and technicians complained about Greedly, to whom, and why wasn’t anything done about it?

■ Are there records and e-mails of these complaints and where are they?

■ Did Ozymandias Memorial submit its related facility fee claims “willfully” in violation of myriad federal criminal statutes (“knowingly” within the meaning of the civil False Claims Act) as the result of mere negligence; or did it rely reasonably on Dr. Greedly’s medical judgment—correct or not—that the services provided were “medically necessary”?

■ Is this an “overpayment” matter that can be resolved quietly by simply repaying Medicare and others for the claims submitted incorrectly?

■ Or will there be enough fraud indicia so that the safer course is to participate in the US Department of Health and Human Services (DHHS) Office of Inspector General (OIG) voluntary disclosure program?

■ If the latter, will Oz be saddled with an OIG-imposed corporate integrity agreement (CIA) and attendant bad publicity?

■ What sort of disgruntled patient malpractice exposure might such publicity cause?

■ Could Dr. Greedly and Oz already be the subject of a qui tam complaint filed under seal, and is the anonymous caller the plaintiff (or “relator”) in such an action?

■ Is the anonymous caller also a current employee, someone who will be reporting back to OIG on how you and others respond to his allegations?

These questions and their possible ramifications are enough to give you a headache. Because you are not a lawyer, you head for the office of Oz’s general counsel (GC), someone whose pay grade is higher than your own.

**Cloaking the investigation under the attorney-client privilege**

The GC’s reaction is that the CEO must be informed immediately. After being briefed, the CEO tells you and the GC that he has heard negative hospital “scuttlebutt” about Dr. Greedly and his methods of practice, but nothing concrete. The CEO and GC consider briefing the chief of the medical staff about the Greedly allegations, but defer any such discussion until after some additional investigation has been done. The GC recommends hiring Snooper & Grill, a local law firm, to team up with you to conduct an internal investigation, in hopes that the results will fall within the

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Integrating the hospital compliance program with the medical staff bylaws

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attorney-client privilege. The CEO agrees, but asks that you and Snooper & Grill proceed cautiously. “If at the end of the day,” the CEO says, “these are questions of medical judgment on which reasonable physicians can disagree, we want to be careful not to damage Dr. Greedly’s reputation or the hospital’s relationship with the Greedly Group.” The CEO suggests talking to Dr. Greedly before running up a big Snooper & Grill legal bill. “Maybe, Greedly can point to reputable authority supporting the proposition that these services were medically necessary,” the CEO adds, “and, then, we can shut this thing down.”

Snooper & Grill would prefer to gather the relevant documents and interview other nurses and technicians, but they acquiesce in the GC’s request that they first talk to Dr. Greedly. Because you know Dr. Greedly, you are asked to call him and set up the interview. After reaching Dr. Greedly, you explain that there has been a complaint that he has provided medically unnecessary surgical services at Oz and that the hospital’s compliance program requires a follow-up inquiry to ascertain whether the allegations have merit. You add that Snooper & Grill have been retained so that the fact of the inquiry and the results thereof will be protected under thehospital’s attorney-client privilege. You ask when might be a good time for the interview. Dr. Greedly says that he is extremely busy, but he’ll get back to you.

A few days later, Dr. Greedly leaves you a voicemail saying he doesn’t have time to be interviewed. Snooper & Grill then write Dr. Greedly a letter describing the need for his interview, but promising to conduct the interview at his convenience and to be as brief as possible. The GC subsequently reports that Dr. Greedly called the CEO complaining that you and Snooper & Grill are impugning his professional reputation, that he is not going to respond to baseless accusations generated by jealous competitors and, if necessary, he will move his patients to another hospital.

The medical staff bylaws

Do the medical staff bylaws require a physician with privileges to cooperate with a hospital’s internal fraud and abuse investigation?

Miffed, you consider filing a complaint with the Medical Executive Committee (MEC) against Greedly for obstructing a compliance program internal investigation. You are seeking the suspension of his privileges to practice at Oz. You review the Oz medical staff bylaws. Surprisingly, there are no references to the hospital’s code of conduct or compliance program in the bylaws. There is a section entitled “Basic Responsibilities of Medical Staff Membership,” which sets forth 16 categories of enumerated duties that members are required to perform. These enumerated duties do not require that members abide by the Oz code of conduct, receive education and training on fraud and abuse issues, or cooperate with a hospital internal fraud and abuse investigation.

Medical staff members are required to abide by “the lawful ethical principles of the State Medical Society or the member’s professional association,” and to provide patients with the quality of care that meets the medical staff’s professional standards. Staff are also required to disclose certain events to Oz’s CEO within a prescribed time period, including the filing of charges or the commencement of a formal investigation of such member by any federal or state law enforcement or health regulatory agency, or exclusion from participation in federal health care programs.

Despite your lofty title, Snooper & Grill point out that the medical staff bylaws do not authorize you to file a complaint against Greedly. Indeed, only the chief of the medical staff, a Staff department or Committee Chair, the CEO, or the hospital’s Board of Trustees may file a “request for corrective action” against a medical staff member.

In short, to seek the suspension of his privileges, you must persuade the CEO to file a complaint with the MEC alleging that Greedly provided medically unnecessary services to Oz patients, that such conduct is both unethical and fails to meet the medical staff’s professional standards, and that it possibly endangers the health of Oz patients. You question whether the CEO currently has the stomach for this. Alternatively, you could go to the Compliance Committee of the Board of Directors and see if the Compliance Committee can persuade the full board to file such a complaint. If you are successful, MEC will conduct its own investigation of Dr. Greedly or designate an ad hoc committee of the medical staff to conduct the investigation.

Frustrated, you ponder where to turn while Dr. Greedly continues to perform procedures at Oz.

The hospital compliance program

Among the questions posed by our Oz hypothetical are:

- Should the Medical Staff bylaws require a non-employed, medical staff physician to abide by the hospital’s code of conduct?
- When a medical staff member is the alleged code of conduct violator, which body enforces the hospital’s code of conduct—the hospital compliance officer and/or Compliance Committee, or the medical staff?
- Should a medical staff member’s failure to cooperate (e.g., failure to consent to an interview) during a hospital’s internal code of conduct investigation constitute grounds for suspension of his or her privileges?
- Should the compliance officer or the Compliance Committee be able to initiate proceedings under the medical staff bylaws?
to suspend a medical staff member's privileges, when he or she either is the alleged violator or fails to cooperate?

Application of the code of conduct
Traditionally, medical staffs were organized and bylaws were adopted principally to ensure that the quality of physician services provided at the hospital met professionally recognized standards of care. Thus, although the bylaws typically are amended periodically, most were formulated and adopted long before the advent of hospital codes of conduct and compliance programs. Many such bylaws contain no reference to the hospital's code of conduct/compliance program. Some require compliance with hospital policies and procedures, but others do not contain any language which might be used to argue that the bylaws indirectly incorporate the hospital's code of conduct or compliance program.

Amending the bylaws to require compliance with the hospital's code of conduct requires medical staff approval and may not be politically popular. To complicate matters further, in certain states, state statutes control the grounds for suspending or terminating medical staff membership privileges.

OIG has recently entered into corporate integrity agreements (CIAs) with several hospitals in which the hospital's active medical staff are expressly included in the definitions of "covered persons" and "relevant covered persons" and, thereby, required to comply with the hospital's code of conduct.1 Within 120 days of the CIA's effective date, covered persons are required to certify in writing that they have received, read, understand, and will abide by the hospital's code of conduct.2 Under the CIAs, covered persons are also expected to report suspected violations of federal health care program requirements or violations of the hospital's policies and procedures.3 The hospitals are required to provide to covered persons one hour of general training on the CIA's requirements, the code of conduct, and those portions of the hospital's policies and procedures that pertain to compliance issues.4

The term "relevant covered persons" includes "covered persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any federal health care program."5 Relevant covered persons are required to receive two hours of specific training on a laundry list of items including:

- Federal health care program requirements regarding accurate coding and submission of claims;
- Policies, procedures, and other requirements applicable to the documentation of medical records;
- The personal obligation of each individual in the claims submission process to ensure that such claims are accurate, and the applicable reimbursement statutes, regulation, and program requirements and directives; and
- The legal sanctions for violations of federal health care program requirements.6

Each relevant covered person must certify in writing that they have received the required training.7

Should today's medical staff bylaws require the active medical staff to understand and abide by the hospital's code of conduct and its policies and procedures, to receive periodic fraud and abuse compliance training, and to report suspected violations? OIG apparently thinks so.

Who enforces the code of conduct?
Which body enforces the hospital's code of conduct when a staff member is the alleged violator—the hospital compliance officer/committee or the medical staff? What if the medical staff member is alleged to have violated pertinent state or federal laws or regulations and is also in violation of the hospital's code of conduct? In other words, what if the staff member's conduct has allegedly caused the hospital to file false claims?

If a code of conduct violation gives rise to hospital criminal, civil, or administrative liability, or requires repayment, the hospital has an obligation to investigate, ascertain the facts, and take appropriate remedial action.

That said, the interface between the enforcement of the hospital's code of conduct and the medical staff's traditional role in governing the conduct of its members raises questions for which there are no easy answers. Which body—the hospital Compliance Committee or the MEC—should determine whether the staff member has violated the code of conduct? What due process rights are accorded the accused staff member? Before having his or her privileges suspended or terminated, is the medical staff member entitled to a hearing, to be represented by counsel, to confront and cross examine adverse witnesses, and to present a defense (i.e., the normal "fair hearing" procedures)? If the MEC is the more appropriate body to adjudicate alleged member violations, does the hospital wait until the MEC has rendered its decision before repaying Medicare, Medicaid, et al?

Certain alleged code of conduct violations (e.g. upcoding) require no medical expertise. Other alleged violations, such as providing medically unnecessary services, do require such expertise, but finding medical staff members willing to serve as adjudicators may be problematic. In such instances, should an impartial hearing officer be retained to decide whether the alleged violator's privileges should be suspended or terminated?

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Integrating the hospital compliance program with the medical staff bylaws
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Although the process may be difficult, the hospital, the chief of the medical staff, and the MEC presumably all have a joint interest in expeditiously resolving alleged code of conduct violations involving medical staff members, particularly where the alleged conduct, if true, may endanger the health of hospital patients.

**Grounds for suspension**

Should a medical staff member's failure to cooperate with a hospital code of conduct investigation be grounds for suspension of his or her privileges? If a hospital-employed physician refuses to cooperate, his or her employment will likely be subject to termination. Should the same obligation to cooperate, (e.g. meeting with the hospital's lawyers conducting the investigation and turning over any relevant documents) extend to a non-employed medical staff member? Presumably, the vast majority of physicians will cooperate. Should those who do not face the possible suspension of their privileges?

If, as in our hypothetical example, the staff member refusing to cooperate is the alleged violator, the focus will be whether the allegations have merit, and any refusal to cooperate will be secondary. If the evidence indicates that the code of conduct has been violated, the Board of Trustees or the CEO will likely file a complaint under the medical staff bylaws, seeking suspension of the violator's privileges on those grounds.

Whether the refusal to cooperate by a staff member who is not a suspected code of conduct violator should be grounds for suspension is a more difficult question. The non-employed staff member does not have the same legal duty of loyalty to the hospital as his or her employed brethren. At the same time, if the staff member is simply a potential witness whom the hospital needs to interview, what is the principled justification for a failure to cooperate? Ultimately, the answer probably depends upon the circumstances, but such situations present tough choices.

**Initiating corrective action**

Should the compliance officer or the compliance committee be able to initiate a corrective action proceeding for a medical staff member's failure to cooperate or for an alleged violation of the hospital's code of conduct? Typical medical staff bylaws allow various individuals and committees to submit a request for corrective action. These include the MEC, the chief of service or department head of the medical staff member, the chief of staff, the hospital CEO, and the hospital board. Should the hospital board's Compliance Committee or compliance officer be authorized to request corrective action? Both of these possible additions to the typical list may create serious political issues for a hospital because, from the medical staff's perspective, these additions will likely increase the number of corrective actions and time-consuming investigations. In addition, if the hospital CEO and board can...
already initiate a corrective action, is there really any reason why individuals or committees that report to them, respectively, should also be able to initiate an action? Probably not, as long as the compliance officer or the Compliance Committee has direct access to the Board of Trustees in the event that the CEO is unwilling to act. Presumably, when reasonable grounds exist and given the stakes involved, the compliance officer or Compliance Committee will not find it difficult to persuade the CEO or full board to go forward.

**Conclusion**

To return now to our hypothetical, while the CEO vacillates about taking on Dr. Greedly, help arrives in the form of a federal grand jury subpoena seeking all hospital documents relating to procedures Dr. Greedly performed at Oz during the past 5 years. Concerned about the hospital's exposure, the CEO pushes for Dr. Greedly's suspension. While protesting his innocence, Dr. Greedly resigns from the medical staff on the advice of his attorney.

Two years later, the hospital learns that the grand jury investigation arose as the result of a *qui tam* action filed by a former Greedly Group physician against Dr. Greedly, the Greedly Group, and the hospital. The US Department of Justice intervenes in the *qui tam* action and, citing the complaints of operating room nurses and technicians, asserts that Oz knew that Dr. Greedly was performing medically unnecessary procedures. On Snooper & Grill's recommendation, Oz settles by paying the U.S. $3.5 million dollars and an additional $250,000 in reasonable attorneys fees and costs to the former Greedly Group physician/whistleblower to resolve the *qui tam* action.

Lest you think this hypothetical too fantastic, consider the *qui tam* action filed by Dr. Christopher T. Mallavarapu against Dr. Mehmood M. Patel, Acadiana Cardiology LLC, and Our Lady of Lourdes Regional Medical Center, in the US District Court for the Western District of Louisiana. Dr. Mallavarapu alleged that Dr. Patel was performing numerous medically unnecessary, improper, and excessive procedures at Our Lady of Lourdes, that he reported his concerns to the hospital, requested peer review panels be established to determine whether Dr. Patel's procedures were medically necessary, and that the hospital took no action.9

In August 2006, Our Lady of Lourdes, while denying any liability, paid the US government $3.8 million to resolve allegations that Dr. Patel had performed medically unnecessary angioplasty, angiograms, and stenting procedures at the hospital.8 It reportedly also paid an additional

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$7.4 million to settle a class action brought by Dr. Patel’s patients. Dr. Mallavarapu received $760,000 of the government’s $3.8 million recovery from Our Lady of Lourdes under the qui tam provisions of the Civil False Claims Act.

Like our hypothetical Dr. Greedly, Dr. Patel also performed procedures at a second hospital, Lafayette General Medical Center (LGMC) in Lafayette, Louisiana. In late 2006, Dr. Mallavarapu added LGMC as a defendant in his qui tam action. In January 2008, LGMC, while denying any liability, paid the United States $1.9 million to settle this action. In April 2008, LGMC agreed to pay an additional $1.8 million to settle approximately 100 malpractice suits brought by former patients of Dr. Patel. Dr. Mallavarapu received $380,000 of the government’s $1.8 million recovery from LGMC.

At the time of the January 2008 LGMC settlement, Donald Washington, then the United States Attorney for the Western District of Louisiana, said:

Hospital providers like LGMC are not entitled to be paid by federal health plans for medically unnecessary procedures. And they may not simply rely on the representation—or in this case the misrepresentations—of the physicians they allow to practice within their facilities. Providers like LGMC have a separate, independent and on-going duty to review the practices and procedures of the physicians they credential, assess those activities in light of the applicable standards of care, and consistently act in whatever manner is necessary to ensure the medical necessity of procedures and the accuracy and integrity of every claim the hospital submits.

In 2009, after a criminal trial, Dr. Patel was sentenced to 10 years imprisonment, fined $175,000, and ordered to make $387,511.56 in restitution as a result of his conviction for making false claims to federal health care programs and private insurers.

Are hospitals at risk if their medical staff bylaws are not updated to address compliance issues? Our Lady of Lourdes and LGMC ordeals suggests the answer is Yes.


5. See Department of Justice, supra note 9.

6. See Amendment to Complaint in United States ex rel. Mallavarapu v. Acadia Cardiology, Civil Action No. 04-0732, ¶ 10-12 (W.D. La.).


9. See Department of Justice, supra note 9.

10. See Amended Complaint in United States ex rel. Mallavarapu v. Acadia Cardiology, Civil Action No. 04-0732, ¶¶ 9-10 (W.D. La.).


15. For details e-mail margaret.dragon@hcca-info.org with your topic ideas, format questions, etc. Articles generally run between 1,300 and 2,600 words; this is a guide, not a limit. Compliance Today uses the Chicago Manual of Style. We require footnotes to be 10 or less with references appearing at the end of the article. Please do not use the footnote feature in Word. The author’s contact information must be included in the article as well as the article title. Articles should be submitted as a Word document with very limited formatting. Please select a deadline from the list below.

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- July 1
- August 2
- September 1
- October 4
The big score in compliance: Scoring audits with the error percentage method

By Cynthia Centerbar

Editor’s note: Cynthia Centerbar is a Senior Health Care Consultant at Hayes Management Consulting in Newton, Massachusetts. She has more than 3 years experience assisting health care organizations with implementation and support of auditing applications. Cynthia may be contacted by e-mail at CCenterbar@hayesmanagement.com.

Professional compliance auditing software enables you to automate the process that used to take hours to complete. But, as with all software applications, it is important to understand that these products are tools to help you with a given process, such as audit scoring.

Organizations develop their processes based on legal advice and regulatory compliance. Many variances can exist between audits conducted in southern California versus South Carolina. As such, auditing applications need to be programmed with organization-specific rules. In addition to outside rules, you should take into consideration best practices.

So, what are the essential elements of a good scoring methodology? Most compliance software users wrestle with this question; however, there appear to be three consistent elements:

1. A clear mathematical threshold for reaching a failed state, necessary for triggering the organization’s escalation and remediation process
2. A mechanism to identify education needs
3. The ability to correlate risk with audit findings

To help identify educational needs, findings are categorized by error type, such as overcoding, undercoding, modifier error, Teaching Physician Rules (for physicians at teaching hospitals), etc. (See sample in Table 1 below).

When cases are audited, all findings are recorded. For example, even if the initial finding is “Teaching Physician Rules not met,” the auditor would continue to evaluate the level of service and modifier usage to ensure that the educational objective is satisfied. There is no point limit set per case or audit.

In the error percentage method, there is:

- A correlation between risk level and expected outcome
- Fewer high-risk findings are required to reach a failed state
- More low-risk and moderate-risk findings are required to reach a failed state
- An ability to identify all educational needs
- A clear threshold for determining outcome
- A correlation between the number of transactions audited and calculating the error percentage

Following are three examples of this methodology in practice.

<table>
<thead>
<tr>
<th>Finding</th>
<th>Point</th>
<th>Error Type</th>
<th>Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agree with selected E&amp;M</td>
<td>0</td>
<td>Agree</td>
<td>Low</td>
</tr>
<tr>
<td>Agree with selected procedure</td>
<td>0</td>
<td>Agree</td>
<td>Low</td>
</tr>
<tr>
<td>E&amp;M service overcoded one level</td>
<td>0</td>
<td>Overcoding</td>
<td>Low</td>
</tr>
<tr>
<td>E&amp;M service overcoded two or more levels</td>
<td>1</td>
<td>Overcoding</td>
<td>High</td>
</tr>
<tr>
<td>E&amp;M service undercoded one level</td>
<td>0</td>
<td>Undercoding</td>
<td>Low</td>
</tr>
<tr>
<td>E&amp;M service undercoded two or more levels</td>
<td>1</td>
<td>Undercoding</td>
<td>High</td>
</tr>
<tr>
<td>Incorrect E&amp;M category</td>
<td>0.25</td>
<td>E&amp;M category change</td>
<td>Low</td>
</tr>
<tr>
<td>Consultation criteria not met</td>
<td>0.5</td>
<td>E&amp;M category change</td>
<td>Moderate</td>
</tr>
<tr>
<td>Teaching Physician Rules not met</td>
<td>1</td>
<td>Teaching Physician Rules</td>
<td>High</td>
</tr>
<tr>
<td>Anesthesia Medical Direction Rules not met</td>
<td>1</td>
<td>Teaching Physician Rules</td>
<td>High</td>
</tr>
<tr>
<td>CPT bundling/Unbundling</td>
<td>0.5</td>
<td>Bundling</td>
<td>Moderate</td>
</tr>
<tr>
<td>Modifier incorrect statistical</td>
<td>0</td>
<td>Modifier usage</td>
<td>Low</td>
</tr>
<tr>
<td>Modifier disagrees with selection</td>
<td>0.5</td>
<td>Modifier usage</td>
<td>Moderate</td>
</tr>
<tr>
<td>Insufficient documentation for procedure</td>
<td>1</td>
<td>Documentation basics</td>
<td>High</td>
</tr>
<tr>
<td>Insufficient documentation for E&amp;M</td>
<td>1</td>
<td>Documentation basics</td>
<td>High</td>
</tr>
</tbody>
</table>

E&M = Evaluation and Management

Table 1

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The big score in compliance: Scoring audits with the error percentage method

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Case Example A

In this example (Table 2), there are ten audit cases representing 14 lines of service. The audit sample consists of:
- 4 office visits
- 4 consults
- 2 procedures

Each transaction has only one finding for a total of 14 findings. The organization’s error tolerance is 20%. The presence of a low, moderate, and high risk finding does not produce a failed outcome.

Table 2

<table>
<thead>
<tr>
<th>Case</th>
<th>Findings</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Office visit</td>
<td>Agree with Select E&amp;M (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insufficient documentation for procedure billed (1)</td>
</tr>
<tr>
<td>2</td>
<td>Office visit, with 2 procedures</td>
<td>Agree with selected E&amp;M (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Agree with selected procedure (0)</td>
</tr>
<tr>
<td>3</td>
<td>Office visit, with procedure</td>
<td>CPT bundling/Unbundling (0.5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Agree with selected procedure (0)</td>
</tr>
<tr>
<td>4</td>
<td>Office visit</td>
<td>Incorrect E&amp;M category (.25)</td>
</tr>
<tr>
<td>5</td>
<td>Consult</td>
<td>Agree with selected E&amp;M (0)</td>
</tr>
<tr>
<td>6</td>
<td>Consult</td>
<td>Agree with selected E&amp;M (0)</td>
</tr>
<tr>
<td>7</td>
<td>Consult</td>
<td>Agree with selected E&amp;M (0)</td>
</tr>
<tr>
<td>8</td>
<td>Consult</td>
<td>Agree with selected E&amp;M (0)</td>
</tr>
<tr>
<td>9</td>
<td>Procedure</td>
<td>Agree with selected procedure (0)</td>
</tr>
<tr>
<td>10</td>
<td>Procedure</td>
<td>Agree with selected procedure (0)</td>
</tr>
</tbody>
</table>

To calculate the error percentage, the total points accumulated are divided by the number of transactions audited and multiplied by 100.

\[(\frac{1.75}{14} \times 100) = 12.5\%\]  
Audit outcome: Pass

Having categorized the findings by risk, a visual graph may be created to help illustrate the provider’s risk related to the findings. From this graph (Figure 1) it is clear that the provider’s risk is low.

Case Example B

In this example (Table 3), there are ten audit cases representing 14 lines of service with 15 findings. One of the transactions has two findings. The audit sample consists of:
- 4 office visits
- 4 consults
- 2 procedures

The error tolerance is again 20%. In this example, a moderate risk error trend causes the audit to fail.

Table 3

<table>
<thead>
<tr>
<th>Case</th>
<th>Findings</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Office visit, with procedure</td>
<td>Agree with selected E&amp;M (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Agree with selected procedure (0)</td>
</tr>
<tr>
<td>2</td>
<td>Office visit, with 2 procedures</td>
<td>Agree with selected E&amp;M (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Agree with selected procedure (0)</td>
</tr>
<tr>
<td>3</td>
<td>Office visit, with procedure</td>
<td>Incorrect E&amp;M category (.25)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>E&amp;M service overcoded two or more levels (.25)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Agree with selected procedure (0)</td>
</tr>
<tr>
<td>4</td>
<td>Office visit</td>
<td>Agree with selected E&amp;M (0)</td>
</tr>
<tr>
<td>5</td>
<td>Consult</td>
<td>Consult criteria not met (.5)</td>
</tr>
<tr>
<td>6</td>
<td>Consult</td>
<td>Consult criteria not met (.5)</td>
</tr>
<tr>
<td>7</td>
<td>Consult</td>
<td>Consult criteria not met (.5)</td>
</tr>
<tr>
<td>8</td>
<td>Consult</td>
<td>Consult criteria not met (.5)</td>
</tr>
<tr>
<td>9</td>
<td>Procedure</td>
<td>Agree with selected procedure (0)</td>
</tr>
<tr>
<td>10</td>
<td>Procedure</td>
<td>Agree with selected procedure (0)</td>
</tr>
</tbody>
</table>

The error percentage calculation is:

\[(\frac{3.25}{14} \times 100) = 23\%\]  
Audit outcome: Fail

The error percentage for this case is higher than the first case. From the pie chart below (Figure 2), it is clear that the moderate risk finding is increasing the overall risk.

![Figure 1](Image)

![Figure 2](Image)
Because the findings were also categorizing by error type, a visual graph (Figure 3) summarizing the error type helps identify where the education need to occur to remediate the error. This provider needs education on selecting the appropriate E&M category.

**Case Example C**

In this example (Table 4), ten audit cases represent 12 transactions. The sample is the same as the first two examples, as is the error tolerance. Two of the transactions have two findings for a total of 14 findings. Here, the presence of high and moderate risk errors causes the audit to fail.

<table>
<thead>
<tr>
<th>Case</th>
<th>Findings</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Office visit, with 2 procedures</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>E&amp;M Service overcoded two or more levels (1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Modifier disagrees with selection (.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Agree with selected procedure (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Agree with selected procedure (0)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Office visit</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Agree with selected E&amp;M (0)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Office visit</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>E&amp;M service overcoded one level (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Teaching Physician Rules not met (1)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Office visit</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Agree with selected E&amp;M (0)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Consult</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Agree with selected E&amp;M (0)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Consult</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Agree with selected E&amp;M (0)</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Consult</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Agree with selected E&amp;M (0)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Consult</td>
<td>.5</td>
</tr>
<tr>
<td></td>
<td>Consult criteria not met (.5)</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Procedure</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Agree with selected procedure (0)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Procedure</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Agree with selected procedure (0)</td>
<td></td>
</tr>
</tbody>
</table>

The error percentage calculation is:

\[
\frac{3}{12} = .25 \times 100 = 25\%
\]

Audit outcome: **Fail**

The graph of the error types (Figure 5) illustrates that this provider needs more general education.

**Figure 4** illustrates that a mix of high and moderate risk errors contributed to the provider's increased risk.

**Conclusion**

The error percentage method satisfies the common objectives for scoring audits:

- It defines a clear threshold for audit passage
- It associates risk level with each finding
- It categorizes findings into error type for educational purposes

Your organization may want to follow the above methodology, or you may have additional requirements imposed due to previous compliance audits or oversight. Remember, software will give you the tools to consistently audit and yield the data that you need with less effort (and manpower) than a manual process. However, it is incumbent upon you to make sure the rules are built correctly.
Managing security risks in business associate relationships


Newspapers and trade journals feature a growing number of stories detailing instances in which organizations have entrusted their most sensitive information and data to a vendor or other business partner, only to see that information compromised because the vendor failed to implement appropriate information security safeguards. Worse yet, those same organizations are frequently found to have performed little or no due diligence regarding their vendors and have failed to adequately address information security in their vendor contracts. In many instances, this leaves the organizations without a meaningful remedy for the substantial harm they have suffered as a result of a breach or compromise. That harm may take a variety of forms: damage to business reputation, loss of business, potential liability to the data subjects, and regulatory and compliance issues. Recent studies by the Ponemon Institute have shown that on average a company will pay $202 per record compromised and, in the aggregate, an average of $6.6 million if they experience a security breach.¹

Those organizations, entities, and individuals that provide health care services possess extremely sensitive and valuable information about patients, including both health and financial information. In today’s business and legal environment, health care providers must be far more rigorous when entering into vendor relationships in which patient-identifiable information will be placed at risk. The recently enacted HITECH Act provisions of the American Recovery and Reinvestment Act strengthen the privacy and security requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations. For the first time, providers have a mandate to notify patients of security breaches that involve their information. Specifically, the HITECH Act requires providers to notify patients of security breaches of “unsecured” patient-identifiable information, defined and referred to as protected health information (PHI).

Shortly after issuance of the HITECH Act, the Department of Health and Human Services (HHS) published a guidance document indicating that PHI can be properly “secured” if it is encrypted or destroyed in accordance with HHS guidance. If PHI is “secured,” then it is not subject to the security breach notification requirements. However, it is virtually impossible to maintain PHI in an encrypted state when it is in “use” (i.e., being created, viewed, modified, etc). As a result and from a practical perspective, at any given moment, providers will have significant PHI at risk of a security breach that will trigger the notification requirements.

Health care providers frequently hire vendors, referred to as business associates (BAs), to perform services involving PHI, including services that require the BA to create, view, or modify PHI. Such PHI is also subject to the HITECH Act security breach notification requirements. However, if a BA has a security breach that triggers the notification requirements, that BA’s sole obligation under the HITECH Act is to notify the provider. The obligation to notify affected patients and to take other required action remains with the provider. There could be
significant costs associated with security breach notification, including
(but not limited to) the cost of creating and sending out the required
notifications and responding to queries and complaints from affected
patients, as well as the costs to implement mitigation steps, such
as free credit report monitoring. Costs may also be associated with
negative publicity and governmental investigation and enforcement
action. Absent contractual provisions that address allocation of liability
for costs associated with security breach notification requirements, a
provider will likely find itself liable for all costs connected to security
breaches of PHI that was under the control of a BA.

HIPAA and the HITECH Act contain requirements that providers
must follow when contracting with BAs, including contractually
binding their BAs to implement security measures to protect PHI.
However, providers are not legally required to monitor a BA’s con-
tractual or statutory compliance with HIPAA and the HITECH Act.
Although BAs are directly subject to the HIPAA Security Rule under
the HITECH Act, as noted above, much of the risk and liability asso-
ciated with security breaches remains with the providers. Therefore,
in this new environment, providers should take a more regimented
approach to security to further mitigate risk. The recommendations in
this article are intended to reduce the likelihood of security breaches
by ensuring that BAs are obligated to provide “best practice” protec-
tions for handling PHI.

Reducing information security threats
Providers have three tools they can immediately put to use to
substantially reduce the information security threats posed by their
BAs, ensure proper due diligence is conducted and documented, and
provide remedies in the event of a compromise.

Those tools are:

- the due diligence questionnaire,
- key contractual protections, and
- the use in appropriate circumstances of an Information Security
  Requirements exhibit.

Whenever a BA will have access to an organization’s network, facilities,
PHI, or other sensitive or valuable data, one or more of these tools
should be used.

Use of these tools will enable a provider to achieve a number of
important goals, including:

- Reduce risk of security breaches that trigger notification require-
mements under the HITECH Act and minimize potential liability. As
  noted above, costs arising out of security breaches and associated
  with security breach notification can be substantial. In addition to
  investigations by government agencies of HHS, security breaches
could result in actions by state attorneys general.

- Protect valuable assets of the provider. In many instances, a
  provider’s proprietary and confidential information is the most
  important asset of the company (e.g., new service lines, future
  marketing activities, prospective transactions, trade secret informa-
tion, computer source code). Such information in the hands of
  a competitor could result in material harm for the provider. For
  publicly traded providers, a compromise of corporate data may
  result in shareholder suits against the officers of the corporation for
  failure to exercise reasonable business judgment in protecting that
  information.

- Create contractual remedies for providers in the event of a secu-
  rity breach with a BA.

- Establish the provider has used due diligence in protecting PHI
  and its information systems. In the event of a compromise, the tools
  will assist the provider in documenting its efforts to minimize risk.

- Protect the provider’s reputation and avoid the public embarrass-
  ment associated with a security compromise.

Due diligence: The first tool
Providers may conduct some form of due diligence before entrust-
ing BAs with PHI or with access to their systems. However, the due
diligence is often done informally, in a non-uniform manner, and
not clearly documented. In very few instances is the outcome of that
due diligence actually incorporated into the parties’ contract. This
ad hoc approach to due diligence may no longer be appropriate or
reasonable in the context of today’s business and regulatory environ-
ment. To help ensure proper documentation and uniformity of the
due diligence process, especially for high risk arrangements, providers
should consider developing a standard “due diligence questionnaire”
for prospective BAs to complete. Areas covered by the questionnaire
would include: corporate responsibility, insurance coverage, financial
condition, personnel practices, information security policies, physical
security, logical security, disaster recovery and business continuity, and
other relevant areas.

Use of a standardized questionnaire has a number of significant benefits:

- It provides a uniform, ready-made framework for due diligence.
- It ensures an “apples-to-apples” comparison of BA responses.
- It ensures all key areas of diligence are addressed and none are
  overlooked.

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Managing security risks in business associate relationships  ...continued from page 33

- It provides an easy means of incorporating the due diligence information directly into the party’s contract. That is, the completed questionnaire can be attached as an exhibit to the final BA agreement, which will be executed along with the underlying services agreement.

From the outset, BAs must be on notice that the information they provide as part of the due diligence process and, in particular, in response to the due diligence questionnaire will be (1) relied upon in selecting the BA; and (2) incorporated into and made a part of the final BA agreement, together with the underlying services agreement between the parties. To be most effective, the questionnaire should be presented to potential BAs at the earliest possible stage in the relationship. It should be included as part of all relevant RFPs or, if no RFP is issued, as a stand-alone document during preliminary discussions with the BA.

Key areas for the due diligence questionnaire include:

- **BA’s financial condition.** Is the BA a private or public company? Can the provider obtain copies of the most recent financial statements? Financial condition may not appear to be a critical factor for information security purposes, but the possibility a BA may file bankruptcy or simply cease to do business while in possession of a provider’s most sensitive information presents a substantial risk, especially in today’s current economic environment. In such instances, it may be difficult, if not impossible, to retrieve the data and ensure it has been properly scrubbed from the BA’s information systems.

- **Insurance coverages.** What types of coverage does the BA have? What are the coverage limits and other terms? Is the coverage “claims made” or “occurrence based”? Does the BA’s insurance cover liability related to privacy violations or security breaches?

- **Corporate responsibility.** Are there any criminal convictions, recent material litigation, or instances in which the BA has had a substantial compromise of security? Has it ever been investigated for privacy violations, etc.?

- **Subcontractors or affiliates.** Will the BA use subcontractors or affiliates in the performance of its services? Will the BA use subcontractors or affiliates outside the United States? Where are the subcontractors and affiliates located? What types of services will they provide? What information, if any, of the provider will be sent to these entities? Transmission of PHI to contractors or subcontractors located outside the United States has been identified as creating unique risk. Such entities will not be subject to US court jurisdiction. There have been highly publicized reports of situations where...
PHI was potentially subject to unauthorized disclosure, including an instance in which a non–US-based contractor threatened to publish the PHI if it did not receive payments.

- **Organizational security procedures.** What are the BA’s information handling policies? Does it have a dedicated information security team? Is there an incident response team? What are the BA’s information security practices with contractors and agents (e.g., due diligence, requiring non-disclosure agreements, specific contractual obligations relating to information security)?

- **Physical security.** What physical security measures and procedures does the BA employ?

- **Encryption.** Does the BA use appropriate encryption technologies to protect PHI and other sensitive information?

- **Document destruction.** Does the BA destroy PHI and other sensitive information through appropriate methods, such as shredding paper, film or other hard copies, and clearing, purging or destroying electronic media in accordance with HIPAA requirements?

- **Audit trail.** Does the BA have appropriate access controls and logging/audit trail capabilities?

- **System access control.** Does the BA use system access control to limit information access to only those of its personnel who are specifically authorized?

- **Development and maintenance of code.** If the BA is a software developer, what are its development and maintenance procedures? What security controls are used during the development lifecycle? Does BA conduct security testing of its software? Does the BA maintain separate environments for testing and production? Does the BA license code from third parties for incorporation into its products? If so, what types of code?

- **Security policy and privacy policy.** If PHI is at risk, does the BA have an information security policy and privacy policy? What is the revision history of its policies? Are there any instances where the BA has had to contact patients or consumers regarding a breach of security?

- **Disaster recovery.** What are the BA’s business continuity/disaster recovery plans? When was its last test? When was its last audit? Were there any adverse findings in the audit? Have deficiencies been corrected? What is the revision history of its plan? What security procedures are followed at the recovery site?

- **Red Flag Rules.** Does the BA have an identity theft program designed to identify, detect, and respond to Red Flags (see Title 16 of the Code of Federal Regulations Part 681)? What is their process for notifying providers of potential Red Flags?

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**Key contractual protections: The second tool**

In the overwhelming majority of engagements, the underlying services contract entered into between a provider and its BAs has little or no specific language relating to information security. At most, a passing reference is made to undefined security requirements set forth in the BA agreement and a basic confidentiality clause. Of course, the BA agreement should contain language requiring the BA to “implement reasonable and appropriate administrative, physical, and technical safeguards to protect the confidentiality, availability, and integrity” of PHI. However, today’s best practices in BA contracting suggest far more specific language is required.

Moreover, the personnel responsible for negotiating the underlying services agreement are often not those charged with negotiating the BA agreement. As a result, there is often a disconnect between the risks to PHI implicated by the types of contemplated services and the terms to protect such PHI, as well to protect the provider, in the BA agreement. Providers should consider inserting very specific language into underlying agreements, referencing information security provisions in the BA agreement, and clearly incorporating such agreement into the underlying services agreement. The underlying services agreement and the BA agreement should be read together to ensure that ambiguities related to information security are eliminated (e.g., confidentiality provisions in the underlying agreement that could be interpreted to apply to PHI, which conflict with the terms of the BA agreement).

Providers had until February, 2010 to amend their BA agreements to include language required under the HITECH Act. This presented a critical opportunity to more specifically address information security. In addition to other provisions that must be inserted under the HITECH Act, the following protections related to information security should be considered for inclusion in relevant BA agreements.

**Warranties**

In addition to any standard warranties relating to how the services are to be performed and authority to enter into the underlying services agreement, the following specific warranties relating to information security should be considered for BA agreements:

- A warranty requiring the BA to comply with “best industry practices relating to information security;”

- Compliance with the provider’s privacy policy in accessing, using, and disclosing PHI;

- A warranty against sending PHI to offshore subcontractors or affiliates, unless specifically authorized to do so by the provider; and
A warranty stating that the BA’s responses are true and correct, for those arrangements in which the due diligence questionnaire has been completed. A copy of the completed questionnaire should be attached as an exhibit to the contract.

**Information security obligations**

In addition to the provisions relating to the BA’s compliance with the HIPAA Security Rule, and generalized language relating to the BA’s obligations to take all reasonable measures to prevent unauthorized uses or disclosures of PHI and to report all breaches or potential breaches of security to the provider, consider addressing more specific information security obligations. Consider, where appropriate, inserting specific language requiring the BA to:

- secure and defend its information systems and facilities from unauthorized access or intrusion,
- participate in joint security audits,
- periodically test its systems and facilities for vulnerabilities,
- use appropriate encryption and access control technology where applicable, and
- use proper methods and techniques for destruction of PHI to render such PHI “secure,” as set forth in the HHS guidance.

**Indemnity**

Consider including with general indemnity language, a specific provision requiring the BA to hold the provider harmless from claims, damages, and expenses incurred by the provider that result from a breach of the BA’s security. That is, the BA should protect the provider from lawsuits and other claims that result from the BA’s failure to adequately secure its systems. In the past, indemnity provisions were often negotiated out of BA agreements. However, in light of the heightened enforcement environment (including the authority conferred upon state attorneys general to bring civil actions against providers), decisions to forego indemnification should be reevaluated for risk under each BA arrangement.

**Costs for security breach notification**

As noted above, there could be significant costs associated with security breach notification, including costs related making the required notification, as well as costs associated with negative publicity and governmental investigation and enforcement action. Consider inserting provisions into the BA agreement that require the BA to pay for all costs associated with security breach notification requirements, if a security breach occurs with PHI in the control of the BA.

**Other provisions**

In addition to the BA agreement, other provisions impacting information security in the underlying services agreement should be evaluated as follows.

**Limitation of liability**

Most software/services agreements, and many other services agreements have some form of “limitation of liability” (i.e., a provision designed to limit the type and extent of damages to which the contracting parties may be exposed). It is not uncommon to see these provisions disclaim the BA’s liability for all consequential damages (e.g., lost profits, harm to the provider’s reputation) and limit all other liability to some fraction of the fees paid. These types of provisions are almost impossible to remove from most underlying services agreements, but it is possible to require the BA to exclude from the limitations those damages flowing from the BA’s breach of the BA agreement, including breaches related to information security obligations. Without these exclusions, the contractual protections described above would be essentially illusory. If the BA has no real liability for breach of privacy or confidentiality, because the limitation of liability limits the damages the BA must pay to a negligible amount, the providers contractual protections are rendered meaningless.

**Confidentiality**

The BA agreement is the venue for protecting the privacy and security of PHI. However, a fully-fleshed out confidentiality clause should be the cornerstone for information security protections related to non-PHI in every underlying services agreement. The confidentiality clause should be broadly drafted to include all information the provider desires to be held in confidence. Specific examples of protected information should be included (e.g., source code, proprietary care plans, marketing plans, new product information, trade secrets, financial information). Although the term of confidentiality protection may be fixed (for, say, five years), ongoing perpetual protection should be expressly provided for valuable information, such as trade secrets of the provider. Requirements that the provider mark relevant information as “confidential” or “proprietary” should be avoided. These types of requirements are unrealistic in the context of most arrangements. The parties frequently neglect to comply with these requirements, resulting in proprietary, confidential information being placed at risk. It will be important to read the confidentiality provision carefully in conjunction with the protections for PHI under the BA agreement to ensure there is no ambiguity.
Information security requirements exhibit: The third tool

The final tool in minimizing BA information security risks is the use of an exhibit or statement of work to specifically define the security requirements relevant for a particular transaction. For example, engagements in which PHI or other highly sensitive information will be entrusted to a BA may require the BA to observe strict practices in its handling of the information.

For example, the information security requirements exhibit may prohibit the BA from transmitting the provider’s information over internal wireless networks (e.g., 802.11a/b/g) or from transferring that information to removable media (e.g., flash drives, CDs) that could be easily misplaced or lost. The exhibit may also contain specific requirements for use of encryption and access control technology, and decommissioning hardware and storage media on which the provider’s information was stored. These measures ensure that the information is properly scrubbed from the hardware and media. Other specific physical and logical security measures should be identified as relevant to the particular transaction.

Conclusion

Providers are presented with unique risks when they entrust PHI and their proprietary and confidential information to their BAs. Those risks can be minimized by employing the tools discussed in this article: appropriate and uniform due diligence, use of specific contractual protections relating to information security, and use (where relevant) of exhibits or other attachments to the agreement detailing unique security requirements to be imposed on the BA. }

1. Available at www.ponemon.org/news-2/23
2. 74 Fed. Reg. 19006 (April 27, 2009). This guidance was updated and reissued as part of the Interim Final Rule on the HITECH Act security breach notification requirements, Breach Notification for Unsecured Protected Health Information, 74 Fed. Reg. 42740, 4271 (August 24, 2009).
Research compliance: PhRMA guidance on professional conduct in clinical trials

By Sharon Parsley, JD, MBA, CHC

In the 1946 Nuremberg doctor trials, 23 German physicians were tried, and the majority were convicted of conducting medical experiments on concentration camp prisoners without their consent. The atrocities involved ranged from mutilating surgeries to deliberately infecting the prisoners with lethal pathogens. These trials ultimately led to the first development of principles governing the ethical performance of research involving human subjects, known as the Nuremberg Code. As recently as the 1970s, a variety of similarly disturbing revelations led to the enactment of the National Research Act. In the late 1970s, the U.S. Department of Health, Education and Welfare created the initial framework for federal regulation to protect the rights and welfare of participants in human subjects research.

Few would argue that clinical research is an imperative in advancing medical science. Structured clinical trials perform the vital function of allowing researchers to identify better ways to prevent, diagnose, and treat disease, and to collect, in a meaningful and systematic manner, data about the safety and efficacy of new drugs and medical devices.

Fast forward to the present, a time when the constituents of the clinical research process are now faced with an intimidating alphabet soup of acronyms and an array of agencies that have purview over clinical research. WMA, ICH, HHS, NIH, OHSR, FDA, CDRH, CBER, CDER, AHRQ, OHRP and AAHRPP (to name just a few) are among the internationally recognized bodies and federal agencies and agency subdivisions promulgating regulation, policy, and guidance on the integrity of research involving human subjects. Among recent developments on this front is that The Pharmaceutical Research and Manufacturers of America (PhRMA) has published guidance, effective October 1, 2009, entitled “Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.”

The PhRMA principles are articulated with an eye toward governing the conduct of pharmaceutical and biotech manufacturers; however, these principles also serve as meaningful guideposts to ensure research objectivity in the conduct of investigators, investigational review boards (IRBs), and other research personnel involved in the clinical trials process. Research compliance officers in academic medical centers, teaching hospitals, and life science organizations should also be mindful of this guidance when evaluating the effectiveness of their internal systems for maintaining research compliance. The balance of this article examines the key concepts articulated within the first section of the PhRMA guidance “Principles on Conduct of Clinical Trials.”

Independent review and safety monitoring

Long-standing NIH policy suggests that every clinical trial requires an appropriate level of data and safety monitoring, which should be commensurate with risks associated with the specific study. The size and complexity of the monitoring effort can range from the principal investigator performing ongoing study monitoring for a small Phase I study, up through ongoing monitoring of a large Phase III trial being performed by an independent Data and Safety Monitoring Board (DSMB). Factors that might be indicative of a need for a more formalized monitoring approach include: a large study population, multiple study sites, expectations about high rate of study morbidity, or when the subject device or drug is highly toxic or dangerous.

Clinical trials are often performed in a “blinded” manner to minimize the influences of investigator bias and the so-called “placebo effect” on participants. The PhRMA principles suggest that “triple-blinded” studies are particularly effective (in which none of the participants, investigator, or statisticians who evaluate the data know which of the study subjects received the study drug or treatment and which received a placebo). PhRMA further suggests that a DSMB continuously monitors all randomized, multi-site interventional studies as an effective tool to minimize bias.

The effectiveness of a DSMB is, in large part, a byproduct of its composition and membership. Much like an IRB, an effective DSMB will be composed of persons having diverse backgrounds and expertise, and should ideally include clinicians having knowledge of the disease and treatment that is the subject matter of the study, as well as, biostatisticians and bioethicists. Members of the DSMB should, ideally, have no other association to the study. No DSMB participant should have a financial or other conflict of interest that would be likely to influence that person’s
judgment. The research site should have an appropriate process in place to appropriately manage any DSMB conflict of interest.

**Payments to study subjects**

It is said that in 1900, renowned military surgeon Walter Reed paid $100 in gold to individuals, who were then repeatedly bitten by mosquitoes infected with yellow fever to facilitate study of the effects of the disease. Today, it is fairly commonplace to see and hear study recruitment ads offering not only “free treatment,” but also to indicate that compensation for time and travel is provided.

FDA guidance about payments to research subjects suggests only that “recruitment incentives” be earned or accrued throughout the study life cycle and not be contingent on the participant completing the study. That guidance further indicates that payment of a small completion bonus is acceptable, provided that it isn’t so large as to unduly influence participants to complete the study where, without the completion bonus, the participant would have elected to withdraw.

Interestingly, little discrete guidance exists to help clinical investigators in determining whether and how much to pay study subjects. Current FDA regulation suggests only that the total amount and the proposed method and timing of all payments should be evaluated and approved by the IRB during the initial review process, to eliminate coercion and undue influence. Similarly, the PhRMA guidance suggests that any payment to a study subject for participation should be:  

- preapproved by an independent IRB/EC;  
- designed to reimburse for reasonably incurred out of pocket expenses associated with participation; and  
- consistent with the principles of the informed consent process being voluntary and free of undue influence or coercion.

**Payments to clinical investigators**

Scrutiny of the financial relationships between physicians and pharmaceutical and device companies has been dialed up dramatically over the past few years, with no indication of that trend reversing. Recently, the reputations of a handful of most esteemed academic medical institutions in the nation have been tainted by scandal after renowned physician-researchers have been identified as having lucrative, but undisclosed, financial relationships with the drug and device industries.

The following “rules of thumb” should be considered in all research compliance monitoring of contracting activities:  

- Payments to a study site or investigator must be outlined in a written contract or budget with the formula or basis for payments being clearly demonstrated and tied to specific services or milestones;  
- Aggregate compensation must always be reasonable for the work actually performed;  
- Compensation from a commercial sponsor should never be contingent on, or tied to, trial outcome;  
- Compensation should never include stock or stock options; and  
- Payment for travel time and reimbursement of reasonably incurred travel expenses is acceptable, provided that the recipient of the travel benefit provides services as a speaker or presenter at the event.

In January 2009, the OIG’s Office of Evaluation and Inspections issued a report entitled “The Food and Drug Administration’s Oversight of Clinical Investigators’ Financial Information.” The objectives of the study on which this report is formulated were to evaluate financial interests reported by researchers in all marketing applications approved by the FDA during fiscal year 2007, and to evaluate the effectiveness of the FDA’s oversight on these issues.

Among the findings from that study were that only 1% of the 29,691 individually identifiable clinical investigators disclosed a single financial interest or payment, with only a handful of investigators reporting multiple financial interests. More than three fourths (77%) of disclosed financial interests were sponsor payments, with another 23% of disclosures relating to equity, stock, and other proprietary interests. More than four in ten (42%) of the approved marketing applications reviewed were missing key financial information, and in 31% of the approved marketing applications, it appeared that no review of financial information was performed by the FDA reviewing panel. The report ultimately concluded that the FDA’s oversight in this area was grossly deficient in a variety of ways, and it makes several specific recommendations that are likely to raise the bar and result in additional scrutiny on issues relative to making proper and timely disclosure of financial interests.

Also worth note is that, as of the date of this writing, the Senate Finance Committee’s health insurance reform proposal, the Chairman’s Mark on America’s Healthy Future Act of 2009, contains a host of “physician payment sunshine provisions” which, if implemented, will require manufacturers of drugs, devices, biologics, and medical supplies to report every payment or transfer of “value” exceeding $100 in the aggregate in any year to each physician recipient. Failure to disclose would trigger a tiered system of civil money penalties ranging up to $100,000 for each willful violation of the reporting duty.

**Conflicts of interest**

Research conflicts of interest are, at least arguably, not completely unavoidable, and as result, must be carefully examined, managed, and disclosed to facilitate ethical industry
Research compliance: PhRMA guidance on professional conduct in clinical trials  ...continued from page 39

...collaboration; yet establish relationships with integrity and an appropriate degree of transparency. The burden on compliance professionals to keep research-related policies in harmony with the overall landscape (not to mention maintain defensible documentation about the identification, management and disclosures relating to research compensation and financial relationships) has grown exponentially.

Recently, legislative and regulatory forces seem to have coalesced to attack a variety of practices and interactions between the physician-researcher community and the drug and device industries. Near the top of the list of activities that appear under fire are:

- consulting agreements,
- royalty payments for intellectual property developed in the context of a clinical trial, and
- industry-sponsored symposia and scientific or professional meetings.

As of the date of this writing, one prominent research institution, which has recently been the subject of a congressional inquiry, is presenting to its Board of Regents one of the most comprehensive conflict-of-interest policies in the nation. If adopted, it will govern conduct at the university level, as opposed to specifically at the academic medical center. Among the concepts included in the proposed policy is a bar on the practice of ghostwriting (i.e., listing a physician-researcher as an author of an article that was, in reality, written by a commercial sponsor). Further, the policy would ban altogether accepting free meals and entertainment from industry sales representatives and prohibit university staff from accepting common low-value promotional items like pens, mugs, and notebooks.

A few “best practice” observations for compliance professionals would include ensuring that all terms and conditions relating to physician consulting and speaking engagements are outlined in a written contract. Events should occur at a venue that is appropriate for and in keeping with conducting legitimate scientific and educational objectives. Investigators should be mindful of accepting speaking engagements at meetings hosted at lavish or extravagant resort destinations. Invitations for free entertainment, recreation, and sporting events not directly related to the symposia, while tempting, should be declined; and, in fact, only modest meals incidental to the event should be provided or accepted.

Those with research compliance duties, particularly those in the pharmaceutical and device sector, should also be aware that on May 5, 2009, New Jersey Attorney General Anne Milgram announced that the state had entered into an five-year Assurance of Voluntary Compliance (AVC) agreement with Synthes, Inc., a global manufacturer of spinal and trauma products and devices. There, the underlying investigation was based on...
certain physician investments in spinal implant products that were the subject of clinical trials in which the physicians also served as clinical investigators.

In summarizing her findings in a letter to the then Acting Commissioner of the FDA, Milgram described undisclosed financial interests “rampant” and called on the FDA to heighten its oversight of and to rigorously enforce its conflict-of-interest regulations, and to promulgate additional regulation requiring device and pharmaceutical companies to make additional conflict-related disclosures to the public. Milgram’s letter to former Commissioner Sharfstein concludes by indicating her hope that the Synthes AVC “will become part of best practices for the entire medical device industry.”

The May 2009 Synthes AVC provides a useful framework for consideration by compliance professionals in the research arena, because it outlines, in detailed fashion, the Attorney General’s expectations of the target company relating to investigator and consultant contracting, the creation of procedures to collect and disclose financial interest data from investigators, payments at fair market value, training, records retention, and the tracking and disclosure of financial interests. Although an entire article could easily be dedicated to best practices in managing either individual or institutional research-related conflicts of interest, the PhRMA principles simply state that as to researchers, any “financial or personal relationships that could bias their work” and that the role of the study sponsor “in the collection, analysis, and interpretation of data” should be clearly disclosed in any study-related manuscript, article, or other journal submission.

In conclusion, the clinical research environment is rife with complexity, not to mention public relations and regulatory enforcement risks. The current level of scrutiny on the conduct of clinical trials, particularly on research-related financial relationships, warrants systematic and thoughtful compliance planning and ongoing monitoring to ensure that your organization’s research compliance exposures are minimized.

1. World Medical Association (WMA) The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
   U.S. Department of Health and Human Services (HHS)
   National Institutes of Health (NIH)
   Office of Human Subjects Research (OHSR)
   U.S. Food and Drug Administration (FDA)
   Center for Devices and Radiological Health (CDRH)
   Center for Biological Evaluation & Research (CBER)
   Center for Drug Evaluation and Research (CDER)
   Agency for Healthcare Research Quality (AHRQ)
   Office of Human Research Protections (OHRP)
   Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
4. 21 CFR §50.20.
5. PhRMA, Principles on Conduct of Clinical Trials at 14.
6. Ibid at 15 and 16.
8. Ibid at 17 and 18.
9. Ibid.

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n recent years, instances of Medicare and Medicaid fraud, waste, and abuse have made headlines throughout our country. HCCA, in partnership with Atlantic Information Services (AIS), has kept its members up to date with reports on the national efforts of Congress and the Centers for Medicare and Medicaid Services (CMS) in Medicaid Compliance News.

In addition, HCCA has provided links to important news articles that describe individual state actions, such as the Newsday.com headline “Schumer, Rice push for Medicare fraud crackdown.” It follows that, as agencies responsible for oversight of government programs develop more sophisticated auditing techniques, the issues examined will become more complex. One of the most important issues in today’s health care environment will become medical necessity. In home health care, this is especially true, because the care takes place in the community, the plan of care is developed by a nurse or therapist, and the oversight lies within the home care agency (in conjunction with the personal physician) to determine the appropriateness of that care.

The task of managing a home care agency is beset by a host of complicating factors in the 21st century, issues that were never even imagined 30 years ago. Whereas in the past, a competent and experienced home care nurse could use the knowledge and skills learned in the field to direct and supervise agency staff, today’s highly regulated and changing environment demands that a clinical supervisor have a myriad of skills never taught in nursing school. In addition to federal and state regulations and with the increasing enrollment of the elderly into managed Medicare programs, home health nurses have had to learn the complicated and ever-changing terms of the many disparate insurance plans offered in the patient’s geographical area. The use of the Outcome and Assessment Information Set (OASIS) and Home Health Compare (HHC) data has forced nurses to look at quality and outcomes on a day-to-day basis.

Yet, despite these challenges, in their March 2009 report to Congress, the Medicare Payment Advisory Commission (Medpac), stated that home health agencies are performing with margins of more than 16%; the number of home health agencies nationally has grown to almost 10,000; and still the quality in home care has remained fairly consistent. This is astonishing in light of the difficulties the rest of the health care industry has encountered in the last decade. Not surprisingly, Medpac recommended reducing payments to home health agencies, eliminating the market basket increase for 2010, and advancing the planned reductions for coding adjustments in 2011 to 2010, so that payments in 2010 are reduced by 5.5% from 2009 levels.

Thus, the predominant question is: How have home care agencies managed to grow and prosper under the weight of these many exigent factors? To answer this question, we must focus on quality-of-care trends and medical necessity issues in home health care, with the hope of being a catalyst for the conversations that need to be held between administrators, compliance officers, and clinical managers in regards to these somewhat vague phrases. The well-known, yet rarely defined, Medicare term “reasonable and necessary” has long provided the ambiguity that allowed for the sometimes excessive services provided to patients and overlapping plans of care between competing community agencies. Providers will have to start to look at the services they provide from a best-practice viewpoint; not simply because it is the right thing to do, but because integrity programs are beginning to explore these issues and create audit guidelines around them.

Nurses have traditionally been patients’ advocates. Across the lifespan, nurses have been with their patients, supporting them and working to serve their needs. No wonder that nurses have such a hard time stepping back and looking at the big picture when making decisions that affect not only their individual patients, but that recognize the difficult reality that there is a finite amount of money and resources available to meet the needs of these patients. This is especially true in home care, where it is the nurse who assesses the patient’s needs and looking at the big picture when making decisions that affect not only their individual patients, but that recognize the difficult reality that there is a finite amount of money and resources available to meet the needs of these patients. This is especially true in home care, where it is the nurse who assesses the patient’s needs and makes recommendations to the physician about the type and frequency of services to be provided.

Physicians, too, want the best for their patients. In the 15 years that I spent working...
in the home health field, there was never an instance when I contacted a physician to recommend a set of services and had the physician refuse. Of course, this represents the way that many general physicians remain financially stable is to “generate a lot of separate billing” in prescribing tests that "may or may not be medically necessary." No wonder it falls to nursing management to balance the equation with a reasonable and necessary line of thinking when it comes to home care services.

In response to the demand that society has placed on oversight agencies to measure and report quality and outcomes, the Institute of Medicine (IOM), the Department of Health and Human Services (HHS), including CMS, have produced an array of information about these topics. These agencies have often depended on clinical journals for their information. One article cited in a 2006 HHS report was the “Assessment of Medicare Quality Improvement Program.” This work examined CMS’ 7th Scope of Work, which focused on nursing homes and home care. Overwhelmingly, provider organizations were found to have significant improvement in quality indicators (e.g., activities of daily living, decreased infections, and fewer hospitalizations) when they received assistance from a Quality Improvement Organization (QIO) than those providers who did not receive the services. This is good news for an aging population that will have an increasing need for these services in the coming years. Yet, it is the degree and manner in which the health care community remains involved to improve the quality of life for their patients that has become a question for many medical researchers. In a recently published landmark study, "Functional Status of Elderly Adults before and after Initiation of Dialysis," researchers concluded that nursing home residents who began dialysis for end-stage renal disease actually had major declines in functional status, indicating that more is not always better when it comes to medical intervention, and that timing and quality of medical decision making may be a more important factor than the quantity of interventions.

More is not always better when it comes to medical intervention

The essential compliance response to this trend is to determine whether the agency has changed behaviors or has only transformed the documentation to meet the quality indicators in the improvement program. Further, we must examine if they are achieving reasonable and necessary outcomes for their patients. Fortunately, the Agency for Health Care Quality and Research (AHCQR) is producing many helpful guidelines in this area. Moreover, government and private auditing agencies are beginning to use more clinicians to review patient charts in efforts to examine the basic diagnoses and interventions that comprise the plan of care.

In many situations, the services are being paid for by a fee-for-service Medicaid program. Traditionally, this program has depended on the signature of the physician on the plan of care to determine medical necessity. Yet, recent reports of fraud and abuse in home care have made it evident that the physician is not always the most knowledgeable and vigilant gatekeeper of the array medical services that should be provided to their patients. In fact, the United States Government Accountability Office (GAO) has recommended that Congress “amend current regulations to expand the types of improper billing practices that are grounds for revocation of billing privileges to include claims that are falsified, for persons who do not meet coverage criteria, and for services that are not medically necessary.” Further, they recommended that physicians receive reports on all of the services that their patients require monthly.

Congress has not yet adopted all of these recommendations, but home care agencies would do well to discuss within their own arena the notions of accountability and self-regulation. One way that they can start doing that is by truly defining “medical necessity” in relation to realistic goals for their many chronically-ill patients. Evidence-based practice and fiscal responsibility are in the forefront of the current healthcare reform debates, and there can be no doubt that the future stability of our public healthcare system depends on whether the administration of these programs adapts and changes as well. As nurses, compliance officers, and administrators, it is time to stand up and advocate, not only for the patient and the provider agency, but for the public trust funds of Medicare and Medicaid as well.
The Stark Law and the "group practice" requirement

By Reza Ghafoorian, MD, Esq.

Editor's note: Reza Ghafoorian is an attorney with The Marbury Law Group, PLLC, located in Reston, VA and may be contacted by telephone at 703/391-2900 or by e-mail at rghafoorian@marburylaw.com.

Many health care practices provide in-office clinical services to which they routinely refer their patients. For example, some practices own, operate, and refer patients to in-office clinical laboratories. Such in-office laboratories are convenient for patients and physicians alike. Patients enjoy the convenience of a one-stop shop for visiting with their physician and getting their lab work done. Physicians are able to provide a better and less interrupted service to their clients and receive laboratory results in a timely manner. However, referring patients to in-office services with which a physician has a financial relationship is not permissible, unless a health care practice qualifies as a "group practice" under the Stark Law and satisfies certain other statutory requirements.

Concerns over the ethical and economic impact of physician self-referrals date back to the 1980s. In 1980, Dr. Arnold Relman's publication in the New England Journal of Medicine sparked a national debate over the ethical risks inherent in physician self-referral.¹ This national debate forced Congress to mandate studies and promulgate a series of laws relating to the role of physicians in the health care business.

In a study mandated by Congress in 1989, the Health and Human Services Inspector General concluded that if a physician has a financial relationship with an entity, the physician tends to refer more patients to that entity. This study documented that physicians who have a financial relationship with a clinical laboratory refer 45% more of their Medicare patients to that clinical laboratory as compared with physicians who do not have a financial relationship with a clinical laboratory. Following this study, Congress promulgated a series of laws to curb the abuses that may occur in the health care business. One such law is known as the Physician Self-referral Law (a.k.a. the Stark Law).²

The Stark Law is primarily set forth in section 1877 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989). This law prohibits physicians from referring Medicare patients to an entity for designated health services, if the physician or the physician's immediate family has a financial relationship with the entity. DHS includes clinical lab services; physical therapy, occupational therapy, and speech-language pathology services; radiology and other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; inpatient hospital services; outpatient hospital services; and parental and enteral nutrients, associated equipment, and supplies.³

In a series of regulatory publications over almost two decades, the Centers for Medicare and Medicaid Services (CMS, formerly HCFA) and the Office of the Inspector General (OIG) have interpreted the Stark Law. As a result, today there exist a number of complex regulatory documents which address different aspects of this law. These regulatory documents may be found on the Department of Human Health Services' (DHHS) website at http://www.cms.hhs.gov/PhysicianSelfReferral.

Even though self referral to DHS is prohibited, the Stark Law provides certain exceptions under which such referrals may be performed. To qualify for these exceptions, physicians must adhere to a number of complex legal and business structure requirements. One such exception is the "in-office ancillary services."⁴ Upon meeting the requirements set forth in this exception, a physician can refer patients for DHS provided that:

- the physician is a member of a group practice (or a solo practice);⁵
- services are performed by the referring physician or under direct supervision of the referring physician or other physicians in the same practice group;
- the designated health services are provided in a facility which is a part of the group practice;
- the designated health services are billed according to the regulations; and
- the referrals do not violate the anti-kickback laws.⁶

Although the "in-office ancillary services" exception provides the basis of a myriad of rules and regulations with which referring physicians must comply, this article focuses on the first element of this exception—providing that a physician must be a "member" of a "group practice." Physician practices must ensure that they comply with this first element (in addition to the other requirements) as intended by Congress and defined by DHHS.
**Definitions**

**Member**
The regulations define a “member” of a group practice to include any physician who owns, or is employed by, the group practice. Although non-physicians, such as nurses and physicians assistants, may be group practice “members,” their membership has no practical effect for purposes of the three group practice tests, or the profits and productivity bonuses provisions described in more detail below.  

**Group practices**
The Stark Law imposes strict conditions on and narrowly defines a “group practice.” In fact, the current laws and regulations govern formation, management, distribution of income and expenses, sharing of profits, and distribution of bonuses related to a qualified group practice. Although some physicians and trade associations have objected to these regulations as micromanaging physician businesses, today, physicians may violate the law if their group practices fail to comply with these regulations and they self refer patients for DHS.

**Formation**
Congress intended that a qualified group practice consist of physician members whose practices are fully integrated, medically and economically. Thus, the regulations define a group practice as a single legal entity that is a bona fide (i.e., true) group practice of two or more physicians. A single legal entity may be organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association. For example, one non-physician entity may form a practice group as long as it organizes a single legal entity which employs at least two physicians. It must be noted that even though formation of group practices is allowed by non-physician entities, the regulations prohibit formation of a group practice by other group practices.  

**Management**
The physician self-referral law also governs the way a group practice is managed by requiring that each group practice comport to the following tests:
- full range of services,
- substantially all, and
- 75% physician-patient encounters tests.

**“Full range of services” test**
This test provides that each physician who is a member of the group practice must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel. This test ensures that physicians in a group practice truly engage in the practice of medicine and identifies situations where a physician has joined a group in name only. This test also ensures that physicians are practicing as part of the group and not using the group to profit from referrals for DHS.

**Patient care services**
The regulations have defined the phrase “patient care services” as “any physician tasks that address the medical needs of patients that benefit the practice.” This may “include, for example, time spent training group staff members, arranging for equipment, or performing administrative or management tasks, as long as these activities benefit the operation of the group practice.”

However, activities such as teaching, overseeing residents, or conducting medical research, are not considered “patient care services.” If a physician in a group practice performs only these non-patient care services activities, the physician will not be considered a member of the group practice. Such a non-member physician may not be considered when determining whether a physician business fits within the group practice definition.

Additionally, different profit distribution schemes must be used for the non-member physicians. For example, to qualify as a group practice, a solely owned Professional Corporation (PC) whose owner physician is considered a non-member must employ at least two other physician members who qualify under the full range of services test. In addition, the non-member sole physician owner would not be eligible for sharing in overall profits or productivity bonuses as prescribed under the “group practice” guidelines.

**“Substantially all” test**
This test provides that substantially all of the patient care services of the referring physicians who are members of the group practice must be furnished through the group and billed under a billing number assigned to the group. This test is designed to ensure that member physicians are economically bound to the group for services other than DHS referrals and are not just members of the group for purposes of profiting from DHS referrals.

“Substantially all” is defined to mean at least 75% of the physician members’ “patient care services” in aggregate. The regulations recommend measuring the “patient care services” by the total patient care time, concluding that the total patient care time is the most straightforward way of measuring “patient care services.” The total patient care time is the actual time spent performing patient care services, whether performed inside or outside of the group practice. For example, consider a two-member physician group in which one member performs 100% of his patient care...
services in the group practice, but the second member renders only 65% of her patient care services through the group practice. In such a scenario, about 82% \([(100% + 65%) / 2 = 82.5\%]\) of the physician members’ patient care services are rendered through this group practice, therefore satisfying the “substantially all” test.

Because the proposed total patient care time scheme may prove burdensome for some practices, group practices are allowed to adopt other alternative means of satisfying the “substantially all” test. However, the alternative measures used by group practices must be (1) reasonable; (2) fixed in advance of the performance of the services being measured (e.g., no \textit{ex post facto} methods); (3) uniformly applied over time; and (4) verifiable.

“75% physician-patient encounters” test
This test provides that physician members of a group practice must personally conduct 75% of the group practice’s patient encounters (measured per capita). An “encounter” is defined as any appointment during which a group practice patient is actually examined or treated by a physician. This test is designed to ensure that the group practice is established legitimately as a medical practice and not primarily for benefiting form the provision of ancillary services.\(^\text{12}\)

For example, if a group practice examines or treats 100 patients, only 25 patient encounters may be performed by non-member physicians. Thus, in a group practice that encounters 100 patients, if the group practice delegates 26 of the patient encounters to non-member providers (e.g., contract physicians, nurses, or physician assistants), the group practice fails to qualify as a group practice under the “75% physician-patient encounters” test.

**Distribution of income and expenses**
The Stark Law requires that “the overhead expenses of and the income from the group practice are distributed in accordance with methods previously determined.” In general this provision of the statute may be interpreted to mean that overhead expenses and income be distributed according to methods that are determined prior to the receipt of payment for services (i.e., services giving rise to the overhead expenses or producing the income).\(^\text{13}\)

For instance, if a physician bills a patient for $100, the group practice can determine a method for distributing this income before payment is received from the patient. Also, if the payment for this service is to be applied to an expense borne from providing this service, the group practice must also establish methods for determining distribution of such expense prior to receipt of the payment. Consequently, group practices can frequently adjust their compensation methodologies as long as they adhere to the requirements of this provision and remain subject to the restrictions on the distribution of DHS revenues as described in more detail below.

The Secretary of DHHS added an additional requirement to this provision of the Stark Law. This newly added provision further requires that a group practice be a “unified business” before distributing its overhead expenses and income.

“Unified business” test
The “unified business” test requires that a group practice possess (1) a centralized decision-making body, representative of the practice, that maintains effective control over the group’s assets and liabilities (including budgets, compensation, and salaries); and (2) consolidated billing, accounting, and financial reporting. This test is designed to ensure that group practices are integrated businesses and precludes group practices which are not bona fide group practices and only operate to benefit from lucrative DHS referrals.\(^\text{14}\)

It is important to note that while the “unified business” test restricts integration of a group practice, it does not dictate specific compensation methods. As such, group practices may adopt different compensation schemes, such as cost center or location-based accounting, as long as the physician member compensation is not based on volume or value of Medicare referrals.

**Profit sharing and productivity bonuses**
The profit sharing and productivity bonus restrictions set forth yet another layer of requirements which health care providers must comply with to qualify as a group practice. For example, to self refer patients to an in-office clinical laboratory, a physician group must ensure that it meets the required group practice methodologies for distributing profits and allocating bonuses to the physicians in the practice.\(^\text{15}\)

According to the Stark Law, a physician who is a member of a group practice may not be compensated directly or indirectly based on volume or value of DHS referrals. However, physicians in group practices may receive profit shares or productivity bonuses based on services performed personally (and services incident to the physician’s personally performed services) as long as the shares or bonuses are not directly based on referred services. Thus, revenues generated by DHS should be distributed based on methods that indirectly take into account DHS referrals.

The regulations set forth certain examples of indirect methodologies according to which revenues may be distributed to group practice members and physicians.
Overall profit sharing methodologies
Before exploring the different sample methods for distributing overall profit shares, it is important to determine the regulatory definitions of “share of overall profits.” “Share of overall profits” may mean a share of the entire profits derived from DHS of the entire group practice. “Share of overall profits” may also mean the entire profits derived from DHS of any component of the group practice that consists of at least five physicians. Following are three sample methods for distributing overall profits derived from DHS according to the regulations:

Sample Method 1. Share of overall profits may be distributed on a per capita basis. In this method, the overall profits are divided by the number of physicians and members sharing the profits. Each physician and member may then receive an equal share based on this calculation. This linear profit sharing method works well for groups in which all partners have equal shares, but it fails to adequately distribute profits in group practices with unequal shareholders. Additionally, this method fails to reward physician members who contribute more time to patient care as compared with those who choose to work less.

Sample Method 2. Revenues received from DHS may be distributed according to the revenue distribution of non-DHS profits. This method provides a more just distribution of profits in group practices where one physician provides more health care services as compared with other physicians in the same group practice. Under this methodology, physicians who work more are rewarded with a larger share of the DHS revenues.

Sample Method 3. Any distribution method may be employed under two conditions: (1) if the DHS revenues are less than 5% of the total revenues of the group practice; and (2) if the portion of the DHS revenues allocated to each physician is less than 5% of the physician’s total compensation from the group practice.

Productivity bonus distribution method
The regulations have also provided sample methods for distributing productivity bonuses. Three such examples are as follows:

Sample Method 1. A productivity bonus may be based on the physician’s total patient encounters or Relative Value Units (RVUs). Under this method, physicians who encounter more patients will receive higher productivity bonus. RVUs describe the resources used to provide physician services and are used to create a fee schedule based on which Medicare pays for physician services. There are different types of RVUs. For example, the physician work RVUs account for the time, technical skill and effort, mental effort and judgment, and stress to provide a service.

Sample Method 2. Similar to the Sample Method 2 for distributing overall profits discussed above, a productivity bonus may be distributed based on the revenue distribution of non-DHS profits. Thus, physicians who receive a larger portion of the non-DHS revenues will receiving a greater portion of the DHS related revenues.

Sample Method 3. Again, similar to the Sample Method 3 for distributing overall profits discussed above, a productivity bonus may be distributed under two conditions: (1) if the Medicare or Medicaid DHS revenues are less than 5% of the total revenues of the group practice; and (2) if the portion of the Medicare or Medicaid DHS revenues allocated to each physician is less than 5% of the physician's total compensation from the group practice.

Conclusion
Definitions of “member” and “group practice” present only a part of the requirements that health care businesses must fulfill to comply with the “in-office ancillary services” exception of the Stark Law. Meeting other requirements presented within this exception, other provisions of this statute, and other laws may be required to fully comply with the existing laws that govern physician self referrals.

Although these complex regulatory laws are regarded as barriers in the path of the practice of medicine, they were designed with the intention of preventing fraud in the health care business. One can only hope that in the future Congress finds a way to simplify these complex laws to reduce the current burden that they impose on health care businesses.
Web 2.0 is about the new, faster, everyone connected Internet.

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Each resource is 100% dedicated to compliance and ethics management. So sign up for whichever one works best for you, or for all four if you’re already living the Web 2.0 life.

Recently, someone asked me how to go about setting up a group on the HCCA Social Network site. I wasn’t sure of the exact steps they needed to take, so I went to the HCCA/SCCE Social Media Manager, Eric Newman.

Here’s what I learned. Eric can set up the group for you (or, if you prefer, you may do it yourself). Below are the details Eric will need to initiate a new group:

1. **A short descriptive group name**
2. **A description for the group.** Here are some example descriptions:
   
   “For the unique Compliance, Legal and Ethical issues faced by the XXX Industry”
   “For the unique Compliance, Legal, and Ethical issues associated with XXX”
   
   Descriptions work best with more detail, such as:
   “Welcome to the Utilities and Energy Network.
   Key Industry Areas include: Electricity, natural gas, oil, nuclear energy, natural gas and oil pipelines and storage facilities, hydropower, energy transmission systems, coal, wind, solar energy ...”
   OR: “Key Regulatory Areas include: FERC (Federal Energy Regulatory Commission), NRC (Nuclear Regulatory Commission), PHMSA DOT (Pipeline and Hazardous Material Safety Administration, Department of Transportation), EPA (Environmental Protection Agency), and OSHA (Occupational Safety and Health Administration), Global energy regulations, emerging CO2 regulation ...”
3. **A welcome note/message** that explains/defines the group’s purpose.
   
   The main reason people do not post is because they feel like they may mess up in public or their opinions are not good enough. So Welcome notes should be inviting and positive, avoiding “don’t do this” or “don’t do that.”
4. **Then post two or three times over the first week to start the ball rolling.**
5. **Follow that up with two or three more posts over the first month to keep the ball rolling.**

Sign onto HCCA’s Social Network site to see how other members are responding.

To read the information posted on blogs, participate in the discussion, review the comments, or just talk with your peers, you can access the Social Network site by going to the link: www.hcca-info.org/sn
New HCCA Members

The Health Care Compliance Association welcomes the following new members and organizations. Please update any contact information using the Member Center on the website, or e-mail Karrie Hakenson (karrie.hakenson@hcca-info.org) with changes or corrections.

Minnesota
- Jane Brue, Univita Health, Inc.
- Robert J. Norman, Essentia Health
- Pam Teske, Metropolitan Health Plan

Mississippi
- Bobby Beebe, Administrative Systems, Inc
- Ann Randy Belton, Administrative Systems, Inc

Missouri
- Amanda Jo Dishman, Sisters of Mercy Health System
- Karen R. Kruger, Cerner Corporation
- Michelle K. Paterson, Sisters of Mercy Health System
- Peter Rao, Lake Regional Medical Group

New Hampshire
- Denise Chouinard, HPHC

New Jersey
- Steven M. Bednar, Dept of Veterans Affairs
- Ruth Harris, Source One Medical Management
- Lawrence Hendricks, Jr., Dept of Veterans Affairs

New York
- Kathleen A. Garvey, Maximus Federal Services
- Patricia Sablesak, Allied Urological Services
- Kathleen Schofield, The Arc Otsego
- Frances A. Scott, Empire State Medical Foundation
- Jessica Skura, Legao, MVP Healthcare

North Carolina
- Carol Denise Clark, Duke Raleigh Hospital
- Malinda Falzarano, Carreter General Hospital
- Anne M. Payne, Carolinas Healthcare Systems

North Dakota
- Shannon Reynolds, MericCare Health System

Ohio
- Vicki R. Bokar, Cleveland Clinic
- Caroline Brill, The Risk Management & Patient Safety Institute
- Janet K. Feldkamp, Benesch, Friedlander, Coplan & Aronoff

New Mexico
- Brian Summers, Galisteo Medical Complex
- Janine M. Valdez, Sun Healthcare Group, Inc

New Mexico
- George L. Kelley, CBIZ KA Consulting Srvs LLC
- Theah M. Scott, Veterans Health Admin Office of Compliance & Business Integrity
- Evan C. Stalter, Veterans Health Admin Office of Compliance & Business Integrity
- Pamela Thomas, Saint Clare’s Health System

Oklahoma
- Joan E. Crall, Oklahoma Univ Medical Center
- Nancy M. Lott, Duncan Regional Hospital

Oregon
- Cyndy L. Harrison, Providence Health & Services
- Nancy Towle, Kaiser Permanente Center for Health Research

Pennsylvania
- Linda G. Bachman, Surgical Specialists of Hazleton
- Ross Cleary, IMA Consulting
- Karen McHenry, Pentec Health
- Michael L. Megill, LW Consulting, Inc
- Susan D. Montross, Allied Services
- Donna J. Walsh, Drexel Univ College of Med

Puerto Rico
- Iris Monrouzeau, Arroyo & Monrouzeau, CSP

South Carolina
- Lori Beard, Hill-Rom Company
- Barry Grosse, Hill-Rom Company
- Thujuana S. Lawton, Piedmont Medical Center

South Dakota
- Toyomi Korde, Regional Health, Inc.
- Carletta Vasknetz, Regional Health, Inc.

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Send your job change information to: peoplemove@hcca-info.org

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Tennessee
- Kirby E. Davis, VA Medical Center - Memphis
- Gloria M. Halpell, Life Care Center of America
- David Hile, FTI Consulting, Inc.
- Sharon Hoover, Center for Spinal Surgery

Texas
- Mary D. Brandt, Scott & White Healthcare
- Whitney Carter, Scott & White Memorial Hospital
- Kita D. Carhey, Baylor Health Care System
- Rhonda Dash, UNT Health Science Center
- Lori A. Davis, Conifer Health Solutions
- Jan M. Davissin, MD Anderson Cancer Center
- Michelle Durham, JD
- Pamela A. Dwyer, Methodist Hospital
- Lisa Fox-Soreff, Univ Texas Southwestern Medical Ctr/Simmons Cancer Center
- Dean E. Francisco, T-System, Inc
- David C. Gardner, T-System, Inc.
- Julia Garner, Terrell State Hospital
- Judy L. Gunnels, Pediatric Assoc of Dallas
- Robbie Hembree, TrustPoint Hospital
- Teresa M. Jacobs, Welmed Medical Mgmt Inc
- Robbie Hembree, TrustPoint Hospital
- Judy L. Gunnels, Pediatric Assoc of Dallas
- Carolyn Miller, CARE Pharmacies, Inc.

Utah
- Rupert Richard, Verisys Corporation

Vermont
- Betsy Nicoletti, Medical Practice Consulting

Virginia
- Raymond Bradley, Goodman & Company
- Barbara Cohoon, National Military Family Assoc
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- Jennifer A. Montgomery, Banner Health Washakie Medical Center
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CERTIFICATION EXAM OFFERED FOLLOWING EACH ACADEMY
REGISTRATION FOR EACH ACADEMY IS LIMITED TO 75 ATTENDEES

“I just wanted to say thank you for helping to coordinate and present such an educational and useful compliance academy. If I knew how much I was going to learn and how many ideas I would leave with to improve our compliance program I would have attended much sooner. The academy helped to energize and inspire me to take our compliance program and myself as a compliance professional to the next level.”

Michael Scudillo, Chief Compliance Officer, Universal Institute, Inc.

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