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COMPLIANCE TODAY

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Chief Compliance & Ethics Officer
Sentara Healthcare
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Improving Governance Practices

Audit & Compliance Committee Conference

October 27–29, 2008

Hilton Fort Lauderdale Beach Resort
Fort Lauderdale, FL

This conference is designed for board members and audit committee members of not-for-profit healthcare organizations who serve on an organization's audit and/or compliance committee. Compliance officers may attend with their board member. CEO, CFO, and other senior officers are welcome to attend.

"Outstanding! This conference is geared for board members—should be a requirement for chairmen of audit committee, a must for compliance officers, and also should be attended by CEO & CFO."

H. James Mueller, Treasures board of Trustees-Chair Audit & Finance Committees, Cheyenne Regional Medical Center

"The conference presented a realistic view of the importance of the role of compliance as it relates to the core operations of a hospital as well as joint ventures and physician relationships."

Jake Easton III, Audit and Compliance Committee Chair, Hoag Memorial Hospital Presbyterian, Newport Beach, CA

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Dan Roach discusses the Audit & Compliance Committee Conference

October 27 - 29, 2008, Hilton Fort Lauderdale Beach Resort

Editor's note: This interview with Daniel Roach, Vice President, Compliance and Audit, Catholic Healthcare West took place in May 2008. In this Q&A, Dan outlines the value and purpose of HCCA's Audit & Compliance Committee Conference.

Q: What was the thinking behind offering the Audit & Compliance Committee Conference?

DR: HCCA recognized that governance, and particularly an audit or compliance committee, plays a critical role in the oversight of an organization. Most for-profit entities have had audit committees for years, and more and more hospitals and health care systems have developed audit committees in recent years. Moreover, the 2004 Federal Sentencing Guidelines for Organizations make it clear both that the board of directors has significant oversight responsibilities with respect to the compliance program, and that the organization's compliance and ethics officer plays an important role in helping the governing body fulfill that role. Because the audit committee frequently oversees compliance and ethics programs, we thought that a program addressing both the audit and compliance/ethics would have value for board members. When we couldn't find anyone else doing it, we decided to build it ourselves.

Q: Who helped to plan this conference?

DR: Many people were involved in the planning of this conference. Two of the major drivers were myself and David LeMoine, President of CHAN, an organization that provides audit services to hundreds of hospitals across the United States.

In addition, we have a wide variety of speakers and professional backgrounds at the conference, including CEOs, hospital finance people, leading lawyers and compliance officers from across the country, and representatives from several major accounting firms. Our goal is to provide the attendees with the basic knowledge necessary to function appropriately in their roles and to ensure that they have specific tools that they can take back with them to exercise their responsibilities more effectively. Judging from the comments we've received from board members in the past, it is time well spent. Moreover, it is a great excuse for a board member or executive to escape the cold weather for sunny Fort Lauderdale in October. That should make a hero of both the CEO and the compliance officer.

Q: What unique issues does the conference address?

DR: The conference provides board members with a comprehensive overview of their role in the context of serving on an audit and compliance committee and/or overseeing the organization's audit and compliance activities. There were programs for the audit committee in the context of Securities and Exchange Commission (SEC) regulation of for-profits, but none of these programs focused on non-profits or on the unique challenges facing hospitals and other health care organizations. This conference covers the many subject matter areas in a way that is specific to health care and the unique laws and accounting rules that apply to health care.

Q: What is the value and or purpose of this conference?

DR: This conference is intended to give members of a non-profit health care organization's audit or compliance committee the tools they need to fulfill their fiduciary obligations in a manner consistent with applicable accounting standards and industry practices, relevant case law, the Federal Sentencing Guidelines for Organizations, and standards imposed by other entities and bodies. Ironically, board members are rarely held liable for making the wrong decision on a specific issue. Typically, when a board faces liability, it is because it failed to provide oversight or insist that the organization have effective internal control processes in place.

Participants will leave the conference with a much better understanding of their oversight role. More importantly, they will also walk away armed with the tools to help them do so.

Q: Are there enforcement issues reviewed during this conference that will help clarify their importance to the Audit and Compliance Committee members?

DR: Yes. One of the opening sessions of the conference is a 90-minute review of the substantive risk areas that hospitals face, including false claims issues, Stark and the anti-kickback laws, HIPAA, and other laws and regulations.

This session helps provide board members who are not health care experts with the background information they need to effectively ask questions and fulfill their fiduciary obligations.

In addition, throughout the meeting we provide attendees with simple, practical tips that they can use to function more effectively and help protect the organization and themselves.

Continued on page 6

Q: Who should attend this conference and who will most benefit from this conference? How will they benefit?

DR: The program is intended or targeted for board members, particularly those who serve on an audit and/or compliance committee. Typically, these board members are accompanied by the organization's compliance officer and/or the head of Internal Audit. In addition, we have received high marks from other senior organization leaders who have attended this meeting, including hospital and health care system CEOs, CFOs, and others. All of these individuals will benefit from the solid foundation this conference provides for those seeking to effectively integrate a quality audit, compliance and ethics program into the organization's fabric. I believe there is particular value when management, board members, and the compliance officer all attend together, as this helps ensure that they are all on the same page when addressing issues related to internal audit, external audit, compliance, and ethics.

Q: Are there specific issues that all or most audit and compliance committees grapple with? If yes, what are they?

DR: Once again, the answer is yes. All US organizations are subject to the Federal Sentencing Guidelines for Organizations, and as a result, compliance and ethics programs need to be structured similarly across all organizations. In addition, hospitals and health systems face a common array of problems, including those related to the documentation coding and billing of claims, strict regulations related to how they do business with physicians and other referral sources, licensure and certification issues, as well as privacy and security matters. The boards and management of health care organizations also face unique issues in the context of financial reporting, the application of generally accepted accounting principles to their business activities, and in auditing and managing risks. This program provides attendees with information about how to structure committees, and how to interact effectively with internal and external audit, the compliance and ethics officer, and members of the organization's management, so that they can achieve the shared goal of improving and protecting the organization.

Q: What are some other session topics?

DR: The opening day of the conference typically includes sessions providing a basic overview of accounting issues faced by hospitals and health care systems, with a particular focus on those issues that are unique to health care. The opening day also includes an introduction to the significant risk areas (False Claims, Stark and anti-kickback, HIPAA, etc.) faced by hospitals and health systems, and an overview of the requirements for an effective compliance and ethics program as described in the 2004 Federal Sentencing Guidelines for Organizations. The second and third day of the program include sessions related to fiduciary obligations, the audit/compliance committee, internal and external audit, tax exemption challenges, and many other topics.

Q: If HCCA members asked you about this conference, what would you tell them?

DR: I would tell them they need to share information about the conference with members of their board of directors and management. They also need to ask themselves what they are doing to ensure that governance is knowledgeable about the compliance and ethics program in the organization and is providing adequate oversight. Boards have an obligation to fill this role, and the failure could expose the board members to fiduciary liability. The reason the compliance officer role exists is to protect the organization, its management, and its board from such exposure.

My view is that every health care compliance officer should provide the board and management with a copy of Section 8.B.2.1 of the Federal Sentencing Guidelines for Organizations. If they are comfortable that they are meeting each of the elements set forth in the Guidelines, there probably is no need to attend the meeting. If they are not sure, attending the meeting will help them better understand the Guidelines and ensure that board members are appropriately exercising their oversight responsibilities.

Q: If members can only attend one conference, why would you tell them to select this conference?

DR: I wouldn't suggest they pick this one. The annual Compliance Institute is a better conference for most of our members.

However, even if the member cannot attend this conference, they can encourage a board or committee member to attend. Moreover, chances are fairly significant that if a board member goes, management will want the compliance officer to attend as well.

Q: Are there any incentives if more than one person from our company attends?

DR: Yes. For each person who registers ($695), a second person may attend for just $395, as long as they register at the same time.

Q: Do you have advice on how to convince my management or board that this is conference that would be worth their time and the expense?

DR: First, board members have a duty to be educated, and their participation in the conference is evidence that a board member is fulfilling his/her fiduciary duties.

Second, all organizations want to improve results and reduce risks. This conference is an inexpensive way to help the organization improve not only board

effectiveness, but organization effectiveness as well. Send the chair of your audit and/or compliance committee or your most skeptical board member. If they are not convinced the conference was worth the cost, we will return their registration fee. Based on prior feedback, we are confident they will find the conference valuable.

Third, the fact that the conference is in Fort Lauderdale in late October (or Scottsdale, AZ in February, 2009) may also be a selling point.

Fourth, give them a copy of this article. A conference brochure is available at www.hcca-info.org/08OctAuditComp_broch.

Finally, if they have questions, they can call me directly at 415/438-5579. ■

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Using adult learning styles in compliance education

By Margie Brackeen, BS

Editor's note: Margie Brackeen is a Regulatory Compliance Specialist with Arkansas Children's Hospital Research Institute in Little Rock, AR. She may be reached by telephone at 501/364-3586 or by e-mail at brackeenmargiei@uams.edu.

The director of compliance education looks around the classroom. Her guest speaker is in the middle of a two-hour lecture concerning the federal regulations which govern informed consent of research subjects. She really thought her researcher population would be interested in this subject; however, the students in the class are distracted. A few yawn and look at their watches while one is quite obviously playing games on her Blackberry®. The room is set up in classic "classroom style" with the desks and chairs in rows all facing the front of the class and today's speaker. When the speaker pauses for a moment, a studious fellow at the front of class raises his hand. The speaker, obviously perturbed at the interruption clears his throat and says, "Yes?" The student asks his question and the speaker looks confused…he stammers a bit then says… "Well, I really don't know that…" At this, the director of education notices that she has basically "lost" the rest of the room. She looks at her watch…

Why aren't these students interested in this speaker? This is the way that classes are traditionally taught from kindergarten to graduate school. The students really need to know the informed consent information that the speaker was presenting to stay within the federal regulations for their research. Why didn't this work?

As a compliance education professional, you can't afford to waste valuable medical professionals' time—or your departmental education funds—on training programs that aren't effective. Keeping these learners' attention seems like a basic concept, but it can be a real challenge. When we become adults, we start to think differently than we did when we were children and young adults. Our focus shifts away from having our identity defined by external sources (e.g., who our parents are, what school we attend, etc) to deriving our identity from our own personal experiences. Malcolm Knowles puts this concept quite aptly in his book *The Modern Practice of Adult Education*[1] when we says, "Adults are what they have done." A child learns easily because they have no past experience in this topic, but learning is very different for adults. Everything adult learners see or hear is filtered through all of their life experiences before it is received as new information. If they were not successful in school, if the instructor looks like a professor they once had who was difficult, or (worst of all) if they do not trust that the speaker knows the subject that he/she is teaching, the information doesn't get in.

Unfortunately, today's adult learners generally have the impression that all of the learning they will require for a lifetime can be learned during their school years. Many see adult education as a way of playing catch-up to learn or re-learn something they missed in their youth. This belief is fueled by phrases such as "getting an education" or "finishing their educations," insinuating that all of the education you require can be "finished" by early adulthood, and then you can go about your life. Fortunately, this premise is slowly changing with globalization and with it the competition to succeed in a global marketplace. In the words of The Economist,[2] "The new jobs in tomorrow's industries, manufacturing, and services alike, …will require workers that are literate, numerate, adaptable, and trainable—in a word, educated."

So, how are you to address this daunting task of presenting information that will be retained by the adult students in your compliance education program? First you must acknowledge that adults require different teaching techniques based on their unique adult learning style. The first rule of teaching adults is to decide how to relate the information you are teaching to the learner's daily life. If the adult learner feels that the information will be useful to them in their job or their life, they are more willing to learn it. A simple way to facilitate learning by adults is by presenting case studies or sharing personal experiences. Adults respond well to this teaching method, because they can visualize their own experiences and can simply add this memory to the already existing one. This also works when teaching difficult concepts to adults. To encourage learning, tie the new concept to less complex information that the learner already knows. For example, if you are teaching informed consent for a research project to a nurse, you may ask her how she performs patient consent for medical care. When she explains this concept, you then instruct how research consent is different yet similar. In this way, she can build on what she already knows. This learning will become complete when she goes back to the workplace and applies what she has learned. Because she is an adult learner, she will also develop this newly acquired skill more completely as she uses it.

When presented with new information, the

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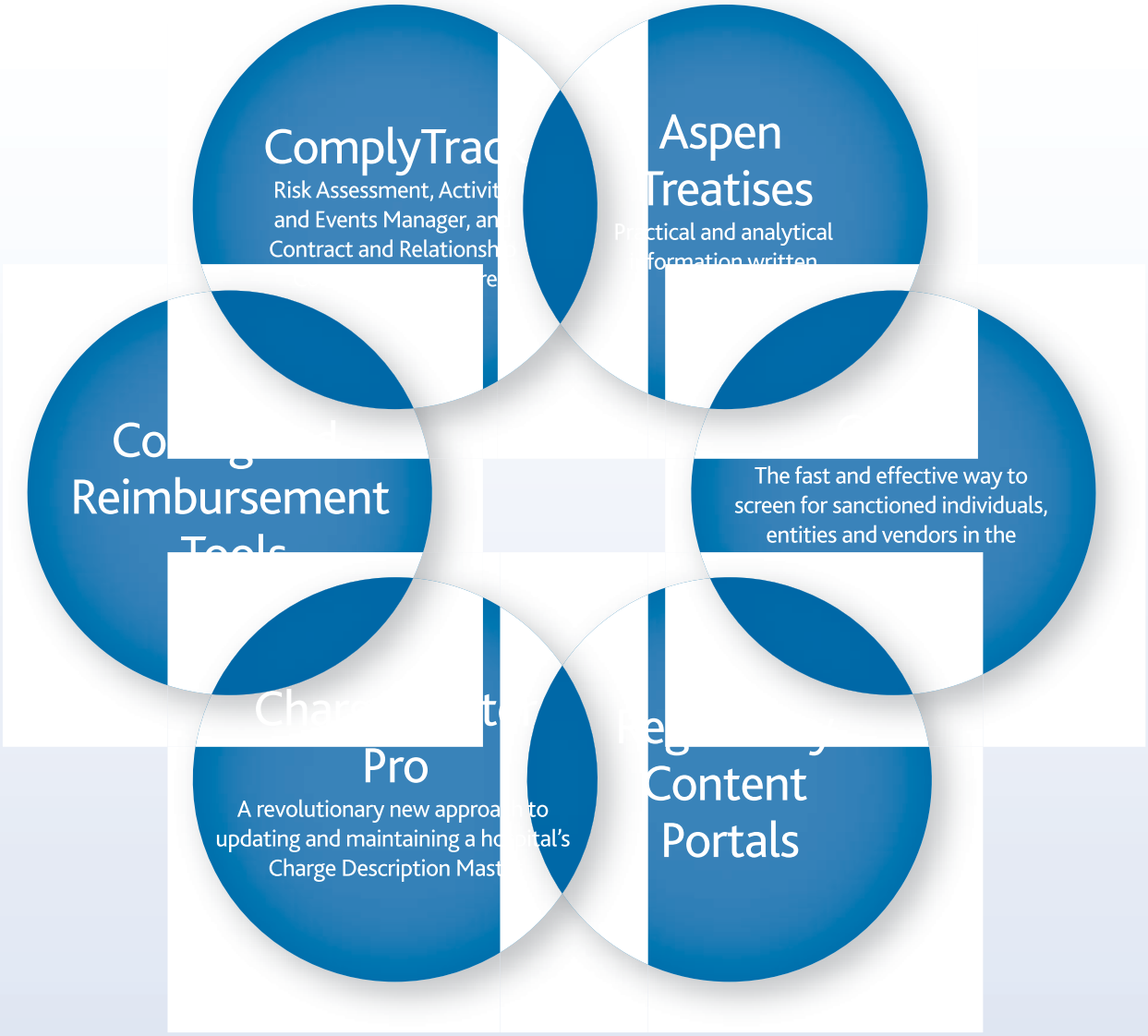

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adult learner may ask, "Why?" Adults are less likely than children to blindly believe the things they are told. Their life experiences have taught them to scrutinize what they are told, and not to take things at face value. As in the case of the nurse learning informed consent, she may ask why informed consent of a research subject is different from that of a patient. This is a teachable moment for the instructor. Adult learners can be extremely serious about their studies, if you can convince them that what you are teaching affects them directly. You can use this time to discuss with her the federal and state regulations as well as Institutional Review Board (IRB) policy by using actual cases and examples. You may tell her of an article you recently read concerning another institution that was audited by the Food and Drug Administration (FDA) and how its informed consent was not properly performed. She will appreciate not only the example, but the fact that the information is current and involves her peers. This conversation may occur one-on-one, but will be more valuable if discussed during a classroom experience. In this way, all of the nurse coordinators present will benefit from this real-life example.

Generally, adults learn one thing at a time. Unlike children who can absorb large amounts of information quickly, the adult learner prefers a set sequence of events. When presenting to adults, consider using a flow chart or numbered list. For example, the study team must complete certain institution-mandated steps in order to transition from a protocol to a working project. You could map out this process via a simple flowchart or checklist that can be printed, laminated, and distributed to the audience, along with a dry erase pen. During this session, describe for them how they can take the laminated chart back to their office, post it in a handy spot, check off their progress as tasks are accomplished, and when completed, wipe it clean for next time. This type of visualization works well for adult learners. As you describe this process to them in a step-by-step manner, they can visualize in their minds where the chart would be posted and how they would work this into their daily routine. Visualization increases retention and recall—up to five times greater than methods not employing visualization.[3]

Adult learners can be extremely serious about their studies, if you can convince them that what you are teaching affects them directly.

Arrange the chairs in a circle! The adult learner does not respond well to the traditional "classroom-style" room set-up. You have organized the best workshop ever planned. You have a really great, engaging speaker. You have all the right tools and methods for adults. Unfortunately, if you put your adult students in the "classroom" type rows, all facing front, your workshop may not have its full impact. Take a little time before the event to look at your classroom. Do you have room to arrange the tables and chairs in a circle? How about a "U" shape, a diamond, or an octagon? If your students can see each other, they will interact. If they interact, they are more likely to share common experiences that will solidify their learning.

While your adult learners are interacting, they also appreciate progress reports at various intervals. When planning your workshop, you may incorporate several stopping points where the answer to the question at hand is revealed. In this way, students can take a moment to gauge their understanding of the topic presented, and they will be likely to ask questions to clarify any confusing points. If you test adult learners after a long class presented in classic style, and they do not do well, they will simply go away feeling as if they have failed. They will retain very little of the information presented.

Finally, design your yearly curriculum with your adult audience in mind. Every adult learner differs from the next, based on their life experiences, abilities, and background. Further, they learn at different rates. When designing your yearly curriculum, alternate short lectures with workshops, dramatic learning experiences, and fun programs (such as a game show-type program). For instance, plan an informed consent workshop this quarter, and next quarter plan an informed consent lecture or dramatic representation. If you offer solely lectures, you are directing your learning activities to one group: those who benefit from a lecture-style learning environment. By alternating the methods for delivery of your programs, each adult learner will have an opportunity to experience the same basic information in a format where he/she feels most comfortable.

By using the methods discussed here, our exemplary compliance education director can now redesign her program. With these simple tools, she can keep her students involved, interested, and coming back for more. The adults in her class want to learn. It is our job to make that process as effortless and useful as possible. ■

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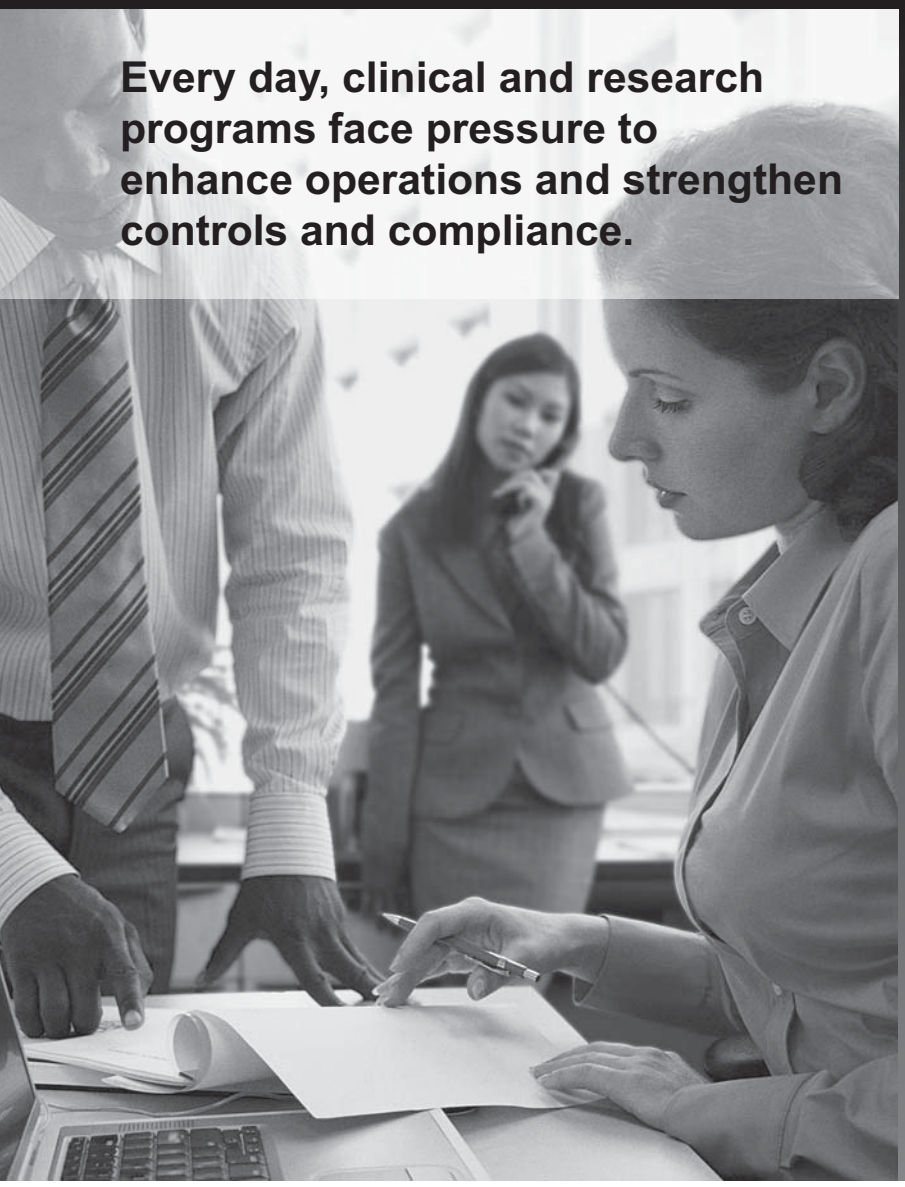

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01/08

FYI FOR YOUR INFORMATION

Medtronic Agrees to Pay $75 Million

On May 22, 2008, *Reuters* reported that Medtronic, Inc. announced it will pay $75 million to the United States to settle allegations that Kyphon Inc., "a company it acquired, caused hospitals to submit false claims to Medicare, the Justice Department said." For more: *http://www.reuters.com/article/marketsNews/idUSN2228964220080522*

Anderson Named New Jersey Medicaid Inspector General

On May 19, 2008, New Jersey Governor Jon Corzine nominated Mark Anderson, an assistant federal prosecutor for the Eastern District of Pennsylvania, for the newly created post of Medicaid Inspector General, according to a *Newsday* report. For more: *http://www.newsday.com/news/local/wire/newjersey/ny-bc-nj--medicaidfraud-0519may19,0,7733417.story*

Arrests Related to Medical Equipment Scam Announced

On May 16, 2008, R. Alexander Acosta, United States Attorney for the Southern District of Florida, announced the arrest of four individuals in connection with a $5.4 million health care fraud and money laundering scheme. For more: *http://www.usdoj.gov/usao/fls/PressReleases/080516-03.html*

Baptist Health South Florida Settles

The South Florida Business Journal reported on May 13, 2008 that "Baptist Health South Florida has agreed to pay $7.775 million to the U.S. government to settle claims it paid excessive compensation to an oncology group that was a source of patient referrals to two of Baptist's hospitals." For more: *http://www.bizjournals.com/southflorida/stories/2008/05/12/daily16.html*

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CHC CERTIFIED IN HEALTHCARE COMPLIANCE

The Compliance Professional's Certification

The Compliance Certification Board (CCB) compliance certification examination is available in all 50 states. Join your peers and become Certified in Healthcare Compliance (CHC).

CHC certification benefits:

- Enhances the credibility of the compliance practitioner
- Enhances the credibility of the compliance programs staffed by these certified professionals
- Assures that each certified compliance practitioner has the broad knowledge base necessary to perform the compliance function
- Establishes professional standards and status for compliance professionals
- Facilitates compliance work for compliance practitioners in dealing with other professionals in the industry, such as physicians and attorneys
- Demonstrates the hard work and dedication necessary to perform the compliance task

Since June 26, 2000, when CHC certification became available, hundreds of your colleagues have become Certified in Healthcare Compliance. Linda Wolverton, CHC, says she sought CHC certification because "many knowledgeable people work in compliance and I wanted my peers to recognize me as one of their own."

For more information about CHC certification, please call 888/580-8373, e-mail ccb@hcca-info.org or click on the CCB Certification button on the HCCA Web site at *www.hcca-info.org*.

Congratulations on achieving CHC status! The Compliance Certification Board announces that the following individuals have recently successfully completed the Certified in Healthcare Compliance examination, earning CHC designation:

Julie Lyn Agris
Jean A. Auger
Joan M. Ballard
Maureen Ann Bartolo
Elizabeth Ann Baxter
Christine L. Borowski
Mary S. Bramblett
Christopher Wayde Brechtel
Susan K. Burgess
Catherine Elaine Campbell
Laura T. Carrico
Ellen Cathcart-Franklin
Alana M. Chapman
Dorothy Cook-Walter
Nicci L. Dickinson
Sharon S. Dunlap
Tanya Elliott
Kenneth L. Ensley
Carol H. Eyer
Charles Joseph Fletcher
Robin Overstreet Friday
Maria Mercedes Gross
Brian Hake
Courtney L. Hanna
Shelly Lyn Harris
Kimberly Herron
Max Holder
Melody L. Hoskins
Kimberly Marie Hrehor
Peter Joseph Hughes
Lynn Laney Hutt
Bernabe A. Icaza
Mary Beth Ireland
George Antonio Jaquez
Cathy Denise Johnson
Carolynn Renee Jones
John Kelley
Kevin J. Kelley
Jawanna Lynn King
Judy Allums Kuczynski
Cynthia Ledford
Royal Johnson Link
Sharon Long
Timothy B. Maguire
Robert David Malove
Robert Wayne Markette
Glenn Martin
Judi McCabe
Chad Brian Mcintosh
Sara Lyn Michener
Robin E. Mims-Rich
John David Mitchell
Regina Gabrielle Morano
Jane Marie Morgan
Mariloly Muller
Kathleen M. Naughton
James Edward Nelson
Christine Helen Newgren
Heather L. Noughton
Nancy O'Neill
Pamela R. O'Rourke
Claire S. Owens
Brandi Periera
Meredith Roxanne Phillips
Topaiz A. Polk
Anna Polyak
Anna Juliette Quinn
Jennifer Ellen Ramerman
Jennifer M. Raymond
Tammy Jeneanne Ree
James J. Riley
Vickie W. Saucedo
Brenda Ann Schillinger
Maureen Shaw
Sherri J. Shockey
Fern S. Silverman
Leanne Floasin Smith
Sheryl Lyn Spohn
Doran Lewter Stamps
Denise L. Theriault
Angela Lynn Tobias
Molly Beth Tomlin
Audrey S. Tyree
Dana Kay Watts
Nancy Lou Wenning
David E. Westlake
Elizabeth R. White
Veronica L. Wilbur
David Wilkens
Kathy Jo Williams
Theodora Leah Wills
Ken G. Winston
Cathy M. Woodall
Wendi W. Wright
Yvonne Zachman-Fiedler
Veronica R. Ziac

feature article

Meet Greg Burkhart

Chief Compliance & Ethics Officer, Sentara Healthcare

Editor's note: Jennifer O'Brien, an attorney with Halleland Lewis Niland & Johnson PA in Minneapolis and HCCA Second Vice President, conducted this interview with Greg Burkhart in May. Greg may be contacted by e-mail at dgburkha@sentara.com.

JO: Tell us a little bit about Sentara Healthcare and some of your responsibilities as Chief Compliance & Ethics Officer of the system?

GB: Sentara is a not-for-profit health care provider in southeastern Virginia and northeastern North Carolina comprised of seven acute care hospitals, two outpatient care campuses, seven nursing centers, three assisted living centers, and a medical group of more than 350 physicians. We also offer a full range of health plans, home health and hospice services, physical therapy and rehabilitation services, and medical transport services.

As to my duties as Compliance Officer, they encompass most of what you would expect. With the help of my staff and others throughout the organization, I am responsible for maintaining an effective compliance program. To that end, we provide annual training to our employees and maintain a hotline and other avenues through which Sentara personnel can report concerns. We conduct regular compliance reviews and audits throughout the organization, and conduct investigations as the need arises. With the help of our operational leaders, we oversee ongoing monitoring and self-assessment programs at each of our divisions and conduct an annual compliance risk assessment. HIPAA privacy is the one area for which many compliance officers are responsible that I am not. Our Vice President of Health Information serves as the Privacy Officer.

JO: You have a legal background. Did you set out to take on the compliance role or did the role find you, so to speak?

GB: It was a complete accident. I was brought into the Legal department on a temporary basis to work with outside counsel in reviewing the compliance function, and I had really only expected to be in Virginia for a short time. The review ended up being fairly detailed and went on longer than expected. By the end of it, I had learned quite a bit about compliance programs and health care law. I also had a solid understanding of Sentara as a company and developed many positive working relationships. Another benefit was that I had a good sense of what had worked and what hadn't in the initial execution of the compliance program. Toward the end of the review, outside counsel, Sentara's general counsel, and the vice president (to whom Compliance reported at the time) all asked me to consider staying on permanently. I enjoyed the problem solving nature of the work, and the time I spent on the review gave me a very positive impression of the organization, so I accepted what was, at the time, the position of Compliance Manager. That was 11 years ago.

JO: You are part of a large system. Can you share with us your compliance structure and how you are able to offer system-wide support to your organization?

GB: We are pretty lean at the corporate level, having just four employees in the Corporate Compliance & Ethics department. In addition to me, we have an audit manager, a program coordinator and an analyst. Our department is responsible for all the day-to-day activities of the compliance program – training, the hotline, investigations and reviews, compliance audits, etc. I report directly to the CEO and meet quarterly with the audit and compliance committee of the board.

In addition to the corporate staff, we have 15 division-level compliance liaisons – one at each of the seven hospitals, one for each

of our non-hospital divisions, and additional liaisons for areas like billing, coding, and pharmacy. All of our liaisons already have full-time positions at their facilities, so compliance is an additional responsibility for them. In addition to other responsibilities, they help us coordinate much of our monitoring program, facilitate our annual risk assessment, and champion our training programs. Because of the unique regulatory environment in managed care, we also have a dedicated compliance function for our health plans.

I know from conversations over the years with my fellow compliance officers that there are as many staffing models as there are compliance programs. The first question in a conversation like this is inevitably some variation of "How big is your staff." When I answer "Four," I am often greeted with looks of surprise. As I explain the rest of the structure, it begins to make more sense, but for me the real benefit of our staffing model is that we have always had to manage by influence and work collaboratively with our operational folks. Failure to obtain buy-in from management and staff at the operational level is probably one of the leading causes of death for compliance initiatives. With our structure, we have to get that buy-in because we need their help to manage the workload and also need the benefit of their expertise.

JO: If you had to name the top three compliance risks areas, what would they be and why?

GB: The first would be quality of care/medical necessity. Not only are there various compliance concerns, the stakes are high. Anytime you are looking at compliance issues that have implications for patient safety, the risk profile immediately rises. Add to that the number of moving parts in the decision-making processes involved and the number of people who impact whether the appropriate decisions are made, and it's a challenge. Not to mention the focus of the Recovery Audit Contractors in this area. Addressing these risks for an entire organization is an enormous undertaking, requires a methodical approach, and a considerable time investment from a lot of people.

The second would be financial arrangements with physicians. To do deals with doctors, you have to jump through lots of hoops, and they aren't easy hoops to get through because they involve a significant degree of technical legal analysis. And hospitals paying physicians always have and always will draw a great deal of regulatory scrutiny. Whistleblowers have always been the primary source of Stark enforcement actions, but I think we are going to see more and more direct scrutiny from regulators. The Disclosure of Financial Relationships Report is in a bit of limbo at the moment, but I think, at the very least, it is a sign that the government is ready to take a closer look at some of these financial arrangements. All health care organizations should be taking a close look at their contracts with physicians and the control mechanisms they have in place to monitor and review them.

Third, I think clinical trials also present a high compliance risk. Clinical trials take some everyday compliance risks like billing, compound them with additional risks that are unique to the clinical trial environment, like primary investigator oversight, and top it all off with a regulatory environment that is unfamiliar to many compliance professionals. The unique nature of the regulatory environment, combined with the prevalence of these trials in the hospital environment, make this an area compliance officers should be monitoring closely.

JO: What has been your single biggest challenge in your compliance function?

GB: This is a tough one; so many challenges to choose from. But there is one area

that has proved to be consistently challenging throughout my time in Compliance. I know it is something that other compliance professionals struggle with, and it comes up fairly often when we roll out a new initiative, conduct a review, or sit down with our operational leaders to tackle (or sometimes, retackle) an issue. I find obtaining physician buy-in to be a constant challenge. And it is something that you simply must have.

Look at an issue like observation. You can have the best process in the world for getting patients into the appropriate status, but if you don't get your physicians at the table, educate them on their role, and convince them that they have a stake in getting patients into the correct status, you won't be successful.

I am talking here about non-employed physicians, and I think their buy-in can be challenging to obtain for a variety of reasons. One is simply time. They have full caseloads and often see these additional responsibilities, requested in the name of compliance, as a distraction from patient care. I think the nature of the relationship between physicians and hospitals can often play a role as well. If you are asking for something that doesn't make intuitive sense to them (observation is, again, a good example), they can sometimes be distrustful of the hospital's motives for making the request. And lastly, I think there

Continued on page 16

are simply instances where the physicians know they don't have a stake in an issue. Most of these folks are very well informed and pay attention to the regulatory environment, at least in a broad sense, and you just don't see many enforcement actions brought against physicians. When they are brought, the cases typically involve egregious conduct. But more often than not, the hospital is the target and the physicians know this, so it can be difficult to convince them that they have a stake in addressing certain problems.

The good news is that I think obtaining physician buy-in, though certainly still challenging, has gotten easier in the last few years, and I expect that this trend will continue. As compliance programs have matured and more physicians have been educated on the issues, they are beginning to understand that many compliance concerns can only be addressed effectively with their help.

JO: How do you respond to the challenge of keeping your program dynamic and keeping education and training valuable and interesting?

GB: Well, for better or worse, the government helps. The regulatory environment changes constantly, so you must have a dynamic program or you will fall behind. There are always new issues and directives and regulations that need to be communicated, and the compliance program is often the best mechanism for making that happen.

As far as our training program goes, it has evolved pretty consistently over the years. We started out doing slide presentations to live audiences. It can be pretty difficult for a small compliance staff and a few trainers to get to 17,000 employees. Eventually, we started making annual training videos. We gave the managers some talking points and asked them to show the videos in staff meetings and facilitate discussions with their employees at the end of the video. Within the last few years, we have been fortunate enough to have some dedicated education professionals brought into our Human Resources department. These folks are responsible for coordinating the training efforts of the entire organization and have been quite helpful to us. With their help, we developed a computer-based training (CBT) module for our general training program – we developed the content and they built the module. We are currently working to transition our specialized training programs to CBT as well. The move to CBT was widely hailed throughout the organization as the end of the long, dark era of watching me on video. Seriously. People were happy about that.

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

GB: If you were to analyze ten different organizations struggling to create a strong compliance and ethics culture, you would probably identify hundreds of contributing factors. But two key factors that would figure prominently in the struggles of all ten would be a leadership failure and a compliance education problem. So my advice would be to identify the source of the leadership failure and correct it…through compliance education. The classic leadership concern that compliance professionals have been warned about for so many years now, is the tone at the top. That applies to the leadership at the facility level as well as the organizational level. But the fact is that regardless of the source of the leadership failure, at least part of the responsibility for that failure resides with the compliance officer. Educating senior leadership and the board and advising them of the state of the compliance environment within the organization is a primary responsibility of the compliance officer, as is providing meaningful compliance and ethics education to all employees. If you need to strengthen your compliance and ethics culture, you should start by spending a little more time with your senior leaders and the board, ensuring there is clarity as to their role and accountability for ensuring they are meeting their obligation of providing the appropriate oversight and resources necessary to support an effective compliance program. You may also want to rethink and revise the message you are sending with your current compliance training.

JO: What tools do you have in place to measure the effectiveness of your compliance program?

GB: We periodically engage outside experts to conduct an assessment of our compliance program. I don't think the value of these of engagements can be overstated. We get an objective viewpoint that gives us a sense of where we are compared with other organizations and, more importantly, identifies potential weaknesses in our program that need some attention. It's easy, in an environment where you are jumping from one hot button issue to the next, to take your eye off the ball in certain areas. These outside reviews help us refocus our attention on these areas. And it doesn't hurt to hear what you are doing well, either!

We also have an ongoing monitoring and self-assessment program that gives us a look at how well various compliance initiatives we have rolled out are working. Additionally, many of the compliance reviews and audits we do give us a sense of how effective our compliance program is throughout the system.

JO: There is increased focus on governance and board engagement. Can you share some effective methods you have used to ensure your board understands their role in providing reasonable oversight regarding your program's effectiveness?

GB: A couple years ago, we brought in outside counsel to do an in-depth training session with the members of our audit and compliance committee of the board. They got a lot out of it, and I think it was helpful for them to hear someone other than

me talk to them about compliance and give them guidance with respect to their leadership role in making the program effective. I think bringing someone in from the outside periodically is an excellent way to keep board members engaged and up to speed.

In addition to that, at each quarterly meeting, I try to devote some time to talking with them about what may be coming up in the future from a compliance perspective. I think taking a few minutes to talk about something that we aren't actively working on yet helps give them some perspective and also a level of comfort that we are looking ahead and keeping our eyes on the ball. We are fortunate enough to have a group of actively engaged members on our audit and compliance committee. They asked me to talk to them about the resource guide for board members that the OIG put out a few years ago. They didn't wait for me to bring it to them.

JO: Where do you see the compliance and ethics world going in the next five years? Ten years?

GB: I suspect that we have reached a saturation point in health care at this point, at least in the United States, so I look for compliance and ethics to begin to develop more rapidly outside the health care industry. I think we are already seeing evidence of that with the growth of the Society of Corporate Compliance and Ethics. The health care industry has developed a good model, and I think it is fair to assume that professionals in other industries will take advantage of the work the health care industry has already done for them and build on it. Having other industries focused on establishing effective compliance and ethics programs will ultimately improve the model, so there will be some benefits flowing back into the health care industry down the road.

JO: What recommendations do you have for individuals looking to focus their career in compliance?

GB: My first recommendation would be to work hard to round out your knowledge base. We all come to compliance from different backgrounds – law, coding, auditing, billing, etc. – but you need a working knowledge of all of these disciplines and more to have a successful compliance career. Your area of expertise provides you with a solid foundation, but you have to move outside your comfort zone if you hope to get the most out of a career in compliance.

Also, make sure you understand what the folks on the ground, who provide care, actually do on a day-to-day basis and how they do it. And do the same with your billers and coders and case management professionals, etc. You won't get very far in the compliance profession by walking onto the floor and telling someone you are going to audit them to help improve their compliance processes, then asking them in the very next breath to teach you what they do. You need to have an appreciation for that before you walk through the door. You owe that to the folks who are doing the work. I think it is important to keep in mind that compliance programs don't exist for their own sake – they exist to support a broader mission. Don't lose sight of that.

JO: HCCA offers a number of educational opportunities. Which most match your needs, and in the alternative, what other areas would be helpful?

GB: The two programs I attend most often are the Compliance Institute and the Fraud and Abuse program done jointly with the AHLA [American Health Lawyers Association]. When I go to the Compliance Institute, it is mainly to get a sense of what my staff is learning. I tend to get more out of the Fraud and Abuse program, but even there, much of the information tends toward basic principles. So, I do think HCCA could do more to cater to the needs of seasoned compliance professionals. I became fairly spoiled earlier in my compliance career. The VHA [formerly Voluntary Hospital Association], of which Sentara is a member, had a Compliance Officer Affinity Group that I found to be very valuable. We had quarterly sessions, and there were usually anywhere from 15 to 25 of us in attendance. At the end of each of these two-day sessions, we set the agenda for the next quarter. There was typically one outside speaker brought in, but beyond that, we selected speakers from amongst ourselves. I learned a great deal at each of these sessions. Not only did we gain issue-specific knowledge, we were able to talk openly with each other about a variety of compliance challenges and get the benefit of all the experience around the table. Unfortunately, that group was disbanded several years ago, but I still seek out the people I met there when I attend HCCA conferences. I think there is a real opportunity for HCCA to fill that void. Small groups of compliance professionals with similar levels of experience, similarly sized or structured organizations, etc.

JO: What do you do to relax and have fun?

GB: This may come as a surprise to some of my peers who know me, but I like to cook. My wife, who has a career of her own, does most of the cooking, but several years ago I started doing it once in a while to give her a break. Since I don't have to do it that often, I like to make new or complicated dishes. Much to my wife's chagrin, I typically judge the success of a meal by how much a mess I can make of the kitchen. My kids help with that, especially my daughter, who loves to pound veal and throw flour all over the kitchen. I also like to travel. My wife and I enjoy Europe. My seven-year-old son and I have begun taking trips to different baseball parks every summer, which has been a great experience for both of us. And I have a couple different groups of friends that get together somewhere different every year or two. Eventually I'll have to think of someplace to take my daughter, but she is only four, so I have some time. The great irony of my love of travel is that I hate to fly. ■

The Jones Day/HCCA iPod® Nano Giveaway!

JULY 1, 2008 THROUGH JUNE 30, 2009

Contribute a compliance-related document to the HCCA Compliance Library and be automatically registered for a chance to win an iPod Nano. For each document that you add to the library, you will increase your chances to win one of 12 iPod Nanos! Log on to the HCCA web site (www.hcca-info.org) and go to "Communities" for more details about the Jones Day/HCCA iPod Giveaway!

Share your knowledge and ideas — contribute compliance-related documents to the HCCA Compliance Library by emailing them to Caroline Lee Bivona at cleebivona@hcca-info.org.

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Jones Day's Health Care Practice is an interdisciplinary practice team of legal counsel aligned to facilitate the exchange of information and targeted knowledge about the health care industry and the ever-changing health care regulations, to better meet our clients' needs. Learn more about Jones Day at www.jonesday.com.

You can only win one iPod. HCCA/SCCE and Jones Day staff are not eligible for the Giveaway.

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Letter from the CEO

The CHC credential is invaluable

The Certified in Healthcare Compliance (CHC) credential has been developed and maintained by Debbie Troklus and we are very grateful for her efforts. Many other very dedicated compliance professionals have helped Debbie with this very arduous process over the past 9 years. They are due a lot of credit. I have been waiting 9 years to say that the CHC credential was invaluable. I have always wanted to declare that the CHC credential was invaluable; however, I felt we needed to wait until the industry said it was so and totally embraced it. No other industry outside of health care has a compliance credential that is as widely accepted. Health care has embraced the CHC credential. We should be very proud.

We have never attempted to push CHC certification on anyone. We never sought the endorsement of anyone. We endured some criticism along the way, such as "This is beneath me," "Who are you to judge us?" and "Who has endorsed this?" We always did what we thought was best for the profession and turned the other cheek. Whenever you attempt anything of any real value, there are a lot of critics. The credential was developed with expert outside credentialing consultants and members of the compliance profession. We felt we had done a good job and that, in time, it would be clear to everyone. The lack of appreciation made the work a little harder, but it made this moment a lot sweeter. The critics are very quiet now.

By the end of this year, there will be 2,000 people with the CHC credential. We are not stopping there. We have developed our first subspecialty area credential for research compliance professionals. We are just now completing the advanced certification for health care compliance professionals. It started to occur to me that the CHC certification had really arrived the day I got a call that started like this: "I have interviewed for a job and the CHC is a job requirement. I need to know how to get certified right away."

In 2008, 21% of our member's organizations required the CHC credential for their Assistant Compliance Officers. In 2008, 58% of our member's organizations preferred CHC candidates for their Assistant Compliance Officer position. CHC certification was also preferred or required in similar percentages for compliance professionals, auditors, coders, trainers, generalists, and attorneys. As the compliance industry continues to grow, employers are increasingly hiring certified compliance professionals, because the certification shows that these professionals have the required commitment and training.

By the end of this year, there will be 2,000 people with the CHC credential

Outside lawyers, consultants, government officials, academics, and many other professionals outside of the Compliance department have earned the credential. Many other people within the Compliance department have received the credential, including educators, auditors, generalists, and attorneys. The CHC credential has been accepted by the compliance profession.

We have branched out into other industries with the development of the Certified Compliance and Ethics Professional (CCEP) credential. It is designed for compliance and ethics professionals who are practicing in any industry. People from other countries have become certified, and the international interest is amazing. We will have 500 compliance and ethics professionals who have earned the CCEP by the end of the year. We are receiving the same criticisms we received with the CHC. It's a little harder to take the second time around. We are a little more confident about our future than we were the first time. However, we must still wait until the CCEP credential has been more widely accepted before we declare it is firmly entrenched in our profession. We can wait. ■

We are pleased to introduce

The Duane Morris, LLP

Certified in Healthcare Compliance (CHC) Scholarship

Health Care Compliance Association

Beginning in 2008, Duane Morris, LLP will sponsor four Certified in Healthcare Compliance (CHC) Scholarships annually.

The Duane Morris, LLP CHC Scholarship is intended to offer health care professionals the opportunity to expand their knowledge and advance their careers by obtaining the Certified in Healthcare Compliance (CHC) credential. Obtaining the CHC credential demonstrates an advanced knowledge of compliance and ethics principles and practice.

Each recipient of the Duane Morris LLP CHC Scholarship will be awarded $4,000 to cover the HCCA Compliance Academy tuition and CHC test fees, as well as a portion of travel expenses to attend the Academy. (Both Academy tuition and test fees have member and non-member pricing, so the portion of travel expenses covered will vary based on membership status.)

All applicants must successfully demonstrate financial need of their employer, as this scholarship is designed to provide educational assistance to health care professionals in organizations that may not otherwise be able to fund Academy attendance and CHC testing. Applicants must also meet the following criteria for consideration:

- Do not presently hold the CHC credential
- Have worked in the Health Care Compliance field for at least one year
- Meet the criteria to sit for the CHC exam
- Commit to prepare and sit for the CHC exam through the professional testing service or at the conclusion of the HCCA Academy

Background: The CHC credential is awarded to candidates who pass the Healthcare Compliance Certification Board CHC Examination. The Examination is offered at the conclusion of the HCCA Compliance Academy. The Compliance Academy offers four days of intense sessions covering the seven elements of health care compliance.

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HEALTH CARE COMPLIANCE ASSOCIATION

Duane Morris LLP and HCCA encourage equal opportunity for all CHC Scholarship applicants and candidates.

Applications are available at www.hcca-info.org, please call 888-580-8373 to receive an application.

If you have questions about the scholarship or the Compliance Academy program please contact Jennifer Power at 952/405-7916 or by email at jennifer.power@hcca-info.org

Patient safety organizations: New protections for quality data

By Suzanne M. Foster, JD and Shannon B. Hartsfield, JD

Editor's note: Suzanne M. Foster is an Associate in the Boston office of Holland & Knight LLP. She may be reached by e-mail at suzanne.foster@hklaw.com.

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On February 12, 2008, the Department of Health and Human Services (HHS) Agency for Healthcare Research and Quality (AHRQ) and the Office of Civil Rights (OCR) issued proposed regulations[1] that implement the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act).[2] Read together, the Patient Safety Act and the proposed regulations establish a framework for hospitals, doctors, and other health care providers to voluntarily report information related to patient safety and quality of care. This information, referred to in the Patient Safety Act as "patient safety work product," would be transmitted to newly formed entities called Patient Safety Organizations (PSOs) on a privileged and confidential basis. No federal funding is in place for any part of this new reporting framework.

The Patient Safety Act was, in part, enacted in response to the Institute of Medicine's (IOM) 1999 landmark report "To Err is Human."[3] This report found that at least 44,000 people, and potentially as many as 98,000 people, die in U.S. hospitals each year as a result of preventable medical errors. One of IOM's main conclusions was that the majority of medical errors are not the result of individuals' recklessness. Instead, most errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. The IOM recommended that, in order to lower the rate of medical errors, the health care system had to make it harder to do something wrong and easier to do something right. Patient safety experts have long argued that improvements to the system can only be developed after reviewing and analyzing the aggregation of significant numbers of individual events in order to identify underlying patterns.

The problem to date, however, is that this kind of large volume of data is not available for analysis. Providers are often reluctant to participate in quality review activities for fear of liability, professional sanctions, or injury to their reputations. Traditional state-based legal protections, typically known as peer review protections, are limited in scope and they do not exist in all states. Furthermore, they typically only apply to hospitals and not to other kinds of health care providers. And most importantly, no system is in place for this kind of data to be shared outside an individual hospital, therefore making it prohibitive for researchers to collect, track, and study patient safety data and develop recommendations for improvement.

The Patient Safety Act and the proposed implementing regulations are an effort to address the barriers to patient safety and health care quality improvement activities. The proposed rules attempt to set forth strong federal confidentiality and privilege protections that will be available in all states and extend to all health care providers. It is yet to be seen if the final regulations will accomplish these goals. Much of the Patient Safety Act's success will depend upon the providers' trust in the federal protections and their willingness to voluntarily self-report their most sensitive and vulnerable information to a third party, a PSO, which is subject to government review and oversight.

Below is a broad overview of the Patient Safety Act and the proposed regulations. The comment period on the proposed rules ended April 14, 2008. AHRQ has publicly stated that the final regulations will be issued "expeditiously."[4]

The Patient Safety Act

Under the Patient Safety Act, PSOs must certify to HHS that they have expertise in patient safety and the ability to provide confidential, expert advice to health care providers in the analysis of patient safety events. A PSO can be a public or private entity, or a component of such an entity.[5] The intent of the statute is that health care providers will report patient safety work product on a confidential and privileged basis to a PSO, which in return will eventually report the information to a central database developed by the federal government. This will allow the aggregation of large volumes of data to be analyzed and studied for purposes of developing improvements in health care safety and quality.

Basic statutory requirements for PSOs

An entity that wants to become a PSO must submit an "initial certification" to the HHS Secretary stating that the entity has policies

Continued on page 22

 ...continued from page 21

and procedures in place to perform each of the patient safety activities described in the statute. The criteria are as follows:

- The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.
- The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.
- The entity, within each 24-month period that begins after the date of the initial listing . . . has bona fide contracts, each for a reasonable period of time, with more than one provider[6] for the purpose of receiving and reviewing patient safety work product. ("Provider" means individuals or entities licensed or authorized under state law to provide health care services, including hospitals, nursing facilities, physician offices, physicians, social workers, pharmacists, etc.)
- The entity is not, and is not a component of, a health insurance issuer.
- The entity shall fully disclose:
  - any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity;
  - if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity;
  - to the extent practical and appropriate, that the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers; and
  - that it utilizes patient safety work product for the purpose of providing direct feedback to providers.[7]

Components of other organizations

Under the statute, if the entity seeking to be a PSO is a component of another organization, then the PSO must, in addition to the above criteria, maintain patient safety work product separately from the rest of the organization, and must have appropriate data security measures in place to protect the confidentiality of the information. The PSO may not disclose patient safety work product to the rest of the organization.

Benefits of PSO status

Patient safety work product is provided privilege and confidentiality protections when reported to a PSO. Patient safety work product is defined as any data, reports, records memoranda, analyses (such as root cause analyses) or written or oral statements which are assembled or developed for and are reported to a PSO.[8] Patient safety work product also includes information developed by a PSO for the conduct of "patient safety activities" and which could result in improved patient safety, health care quality, or health care outcomes.[9] Patient safety activities include:

- Efforts to improve patient safety and the quality of health care delivery.
- Collection and analysis of patient safety work product.
- Development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.
- Using patient safety work product to encourage a culture of safety and providing feedback and assistance to effectively minimize patient risk.
- Maintaining procedures to preserve confidentiality with respect to patient safety work product.
- Providing appropriate security measures with respect to patient safety work product.
- Using qualified staff.
- Activities related to the operation of a patient safety evaluation system and providing feedback to participants in a patient safety evaluation system.[10]

Patient safety work product also includes information which identifies or constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to, a PSO's or a provider's "patient safety evaluation system."[11] The law will not, however, prevent access to all data related to adverse events. Patient safety work product does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.[12] Also, if data is collected or exists separately from a patient safety evaluation system, it will not be considered patient safety work product.[13] Therefore, forms used to report adverse incidents to state regulatory agencies will not be protected.

There are exceptions, however, to the privilege and confidentiality protections. For example, patient safety work product may be disclosed for use in a criminal proceeding, with certain restrictions.[14] It may also be disclosed if authorized by each provider identified in the work product.[15]

Proposed regulations

The proposed rules would add a new Part 3 to Title 42 of the Code of Federal Regulations. The proposed rules address (1) the establishment and operations of PSOs; and (2) privilege and confidentiality protections for patient safety work product and enforcement of the confidentiality provisions. AHRQ will handle PSO certification, and OCR will enforce information protections. Under the proposed rules, HHS may impose a civil money penalty of up to $10,000 for confidentiality breaches.[16]

The Secretary of HHS may request informa-

tion or conduct announced or unannounced reviews or site visits to PSOs to assess compliance.[17] The Secretary will be allowed to inspect and/or be given or sent copies of any PSO records the Secretary deems necessary, including patient safety work product.[18]

Confidentiality and Security

With certain exceptions, patient safety work product is privileged and confidential.[19] In many cases, the protection continues even when patient safety work product is disclosed.[20] The proposed rules specify that it will not be subject to discovery or to a federal, state, or local subpoena, whether in civil or criminal court, or in an administrative disciplinary proceeding against a provider.[21] Patient safety work product, under the proposed rules, would also not be admissible in such proceedings, nor could it be admitted in a professional disciplinary proceeding.[22] The proposed rules contain certain limited exceptions. For example, non-identifiable patient safety work product may be disclosed.[23] The information may also be disclosed under certain circumstances in criminal proceedings when it contains evidence of a criminal act.[24] And it may be disclosed if all providers identified in the work product authorize the disclosure.[25]

PSOs can share patient safety work product with other PSOs, and providers may also share this information with other providers, if the direct identifiers of any providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, workforce or household members are removed. The direct identifiers include:

- Names
- Postal address information, other than town or city, state, and zip code
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers or taxpayer identification numbers
- Provider or practitioner credentialing or DEA numbers
- National provider identification number
- Certificate/license numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers
- Full face photographic images, and
- Removal of all direct identifiers listed in the HIPAA privacy rules.[26]

The proposed rules contain detailed security requirements for patient safety work product. Unlike the provisions governing both internal use and external disclosure of protected health information (PHI) found in the HIPAA privacy rules, the proposed rules would not regulate the use of patient safety work product within a PSO. But a PSO's security framework is required to contain four elements:

- security management
- separation of systems
- security monitoring and control, and
- system assessment.[27]

Remaining open questions

Comments on the proposed rules were due April 14, 2008. The AHRQ apparently understood that there were additional details that needed to be worked out when they issued the proposed rule, because on their Web site they listed 47 questions[28] for which they sought public comment. Although the scope of the privilege and confidentiality protections that the government grants to patient safety work product is yet to be seen, it will be even more interesting to see if these protections alone motivate providers to incur the cost of complying with the rules and to initiate voluntary disclosures of sensitive data. The regulations arguably will provide some level of legal protections to such sensitive information, which will be the reason some providers will participate. Ideally, providers will also participate for more altruistic purposes such as becoming part of a process that may improve patient care and reduce medical errors. ■

1 73 Fed. Reg. 8113 (February 12, 2008).
2 Pub. L. 109-41, amending the Public Health Services Act (42 U.S.C. 299 et seq.) by inserting new sections 921 through 926, 42 U.S.C. 299b-21 through 299b-26.
3 Institute of Medicine, "To Err is Human: Building a Safer Health System", 1999. Available online at http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf. Accessed May 1, 2008.
4 Dr. Carolyn Clancy, Director of AHRQ, in a teleconference February 29, 2008. See also http://www.ahrq.gov/news/press/pr2008/psopr.htm.
5 42 U.S.C. §299b-21(4).
6 See 42 U.S.C. §299b-21(8).
7 42 U.S.C. §299b-24(b)(1).
8 42 U.S.C. §299b-21(7)(A).
9 Id.
10 Id. at (5); see also id. at (6) (defining a "patient safety evaluation system" as "the collection, management, or analysis of information for reporting to or by a patient safety organization").
11 Id. at (7)(A).
12 Id. at (7)(B).
13 Id.
14 42 U.S.C. §299b-22(c)(1)(A).
15 Id. at (c)(1)(C).
16 See Proposed Rule 42 C.F.R. §3.404.
17 See Proposed Rule 42 C.F.R. §3.110.
18 Id.
19 See Proposed Rule 42 C.F.R. §3.206.
20 See Proposed Rule 42 C.F.R. §3.208.
21 See Proposed Rule 42 C.F.R. §3.204.
22 Id.
23 Id.
24 See Proposed Rule 42 C.F.R. §3.206.
25 Id.
26 See Proposed Rule 42 C.F.R. §3.206.
27 See Proposed Rule 42 C.F.R. §3.106.
28 Available at www.pso.ahrq.gov/rulemaking/nprm.htm (Accessed April 8, 2008).

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Laboratory compliance: Shaky compliance starts with a poor foundation

By Jeff Sinaiko

Editor's note: Jeff Sinaiko is president of Sinaiko Healthcare Consulting, one of the nation's leading independent health care management consulting firms, and works with health care organizations nationwide on a diverse range of compliance issues. Mr. Sinaiko may be reached by e-mail at jeff@sinaikohc.com.

In the first article of this series on laboratory compliance, I introduced this topic as a unique and complex compliance challenge, requiring specialized expertise and attention within the parameters of an organization's overall compliance program. Despite considerable guidance, specific enforcement activity, and a history of well-known consequences from poor laboratory compliance, many organizations fail to fully address their laboratory risks.

This brings us to the admittedly odd and heretofore unattributed quote, "A turtle with no legs tends not to go anywhere." OK, so there were lots of choices to imply the importance of a good foundation, but that's the one I chose. Please don't hold it against me.

Laboratory compliance is even more dependent on its foundational elements and key underlying documents than most other specialties. If there are deficiencies in the Test Requisition Forms (TRF), the Physician Acknowledgement Forms (PAF) and the sales and marketing efforts, then compliance risk will exist. Clearly, the place to start is from the ground up. In many ways, this is the equivalent argument to addressing root causes of denials through an active denial management program in your accounts receivable collection, as opposed to chasing resolution of each individual claim at the back-end.

Physician compliance

The PAF is the document that provides the referring physicians with the requisite information they need to know to understand what they are ordering in the custom (non-AMA approved) panels designed for their specialties. Each physician must be provided the PAF and sign it annually, indicating acceptance of the terms and of his/her personal responsibility for ordering only medically necessary tests, including that all components of a custom panel are medically necessary.

PAFs directly impact compliance in that they provide supporting diagnostic rationale for each custom panel, which puts that burden on the referring physician, not the lab. Without a signed PAF, the lab takes on the full responsibility for the medical necessity of the tests. With ongoing scrutiny from the government for the compliance and medical necessity of custom panels, this is a significant issue. Specific compliance recommendations related to the PAF include:

- Strict adherence to the 1998 OIG guidance on the subject;
- The PAF for a specific physician can not be applied to all physicians in a group. This is a common mistake, particularly when applied to physicians of varying specialties (e.g. pediatric cardiologist vs. adult cardiologist) where the medical necessity criteria may, in fact, be different;
- Physicians should be encouraged to order only those tests that are medically necessary for a given patient, whether the tests are the constituents of an AMA-approved or custom panel; and
- Custom panels should be kept to a minimum, because CMS generally frowns upon their use. Education should be provided to physicians about all relevant National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) and alternatives to the custom panel.

Labs should routinely audit and monitor the billing for custom panels at the back-end to ensure that there is no unbundling of the custom panel at billing time, including that the custom panel is being billed at a fixed price, and at no more than the aggregate sum of the prices for the individual components of the panel.

Diagnosis and coding requirements

The other document is the Test Requisition Form (TRF). This is the physician order and flow of information from the physician to the lab. It is part of the patient's medical record, which actually is one of the common risk areas when it is not treated and maintained as such.

The TRF provides critical information with

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compliance implications, including:

- All relevant diagnostic information to support the medical necessity of the test(s) ordered. At no time should lab personnel be completing the diagnosis information based on previous encounters, previous test orders, narrative description, or patient-provided information;
- For specimens referred for surgical pathology examinations, it is essential that the referring physician provide diagnostic information to the highest degree of specificity possible and indicate the anatomical location of the submitted specimen. Absent this information, laboratory personnel should contact the referring physician to elicit this essential information and document such clarifying queries;
- All applicable diagnoses have to be reported by the physician for all tests ordered and the lab has to report all of them when billing. Lab audits often reveal billing where all relevant diagnoses are not provided or where the lab only reports certain diagnoses that may make the tests appear to be billable, when if all the diagnoses been reported, it may have changed that determination;
- The referring physicians must rank the diagnoses in order of severity or clinical appropriateness. If they do not do so, the combination of diagnosis codes may not justify the tests ordered. Many labs are not inclined to place this burden on their referring physicians; however, it is required and appropriate to ensure compliance in the lab's billing; and
- The physicians should associate or link each diagnosis with the test it supports. It is highly recommended that the lab apply National Correct Coding Initiative (NCCI) edits in its billing system.

Unless all this information comes from the referring physician, the lab has to provide some of this information itself to complete the 1500 Form for Claim Submission, so any problems with that information would actually be (or would give the appearance of) providing information for the sole purpose of getting paid.

The design of the TRF should facilitate each of these requirements. Every AMA or custom panel must list all individual constituents to encourage ordering only those tests that are medically necessary and each test should be listed with the corresponding updated and current Current Procedural Terminology (CPT) code.

Finally, there are a handful of other baseline issues involved in building a foundation that enhances laboratory compliance, rather than one that expands the likelihood of compliance problems. Such additional issues include:

- Sales and marketing staff should not be permitted to "sell" custom panels. The initiative and request for tests has to come from the physicians for their specific clinical needs;
- Volume-based discounts should never be offered;
- Laboratory-provided phlebotomists must collect blood only for the relevant lab tests, and the physicians obviously should not be billing for such drawing services;
- Computers and fax machines provided by the lab for ease of communication must be used only for test ordering and results reporting;
- Any blood draw station rental by the lab has to be at fair market value; and
- The laboratory can not provide training or supportive assistance to select and support diagnosis codes/test linkage. This means no "cheat sheets."

In addition to the clinical complexities and unique characteristics of lab billing, the sheer volume for many labs makes eliminating as many problems as possible up-front a realistic necessity. Without a stable and secure foundation to the lab billing operations, the efforts become driven from the back-end, are less efficient, and the likelihood of mitigating potential compliance risks is significantly reduced. ■

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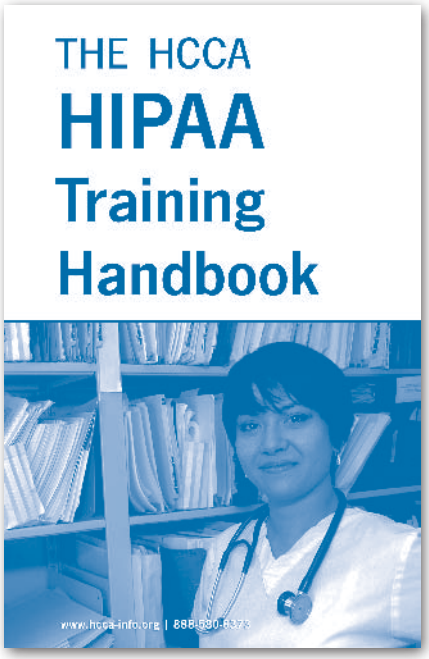

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Patient requests for file amendments: Managing expectations

By Kevin Johnston, RN, CHC and Jerianne LaRoy, RN

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Although it has been almost five years since most health care providers were required to comply with the HIPAA Privacy Rule, questions on the finer points of the regulations continue to arise. Those of us working in health care provider organizations often struggle with doing the right thing when the regulations—or specific situations—are ambiguous or unclear. This article focuses on the patient's HIPAA-granted right to request an amendment to their health records which, to a great extent, is as much about optimizing patient relations and managing expectations as it is about compliance with the regulation.

Patients may expect that, because health records contain information about them, they should be able to correct and add to those records at will. To forestall complaints, mistrust, and accusations of non-compliance, inform patients up front about how the process works. When a patient first makes a request for an amendment, outline the process in plain language. Include information on how requests are processed, what steps are taken when investigating a request, grounds for denial, and the patient's rights for recourse if their request is denied (See sample form in the appendix on page 30.)

As a refresher, a HIPAA covered entity may deny a patient's request for an amendment if it determines that the protected health information (PHI) or record that is the subject of the request:

- Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;
- Is not part of the designated record set;
- Would not be available for inspection under Sec. 164.524; or
- Is accurate and complete.[1]

The first three bullets above are straightforward and easy to determine. However, deciding whether a record is accurate and complete requires judgment, and sometimes a decision is difficult to make. The preamble to the final HIPAA Privacy Rule provides a hint regarding the intent of this section of the regulations. "This right is not intended to interfere with medical practice or to modify standard business record keeping practices. Perfect records are not required. Instead, a standard of reasonable accuracy and completeness should be used."[2]

A prudent approach to determine accuracy and completeness, in the context of an amendment request, involves consultation with the treating clinician whose documentation would be affected. Unfortunately, as is often the case, when the clinician is unavailable or is unable to remember the patient and/or encounter, we're faced with a dilemma: Should we go ahead and accept the patient's proposed amendment because we can't absolutely validate that the record is accurate and complete, or should we assume that the original documentation is accurate and complete? Is the patient's request accurate, or is the record accurate?

It's tempting to give the patient the benefit of doubt and, in the spirit of customer service, accept the proposed amendment. However, accepting an amendment implies that we agree with it. Accepting potentially erroneous information without careful consideration, even if marked as the patient's perspective, may have an unintended impact on subsequent care. On the other hand, denying most or all requests for amendment may result in issues related to compliance, patient satisfaction, and data quality when an amendment represents a valid correction.[3]

When the accuracy and completeness of the health information subject to an amendment request is ambiguous, there are some good reasons to assume that the original documentation is accurate and complete.

- The health record is the legal business document of the organization. Health records are admissible as evidence within a court of law because they are:
  - Documented in the normal course of business,
  - Kept in the regular course of business,
  - Made at or near the time of the matter recorded, and
  - Made by a person within the business with knowledge of the acts, events, conditions, opinions, or diagnoses appearing in them.[4]

  (In a loosely related example, if a physician were asked to give testimony or a deposi-

tion regarding the care and treatment he or she provided, he/she would most likely refer to and rely on his/her documentation performed at or near the time of the encounter. In effect, the physician must assume that his or her documentation is accurate and complete.)

- Accepting a patient amendment without clearly indicating that it is the patient's perspective can lead to clinical errors. Even if an amendment is marked as "patient perspective," clinicians in subsequent encounters can still misunderstand the content and intent, increasing the risk of clinical misjudgments.
- If a patient-requested amendment is accepted after coding and billing have occurred, the clinical documentation may no longer support diagnosis or procedure codes and medical necessity. If not corrected, this can present risks of fraud, abuse, and false claims. The potential effect on coding by itself is not sufficient rationale to deny an amendment request. However, if there isn't a compelling reason to accept the amendment, a denial is appropriate, and may save substantial rework.
- Accepting an amendment that we don't agree with may give the patient the mistaken impression that we do agree with it. If, in fact, we do not agree with the proposed amendment, but have accepted it, this can lead to further misunderstandings between the patient and caregivers, and ultimately, increased patient dissatisfaction.

When designing up-front communications, include the following patient rights:

- Make it easy for patients to exercise their rights by clearly defining the steps to be taken.
- If an amendment is denied, the patient still has the right to have his or her request made a part of the record, and to have it included with any future disclosures of the PHI that is the subject of the amendment.
- The patient may also submit a "statement of disagreement" that describes why he or she disagrees with the amendment denial. If a patient submits a statement of disagreement, all materials associated with the amendment request (or a written summary) must be included in any future disclosures of the PHI that is the subject of the amendment.

In effect, if they pursue either of the above options, patients may feel they have accomplished their goal—their amendment request is included in the record. And, because the amendment request is marked as denied, it should be clear to others who review the record what is considered valid information, and what is not.

Informing patients up front about what to expect when they request an amendment will reduce patient complaints and charges of non-compliance. Consider creating a plain-language "fact sheet" to help the patient understand and navigate the process (see appendix on page 30). Clarifying internally how to make judgment calls regarding accuracy and completeness, and providing patients with clear information on what they can expect in the amendment process, will improve patient and staff satisfaction as well as help promote the integrity of patient health records. ■

1 Standards for Privacy of Individually Identifiable Health Information, 45 CFR § 164.526 (2000)
2 Preamble to Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82558 (2000)
3 Amatayakul, Margret. "Making Amendments Meaningful," Journal of AHIMA, no. 76 (Feb 2005): page 60
4 AHIMA e-HIM Work Group on Maintaining the Legal EHR. "Update: Maintaining a Legally Sound Health Record—Paper and Electronic." Journal of AHIMA 76, no.10 (November-December 2005): 64A-L. Available at: http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_028509.hcsp?dDocName=bok1_028509. Accessed April 21, 2008

Related Item: Appendix: Request for Amendment of Protected Health Information Fact Sheet follows on page 30

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Inserted in this issue of **Compliance Today** is a quiz related to the articles:

- Using adult learning styles in compliance education — By Margie Brackeen (page 9)
- Patient requests for file amendments: Managing expectations — By Kevin Johnston and Jerianne LaRoy (page 28)
- The physics of health care compliance in the medical device sector — By Andrew Leven (page 61)

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Appendix: Request for Amendment of Protected Health Information Fact Sheet

You have the right to request an amendment to your health information. This means that, if you see something in your health records that you believe is inaccurate or incomplete, you may request that new information be added that corrects or completes the record. We call this additional information an "amendment."

We would like you to know that we consider your medical information accurate and complete. Without compelling evidence to the contrary, we may deny your request for amendment. However, we understand that you would like to make a correction or addition. Therefore, if the source of the information to be amended is from our facility, we will add your request for the amendment and the information you would like amended to your medical information, regardless of a denial.

What to expect if you request an amendment to your health information:

- You will be asked to complete and sign a request form, and return it to the Health Information Management (Medical Records) department of the facility holding your information.
- Our staff will examine your records, and may consult with your physician and others involved in your care and treatment.
- You will receive a response from us within 60 days.

If your request is approved:

- We will inform you in writing.
- The amendment you requested will be included in all future releases of your health information to authorized individuals and organizations such as health care providers, health care facilities, and insurance companies.
- We will identify individuals and/or organizations we've released your information to in the past, and ask for your approval to inform them of your approved amendment. We will also ask if you want us to inform anyone else.

We may deny your request for any of the following reasons:

- We find no compelling evidence that the medical information is not already accurate and complete;
- The information you are requesting to be amended came from another source, such as another health care provider or facility;
- The information you are requesting to be amended is not considered to be a part of the "designated record set," which is information used to make decisions about your care, treatment, or payment for your care and treatment; or
- The information you are requesting to be amended is not normally available for your inspection by law.

If your request is denied, you may:

- Submit a written statement to us disagreeing with the denial.
- Request that your amendment and our denial be included in any future releases of your health information to authorized individuals and organizations such as healthcare providers, health care facilities, and insurance companies.
- File a complaint with us and request that we review your request and our denial again.
- File a complaint with the Secretary of the Department of Health and Human Services.

COMPLIANCE 101

A compliance officer's perspective on maintaining a culture of compliance

By Steve Kelly, JD, CHC

Editor's note: Steve Kelly is the Chief Compliance & Privacy Officer with The Carle Foundation in Urbana, IL. He may be reached by telephone at 217/383-3927 or by e-mail at Stephen.Kelly@Carle.com.

It goes without saying that most compliance officers working in health care today know that it is simply not enough to put in place a compliance program that contains the seven elements of an effective compliance program and hope that the program will magically transform itself into one that is embraced in the organization as an integral part of its operating structure. Rather, we recognize that it is our mission to go above and beyond the seven elements by promoting an organizational culture that encourages ethical conduct and a commitment to compliance with the law. Further, we can site chapter and verse from all the guidance documents, which dourly warn against having a "paper program" and instead, encourage us to develop programs that foster a corporate culture of compliance throughout our organizations, starting with the "tone at the top."

But what exactly is a culture of compliance? Perhaps, the best statement that I have read explaining this somewhat elusive concept comes from Lori Richards, Director, Office of Compliance Inspections and Examinations, US Securities and Exchange Commission. In a speech to the National Society of Compliance Professionals at the 2007 National Membership Meeting in Washington, DC last October, she answered this fundamental question by stating:

> Simply put, it means instilling in every employee an obligation to do what's right. This culture will underpin all that the firm does, and must be part of the essential ethos of the firm, so that when employees make decisions, large and small, and regardless of who's in the room when they make them, and whether or not lawyers or regulators or clients or anyone else is looking, they are guided by a culture that reinforces doing what's right. Importantly, a firm's culture of compliance exists outside the compliance department — it exists throughout the firm.[1]

Yet, putting all of these corporate bromides aside, it is still many compliance officers' experience that most people working in health care, while they recognize the need for compliance, in theory, view compliance programs, and all the inconvenience that comes with them, as a necessary evil. After all, these well-intentioned people got into health care for the right reasons and frequently assume that serious violations of the law or ethics are things that happen in other organizations, but certainly not in theirs where workers are genuinely doing their best to take care of patients. Thus, in some cases, they would prefer you to be seen and not heard, and to stay out of the way in their mission of providing top quality care to their patients.

So what can a compliance officer do to nurture an environment where the organization's leaders are setting the right example, and employees are motivated to do the right thing in their work-a-day lives? In my experience, this discussion places too much emphasis on the things that a compliance officer can do to create such a culture, such as having an effective hotline, or requiring performance reviews to expressly consider an employee's adherence to compliance policies and procedures. Indeed, these things are vitally important, but by the same token, not enough time is spent discussing how a compliance officer behaves in the job as a means of promoting a culture of compliance. In a cerebral profession such as ours, it is often overlooked how a compliance officer's personality and behavior can deeply influence how the compliance program is perceived, which, in turn, influences how other individuals within the organization behave. The following are some suggestions for how a compliance officer should behave in order to maintain open lines of communication and to nurture a culture of compliance.

Create a "no-fault" environment. Compliance programs have several major weapons in the arsenal to prevent and detect compliance violations. These are policies and procedures, continued training and education, and auditing and monitoring. However, even with these weapons at your disposal, there remains a certain degree of danger, because unless leaders and staff members are willing to share their concerns with you, you may never get to deploy them. Therefore, the true lifeblood of an effective compliance program is an environment of open communication.

However, sometimes compliance officers are their own worst enemies in this regard. Instead of coming from a place of simply trying to help people solve their problems, they bring to their jobs a prosecutorial or a "gotcha" mentality. A large majority of health care workers are just trying to do a good job in a difficult, highly-regulated industry, and when errors occur, 99 times out of a 100, the errors are normally the product of honest mistakes, rather than outright

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fraud. When compliance officers pass judgment on their colleagues, instead of empathizing with them, they contribute to breaking down the lines of communication, which leaves the organization more vulnerable to the risk that compliance issues won't be brought forward and dealt with proactively.

Be visible. Most compliance officers have more work than they can handle and not enough staff to get everything that needs to get done in a normal work week. So, when issues come up, we sometimes try to handle them by peppering people with a volley of e-mails. Avoid the temptation. In order to become part of the fabric of your organization, it is just as important for you to be seen as it is for you to be heard. So whenever possible, pull yourself away from your desk and actually go visit a department where an issue is occurring. Or, instead of automating all of your training, make a habit of performing some of it yourself, such as compliance orientation. When an issue comes up and you truly don't have time to leave the office, instead of sending out an e-mail, pick up the phone. Not only will these techniques give you more information, it will give you an opportunity to connect and develop rapport with your co-workers, which will lead to better communication in the future.

Don't be afraid to stand out from the crowd. In the fast-paced environment of health care, there is often a divide between clinical staff and the administrative leaders of an organization. In fact, you may be surprised to find that some clinical staff members are intimidated by the senior leaders of your organization. Therefore, you must always set a good professional example, but avoid being lumped in with all the other "stuffed shirts", so to speak. For instance, this year during Compliance & Ethics Week, you may want to reach out to your clinical staff. One way you can stand out is by making midnight rounds to the various units, offering staff light refreshments and just letting them know they are appreciated. Do you think this would cause you to stand out in your organization?

View "fires" as opportunities. The phrase "putting out fires" is frequently used with a negative meaning, connoting that one spends so much time reacting to issues that arise spontaneously that it leaves no time to be proactive. However, as long as you maintain an appropriate balance between your proactive activities and your reactive activities, putting out fires is not always a bad thing. Instead, fires can be viewed as great opportunity to become a valued resource to your organization. Furthermore, if you spend so much time engaged proactively and fail to respond to the fires that come, you may eventually be viewed as not being responsive, which can be extremely detrimental to the lines of communication in your organization. By being perceived as someone who is quick to roll up their sleeves and help fix problems, people will be more apt to bring their issues to you in the future.

Offer practical, realistic advice. A common complaint that business leaders have is that compliance officers don't offer practical, realistic advice. Instead, they complain that all they ever say is "No." Undoubtedly, there are times when the law or ethics leave you with no other option than to say no. However, if you are perceived as someone who always says no, it is human nature that people will cease bringing issues to your attention. Therefore, in your practice, try employing the "stop light approach." When the light is red, and law or ethics clearly prohibits something, you must stand firm and tell your leaders what they may not want to hear. Conversely, when the light is green, tell them so, and get out of the way. The tricky part is when the light is yellow, and the law is unclear on a point. In these cases, make an effort to understand the business needs of your organization and offer suggestions for ways to mitigate risk, or alternative ways to accomplish the business objective without creating risk. For each proposal, tell them where it stands on the risk spectrum, but afford them some room to make intelligent business decisions based on the advice that you have given.

Stay on message. Every interaction you have is a potential teaching opportunity. When I was a JAG (Judge Advocate General) officer in the Navy, assigned to a military hospital, a Commanding Officer (CO) I worked for was a master at using every interaction as an opportunity to convey important messages that he wanted his leaders to internalize. These messages concerned his ideas about how he wanted the business to run or contained fundamental truths about how patients should be treated. He had a few basic mantras that he would frequently recite in one-on-one meetings or in presentations to drive home his ideas. It may sound Orwellian, but the uncanny thing about it was that it worked. At times when the CO was not present, his leaders could often be heard repeating these mantras when discussing decisions that affected the business. Although you may not feel comfortable taking this idea to the same extremes, the point is that if you have some simple themes or teaching points regarding compliance and reiterate them in all your interactions with your colleagues, they eventually will internalize them. At the times when you aren't there, while compliance may not always be their first priority, it will at least be considered in the decision-making process.

Develop the confidence of your executive staff. Intuitively, people know how you feel about them. If you view your leaders with distrust, they will surely sense it and will return the favor. Furthermore, in an industry where people casually joke that any misstep along the way may result in them wearing the dreaded orange jumpsuit, executives are, understandably, a little gun-shy. Although too much shouldn't be made of this, it is fair to say that leaders are clearly a little alarmed by the regulatory

scrutiny they are under. As such, your leaders need to trust you as a team member and not see you as a potential whistleblower. Therefore, any time you are given the chance, taken actions designed to reassure your leaders that you are on the same team, trying to support their business goals, and are not actively trying to subvert them. Developing a trusting relationship with you leaders takes time, so be patient.

Don't take yourself so seriously. When it comes to their jobs, the three things that motivate most people are money, time, and working with people they enjoy. When you don't have the first two, sometimes the only thing that gets people out of bed in the morning is the chance to be around people they like and who make them feel good about themselves. Although it is often said that nice guys finish last, if you are someone that people want to be around, you will find that you get invited to more meetings and are asked to contribute to a greater number of decisions in your organization. With that in mind, remember to:

1. **Be positive.** Compliance officers sometimes fall into the trap of always preaching gloom and doom because, from a regulatory perspective, these are frightening times and they think they can scare people into compliance. This behavior is reinforced, because sometimes it actually works. However, if you always use this approach eventually people will not want to hear your dire predictions, they will not want to be around you, and eventually, people will tune you out.
2. **Be human.** Most compliance officers are very concerned with maintaining credibility and an air of authority, and there is often an unrealistic expectation that you should know everything. However, most people are drawn to people who are like them, and they don't expect you to be perfect. In fact, they prefer it if you are not. So, if someone asks for your input and you don't know the answer, don't be afraid to tell them, with complete candor, that you don't have the answer but would be glad to find it. Admitting to your deficiencies is a great way to relate to another person, but also allows them the freedom to showcase their strengths and collaborate in the decision-making process.
3. **Make people laugh.** Not everyone possesses the ability to make people laugh, but if you have this talent, as long as you remember to be professional, you should not be afraid to use your sense of humor as a way to invite people to listen to you. Compliance can be an extremely dry subject for most people. If you can make the talks you give, the meetings you attend, and the e-mails you send more entertaining by allowing your personality to shine through, people will be drawn to you, and in the process, you will become a better teacher and leader.
4. **Smile.** Things are not as bad as they seem. Unfortunately, there is no magic formula that will transform an organization that previously had no positive culture of compliance into one that does, overnight. Clearly, a robust program that effectively implements the Seven Elements goes a very long way, but a culture of compliance is not solely created in corporate structures, processes, or procedures. Instead, a culture of compliance really exists in the attitudes and beliefs of the employees who make up an organization, and it is well within the power of compliance officers to influence these attitudes and beliefs by the way they conduct themselves professionally and the way they deal with people personally. In seemingly small ways, compliance officers, through their own attitudes and beliefs, through their professional behavior, and through the force of their own personalities can have a major role in determining the corporate culture of an organization. ■

1 http://www.sec.gov/news/speech/2007/spch101807lar.htm

Strike Force Targets Medicare Fraud by LA Area Health Care Companies

The U.S. Department of Justice announced in a May 13, 2008 press release that eleven people have been indicted in the second phase of a targeted criminal, civil, and administrative effort against individuals and health care companies that fraudulently bill the Medicare program. For more: *http://www.usdoj.gov/opa/pr/2008/May/08_crm_399.html*

Florida Physician Settles Fraud Allegations

U.S. Attorney for the Southern District of Florida Alexander Acosta announced on May 12, 2008, that the federal government has settled allegations of healthcare fraud against a Broward County doctor, Aleyda Borge, MD, and the operators of a medical clinic for $6.7 million. For more: *http://www.usdoj.gov/usao/fls/PressReleases/080512-01.html*

Greenwich Hospital Settles

Nora Dannehy, Acting United States Attorney for Connecticut, May 12, 2008 announced that Greenwich Hospital entered into a civil settlement agreement with the Government in which it will pay $605,274 to resolve allegations that it violated the False Claims Act. The allegations against Greenwich Hospital involved charges to Medicare for infusion therapy and chemotherapy administration services. For more: *http://www.usdoj.gov/usao/ct/Press2008/20080512.html*

Morris Testifies on Nursing Home Quality Issues

Lewis Morris, Chief Counsel to the Inspector General testified on May 15, 2008 before the U.S. House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, on the topic of Nursing Home Quality Issues. For more: *http://www.oig.hhs.gov/testimony/docs/2008/testimony051508.pdf* ■

Pharmaceutical manufacturers: Making it despite stringent laws and regulations

By Nick Ciancio

Editor's note: Nick Ciancio is Senior Vice President, Marketing and Business Development of Global Compliance. His may be reached by e-mail at nick.ciancio@globalcompliance.com

To the average consumer, pharmaceutical manufacturers are often thought to be raking in vast profits by overcharging those who are most in need of their products. In truth, pharmaceutical manufacturers are only as good as their next big drug, and the estimated cost of new drug development in 2005 dollars was as high as $1.75 billion to $2.5 billion.[1] The huge expenditures associated with bringing a new drug to the market just do not allow for the profits long-associated with the pharmaceutical industry.

With the public awaiting that next miracle drug, stockholders expecting profits, and physicians ultimately deciding which medicines they will prescribe, prescription drug manufacturers are under tremendous pressure to succeed. Unfortunately, drug makers occasionally use questionable tactics to sell their products, and it is the patient and government health care programs, such as Medicare and Medicaid, who will suffer in the long run.

The Officer of Inspector General (OIG) of the U.S. Department of Health and Human Services, who in their "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers" (Guidance) issued in 2002, suggests pharmaceutical manufacturers include seven fundamental elements to ensure a successful compliance and ethics program:

- Implementing written policies and procedures. Pharmaceutical manufacturers should put into practice an effective code of conduct, along with appropriate policies and procedures to communicate, reinforce, and promote a culture of integrity, security, safety, and compliance.
- Designating a compliance officer and compliance committee with authority to report directly to the board of directors and/or the president or CEO. By selecting a senior member of management to serve as the ethics and compliance officer (ECO), organizations are committed to ensuring that the ECO has the ability to bring about change within the organization as necessary and exercise independent judgment. The selected ECO will be responsible for developing, operating, and monitoring the compliance and ethics program.
- Conducting effective training and education. Online and instructor-led training programs will educate employees on expected workplace behaviors in compliance with legislation, regulation, safety, security, and organizational policies and procedures. Education is key in instilling employees with business integrity, which will serve to protect the organization from legal, reputational, and financial harm.
- Developing effective lines of communication. Frequent communication campaigns ensure topics of business integrity, security, and safety receive proper focus and remain top of mind.
- Conducting internal monitoring and auditing. Employee surveys are an excellent indicator of the level of perception of business integrity within in an organization. Formal audits uncover irregularities, inappropriate conduct, or non-compliance with regulations such as the Prescription Drug Marketing Act (PDMA).
- Enforcing standards through well-publicized disciplinary guidelines. A code of conduct sets the ethical tone in the workplace. Pair this with comprehensive communication campaigns to keep employees up-to-date on changes in company rules and regulations, and what behaviors they are expected to exemplify as part of the organization. Further, employees must be aware of the penalties associated with business misconduct.
- Responding properly to detected problems and undertaking corrective action. Allegation and incident reporting vehicles, as well as employee exit interviews, put management in the know as far as what's going on in the organization. Investigating allegations and incidents, confirming their validity, and reporting findings to company officials is not to be taken lightly, because investigation outcomes and resulting actions will be viewed by employees, company officers, and other stakeholders.

The OIG feels that three areas of risks in the pharmaceutical manufacturing industry should be dealt with by documented policies and procedures:

1. Integrity of data used to establish government reimbursement;
2. Kickbacks and other illegal remuneration; and
3. Compliance with laws that regulate drug samples.[2]

Integrity of data used to establish government reimbursement focuses on the necessity of reporting prices in an accurate manner that considers discounting practices and the significance of complying with the Medicaid Rebate Program. Drug companies are responsible for providing complete and accurate data to the government. The OIG stresses this data must reflect price reductions, rebates, up-front payments, coupons, goods in kind, free or reduced price services, grants, other price concessions, or similar benefits. If a discount or price concession is offered on purchases of multiple products, it should be fairly allocated among the products. The average manufacturer price and best price, which are used to calculate the rebates pharmaceutical manufacturers pay to state Medicaid programs, must be accurately reported.[3]

The second area of risk, kickbacks and other illegal remuneration which may stand in violation of the anti-kickback statute, is given the most attention in the Guidance. Addressing pharmaceutical manufacturers' relationships with three specific groups (i.e., purchasers, physicians, and other health care professionals and sales representatives), the Anti-kickback Statute discussed in the Guidance is important to not only pharmaceutical manufacturers, but also to medical device manufacturers, drug and device distributors, group purchasing organizations, and their individual customers. Federal statutes prohibit anyone from bribing another to choose a certain vendor who is funded by the US health care program, but kickbacks can be quite lucrative and difficult to pass up. Some examples of kickbacks include:

- **Free samples.** Pharmaceutical sales representatives provide a physician with complimentary samples of their products. Unethical doctors, in turn, illegally sell these samples to their patients. Physicians also often present patients with free coupons which they may exchange for a sample of the medicine. The transaction is deemed a sale by the company.
- **Speaking engagements.** A physician is engaged by a pharmaceutical company to speak at a conference or seminar and is lucratively paid to do so. Even if the physician fails to speak, he/she still may receive the agreed upon fee.
- **Retreats.** Physicians are often feted with expensive meals and lavish get-a-ways in return for selecting a drug company's medication.
- **Grants.** A pharmaceutical maker may provide doctors with grants for alleged research purposes, when in fact the grants may be payoffs to procure the physicians' business.
- **Drug trials.** To further promote their products, drug makers will pay physicians to conduct clinical trials.
- **Average wholesale price.** Medicare and Medicaid use the national average wholesale price (AWP) when determining reimbursement costs paid to a provider for medication purchases. Drug companies give physicians hugely discounted prices on various medications, thus assuring the physician that there is a profit to be made, because of the difference between the low selling price and the much higher average wholesale price.[4]

Under the False Claims Act, anyone who defrauds the government of revenue can be held responsible. *Qui tam*, a provision of the federal Civil False Claims Act, allows citizens to file lawsuits on the US government's behalf to recover losses due to fraud. This law is an incentive for employees who are aware of companies (or in some cases, individuals) making false claims for monetary reasons, such as kickbacks, to come forward with their evidence. As their reward for providing information, the informant or "whistleblower" shares in any revenue recovered. *Qui tam* lawsuits against the pharmaceutical manufacturing industry have become more abundant in recent years as employees have increased their knowledge of laws and, in turn, are more cognizant of what constitutes misconduct.

The third area of risk in the pharmaceutical manufacturing industry is ensuring compliance with laws regulating drug samples. Drug samples are directly addressed by the Prescription Drug Marketing Act of 1987 (PDMA). Although, drug samples are meant to promote drug sales, it is illegal for doctors to sell samples to patients. Not only is this practice in violation of the PDMA, but it also may implicate the Anti-kickback Statute and may be typified as submitting a false claim to the government.

In August of 1992, the Prescription Drug Amendments were passed, which amended several parts of the PDMA to:

- Ban the sale, purchase, or trade, (or the offer to sell, purchase, or trade) drug samples and drug coupons;
- Restrict re-importation of prescription drugs to the manufacturer of the drug product or for emergency medical care;
- Establish requirements for drug sample distribution and the storage and handling of drug samples;
- Require a wholesale distributor of prescription drugs to be state licensed, and require the Food and Drug Administration (FDA) to establish minimum requirements for state licensing;
- Establish requirements for wholesale distribution of prescription drugs by unauthorized distributors;
- Prohibit, with certain exceptions, the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs that were purchased by hospitals or other health care entities, or donated or supplied at a reduced price to charities; and
- Establish criminal and civil penalties for PDMA violations.

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Pharmaceutical manufacturers: Making it despite stringent laws and regulations

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As organizations continue to educate employees and implement reporting vehicles and channels, the ease and anonymity of reporting misconduct and the heightened sense of obligation to report have become such that any employee has the capability to blow that proverbial whistle. In an effort to ensure compliance in the pharmaceutical manufacturing industry, the OIG requires that a compliance officer or a member of senior management, who becomes aware of an act of misconduct, has an ethical and legal obligation to report the incident to authorities immediately or within six months, depending upon the nature of the misconduct.

Pharmaceutical manufacturing companies who fail to adhere to the rules and regulations set forth for their industry are certain to face serious repercussions. Not only obvious legal consequences, but a long-reaching reputational impact can take many years to repair. ■

1 Pradeep Suresh, Prabir K. Basu, and Venkat Venkatasubramanian: Impact of Improving Pharmaceutical Product Development and Manufacturing, 2005. Available at http://www.purdue.edu/dp/ptec/aicheV5.pdf
2 McDermott, Will and Emery; Ankur, J. Goel; Gordon, Eric B; et al: Summary of Draft OIG Compliance Guidance for Pharmaceutical Manufacturers, October 2002. Available at http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/16d7a2dd-0fa9-4819-b237-b23f8fcba7bb.cfm
3 Homchick, Robert; Rauzi, Edwin; Olsen, Marissa: OIG Releases Model Compliance Plan Guidance for the Pharmaceutical Manufacturing Industry. David Wright Tremaine LLP, Practice Law Group Bulletin, October 2002. Available at http://www.dwt.com/practc/healthcr/bulletins/10-02_OIGComp.htm
4 Clarislaw: Qui Tam Lawsuits & The Pharmaceutical Industry. Available at http://www.injuryboard.com/topic/qui-tam-lawsuits.aspx

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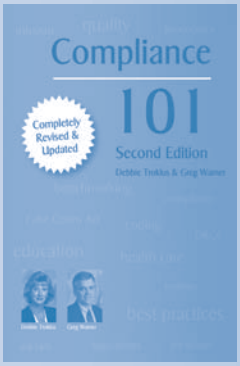

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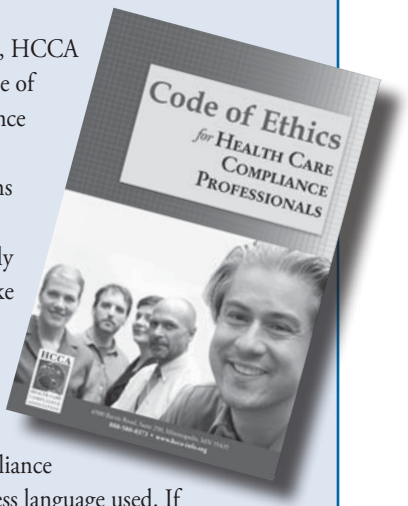

In response to our global market, HCCA is preparing to translate our Code of Ethics for Health Care Compliance Professionals. We are looking for members to verify the translations in German, French, or Italian. HCCA will provide professionally translated copy, but we would like compliance professionals to read the translation and verify that the appropriate words are used. Volunteers must be familiar with the terms used in the compliance industry and fluent in the business language used. If you are willing to help with this project, please let us know which language you would like to review by contacting Patricia Mees at patricia.mees@hcca-info.org.

Danke Schoen!
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Moving beyond the basics: Research billing operations and the issues of compliance

By Beau S. Gostomsky, RN, BSN, MBA

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Many types of health care organizations are struggling with the multi-faceted complexities of compliance issues that surround research billing and the overall general issues of finances related to the conduct of research. A growing collection of well-written, well-researched information about the regulations applies specifically to research billing. This information points organizations in the right direction to start addressing the actual compliance issues that govern the conduct of research billing. But what comes after a research enterprise moves toward developing operations related to billing practices?

Moving from the theoretical into the practical operations of a new process is a daunting prospect for any organization. Often, as in the case of research billing and accurate billing outcomes, once the goal is envisioned, taking those next steps to implementing process change can be overwhelming. What can be more difficult is the varied and unique management and organizational structures of the health care groups which all have different needs, resources, and ideas for achieving a sound and viable research billing operation.

No quick fix or one-size-fits-all solution works for every organization, and it takes more than just the effort of one or two concerned people to be able to implement and maintain the billing operation over the long-term. Like any complex machine, the research billing process involves the interaction of many moving parts, from the front-line research teams who conduct the actual research, to the behind-the-scenes patient registration, patient financial services, organizational financial operations, and multiple service providers. Overseeing the entire process needs a competent, knowledgeable team of management decision makers who can understand and adapt to internal and external changes that affect the research billing operation. Organizations with all types of research enterprises have accomplished the formation and implementation of research billing operations and, in the process, have come to demonstrate to themselves, and to other healthcare systems struggling with the same issues, that the goal of reaching a compliant process can be achieved and run effectively.

This article endeavors to move past the basic aspects of research billing, namely the basic Centers for Medicare and Medicaid Services (CMS) Clinical Trials Policy and the tools, such as a Medicare coverage analysis used to create the foundational information for a research program, into more advanced topics of implementing the process of research billing for various types of research enterprises. The evolution of any research billing program is the ability to implement an operation that takes this basic information and puts it into play across the organization, regardless of size or organization structure. Varying levels of an organization's hierarchy can add to the complexity and difficulty of applying any one research billing approach, but some fundamentals remain consistent for every group:

- Who is managing the work,
- Who is doing the work, and
- Who is assessing the critical points in the operation to assure that the process is following the regulations and processes adopted by the research organization.

By breaking any organization's research billing operation into these three essential parts, each group can then build novel and individual approaches to develop and implement a research billing process that is consistent with existing regulations and uses the available resources wisely.

Managing the research billing operation.

A difficult first step to the operation of research billing is to identify the issues and bring the leadership of an organization into an understanding of the nature and risk implicit in research billing. Perhaps the issue of research billing compliance came from the organization's management or maybe it came from a compliance officer who is in touch with current compliance issues that affect health-care systems. With health care groups ranging from private physician offices that conduct small industry-sponsored phased studies to large academic medical systems with multiple affiliates, schools of medicine, and hospitals, the organizational structures range from simple to complex.

Who are the decision-makers who can gauge the risk-tolerance for the organization and be able to form the foundation research billing policies that direct the rest of the organization's operations? Oversight of the entire research billing operation is a critical

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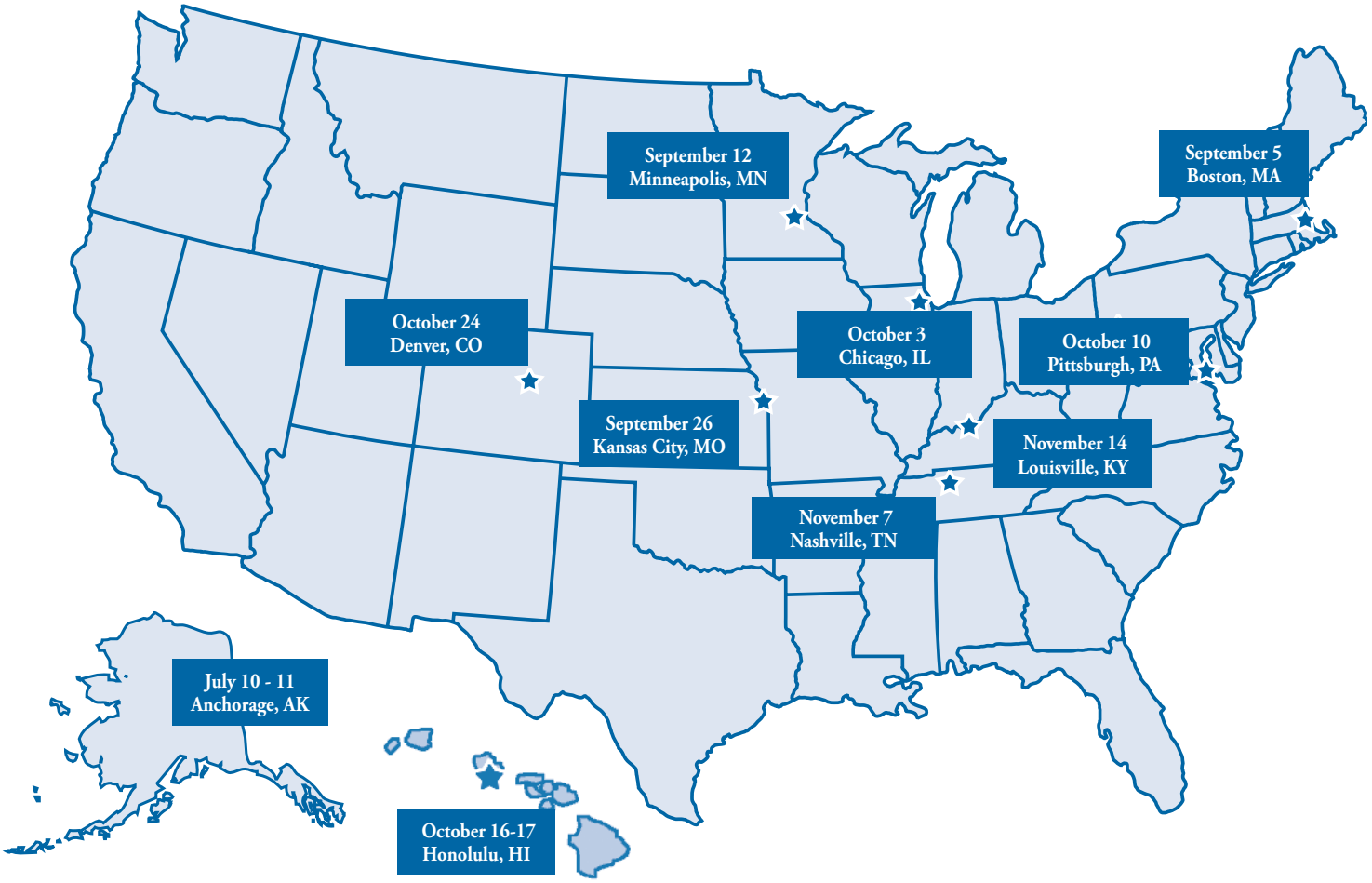

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component to an effective operation. This oversight can be a single person, but is more likely an assembled group who have varied and distinct areas of expertise which all impact the billing process. Decision-making responsibilities reside here. Some larger organizations use an executive governance body that has several working groups operating under it's guidance to manage the various aspects of the research process. Other groups combine all functions into one body with a more comprehensive charge. In almost every configuration, the presence of legal counsel is essential to provide ongoing perspective for any decisions made based on government regulations. Every organization strives for full compliance in every area, but the reality of limited resources, technology, and existing systems make prioritizing essential. Identifying risk assessment is a critical factor when making decisions about a research program.

Looking at those research organizations who have successfully implemented a research billing operation finds a management structure that allows for oversight of the personnel and processes to create an environment where decision-making involves legal, financial, compliance, and administration operations. Different options for an organization's management can depend on the size of the research entity. A smaller work-group of only a few people, who are well-versed in the issues essential to a viable and compliant program, can perform as effectively and efficiently as larger oversight management groups at larger research organizations. It is essential that, regardless of the size, management has a clear understanding of the issues and the operation, understands and places well-qualified personnel at critical touch points throughout the research enterprise and organization, and has a mechanism for sharing essential information. It is demonstrated repeatedly at organizations all over the country that a management team that is distant, uninvolved, or uninterested when charged with implementing and operating a research billing program has an at-risk program in need of attention. Those involved with the hands-on activities of the research process need leadership that understands the frustrations of a complex and challenging regulatory environment and can advocate for possible changes to the current billing and reimbursement systems in place to accommodate new compliance requirements across the research enterprise.

The process

Decisions of where and how to implement the research billing process will be unique to the structure of the organization. For smaller research enterprises, more of the regulatory and administrative tasks could fall to the actual principal investigator and coordinator. Many successful research billing operations rely heavily on the diligence of a knowledgeable research team to accurately assess the reimbursement nature of the projects, actively track not only the clinical parts of the research protocol, but to track budget milestones, invoice sponsors, and pay hospital services.

Some operations require research teams to review actual subject bills prior to being released for reimbursement by third-party payers. This can be an effective strategy. Using existing personnel who have the most practical research experience can also challenge these groups to develop new skills and require a knowledge base they may not be familiar or comfortable with. Tacking on research billing responsibilities to investigators and coordinators without well-planned, well-executed training and education and without explicit expectations of their role in the process can create significant risk to the operation. Care should be taken to evaluate the level of experience of the research team members and to take into consideration that their knowledge levels may vary widely, depending on their backgrounds and years of experience. A minimum understanding of the regulations surrounding billing compliance, both external and internal, needs to be identified and worked into the ongoing research education program provided by the operation. If mandatory research trainings are not available or not practical for smaller operations internally, relevant trainings are available externally through professional organizations involved in research issues.

Initial research billing steps focus on the existing regulations related to the foundation of a compliance program, as a way to understand requirements before steps can be taken to implement the operation around those regulations. CMS's Clinical Trials Policy gives guidance on the concepts of coverage reimbursement for beneficiaries but does not provide instructions for turning that guidance into a practical operation. Institutions in the forefront of the research billing process have devised unique tools and systems to create essential information related to billing for subjects enrolled in research projects and have implemented institution-wide systems for relaying that information to impacted stake-holders. These tools and systems allow them to accurately bill for research services, whether billing external payers, research sponsors, or internal research grants.

Reimbursement analyses of research projects are created and based on the simple idea of identifying the items and services that make up the research. The items are identified as related to the research or related to routine care and what entity is assumed to pay for each. CMS has outlined specific criteria for coverage of research projects for enrolled beneficiaries which adds a second, more complex

layer to the analysis of a research project. Importantly, a knowledgeable person or group must be identified who can apply these regulations and criteria to the project, make an assessment for coverage, and then relay this information ultimately to the organization's patient billing system. The charges are segregated and sent out to payers versus those that must be collected from proposed funding sources such as grants and sponsor budgets.

Some organizations have success moving to a centralized operations model for research billing. A central office is either created, or responsibilities related to coverage review, process changes, and reconciliation on billing claims are redefined for an existing office. Centralizing these operations minimizes the difficulty in keeping a large, diverse research staff continually current on the most recent regulations and in overseeing vast amounts of information moving into and out of the organization. A central office can act not only as a control valve for the flow and approval of information, it can be an excellent resource for training and education, reconciliations, and a bridge to the various groups that make up the whole of the billing operation. Some organizations use these central offices to evaluate and perform coverage analyses, negotiate budgets, review billed claims, and perform spot checks at regular intervals across the enterprise.

The success of this model depends on the diligence and expertise of the office personnel and their ability to understand and communicate with all aspects of the operation. Being able to understand the essentials and specifics of a research project and then translate that information into chargeable data that can be evaluated and understood by non-clinical, financial personnel is a powerful part of any research operation. Additionally, a central office becomes the knowledge center for the changing nature of regulations that affect research billing practices and a resource for many at the organization. Evaluating the size and complexity of the research operation is essential to understanding whether this is a viable model for the enterprise. A smaller physician's office or community hospital with a smaller research portfolio might encompass all these roles into one or two people who might also be coordinating and conducting the research. Larger operations might need a larger office and personnel dedicated specifically to the research billing operations.

The volume of research and the number of enrolled research subjects also can play a significant role in the operation. Understanding the work involved in evaluating research data and financial information can be difficult, especially if the entire process is based on hands-on review of actual claims. Knowing the daily volume one person can handle effectively is essential when looking at the total research subject volume at any given time. Withholding claims for review could delay claim payment and potentially put the reimbursement at risk if it falls outside the contracted time frame for payment, so diligence, not only in the timely review but also in reconciliation, needs to be addressed.

While technology advances and new tools for identifying, tracking, and managing the clinical and financial aspects of research are being introduced all the time, most operations revolve around a manual process and key personnel. The human element in the process is essential, but it does create the possibility of human error, which must be taken into account. A chain is only as strong as its weakest link, and this is demonstrated throughout the research billing operations.

The current state of technology is as varied as the research operations looking for that single, perfect solution. Vendor products are available that have a range of essential functions related to research billing, from basic research subject tracking to full financial functionality that allows for identifying charges and directing them to the appropriate payers, managing accounts receivable, and generating invoices to the appropriate sponsors. It is an easy trap, however, for an organization to think that technology alone will solve research billing issues. If the approach towards technology is that of a useful tool to assist a viable and compliant system, the technology can help create efficiencies in the operation while increasing compliance by reducing the human errors inherent in a manual system. The big leap for technology will be billing systems which allow for research subjects and costs to be identified and appropriately delegated, either with integration from other systems or with internal functionality specifically designed for research billing purposes. Home-grown integrated systems are a popular avenue for some organizations, and some research enterprises have assessed the current tools on the market and found a better return on investment by building and maintaining their own systems. As with any technology, the short- and long-term upkeep and management of technology needs to be carefully evaluated.

Assessing the process

Who is assessing the operation from the beginning to the end, reviewing research subject billing, and tracking the information through the process to identify weaknesses and potential problems? This can often fall to both internal and external groups. Internal review of the processes should be ongoing at all times. Setting up a scheduled review of billing, starting from the initial coverage review through the actual billing and reimbursement from payers, is a viable and active approach to a compliant system. Identifying high-risk,

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complex research trials that can strain and test the system is critical to the understanding of what is working and what needs to be adjusted and evolved. Many oversight work groups have initiated these internal reviews and receive scheduled reports on the volume of the research being conducted, current financials, and a summary of any challenges being faced by the system. The schedule of these reviews might be more frequent at the beginning of a new operation, when problems and corrections are necessary. Being able to continually evaluate the need for these reviews is a good indication of the maturity of a system.

External audits become essential to prove the effectiveness of the system and minimize the bias that might be inherent in any internal review. External auditing with a clear and defined scope related to the research billing process can provide an organization with the information it needs to be able to continue to evolve its system and correct issues at key touch points in the process.

With so much complexity in the research billing process, organizations of all sizes continue to struggle with the overwhelming detail inherent in the compliance operations. Smaller operations might rely more on their front-line staff for the majority of the work and tasks which might fall out of their expertise and training. Larger organizations might have so many levels of hierarchy that decision making can hamper the daily activities necessary as part of the process. Thorough understanding of the process is essential in oversight. Ongoing training and staff education about who performs the various roles related to the billing process should be carefully designed and implemented. Relying and acting on both internal and external reviews becomes an essential component for monitoring the research billing enterprise and evolving it into a more efficient and more compliant operation.

Operating a compliant research billing process is a difficult but achievable goal. Organizations across the country, composed of knowledgeable personnel and supported by insightful and action-minded management, are successfully navigating research billing operations. They are developing novel approaches to conduct their research enterprises, leveraging available technologies, and building solutions that fulfill the scope of their research billing policies. Compliance with the regulations of research billing is achievable by any research enterprise, regardless of size or complexity, but requires the knowledge and fortitude to take essential first steps and understand the key steps required for a robust research billing operation. ■

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feature focus

OIG's Open Letter on the Self-Disclosure Protocol

By Cheryl Wagonhurst, CCEP and Richard K. Rifenbark

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On April 15, 2008, the Office of Inspector General (OIG) of the US Department of Health and Human Services issued "An Open Letter to Health Care Providers" (Open Letter), which details certain "refinements and clarifications" to its Self-Disclosure Protocol (SDP).[1] The SDP, which the OIG originally unveiled in 1998, is a program in which providers who uncover potentially fraudulent activities in their organizations may disclose such activities to the OIG. The potential benefits of such disclosure generally have been a reduction in damages, the avoidance of a government investigation, and a greater likelihood that the provider will not be excluded from Federal health care programs for its misconduct. In the Open Letter, the OIG creates another significant benefit to disclosure—the potential avoidance of a Corporate Integrity Agreement (CIA) or Certification of Compliance Agreement (CCA).

Refinements and clarifications to the SDP

Although providers do take advantage of the SDP (according to the OIG, providers have disclosed approximately $120 million under the SDP) the OIG determined that improvements could be made to the SDP to facilitate increased disclosures by providers. These improvements are designed to make the SDP process more efficient and beneficial to providers.

The Open Letter aims to increase the efficiency of the SDP by requiring providers to make a more complete initial submission, including commitments regarding when the provider's internal investigation and damages estimate will be completed (to the extent not completed at the time of the initial disclosure). The following information must now be provided: (1) a complete description of the conduct being disclosed; (2) a description of the provider's internal investigation or a commitment regarding when it will be completed; (3) an estimate of the damages to the federal health care programs and the methodology used to calculate that figure or a commitment of when the provider will complete such estimate; and (4) a statement of the laws potentially violated by the conduct. The information required in the initial disclosure is in addition to the "basic information" currently required to be disclosed under the SDP, which includes certain information about the provider (e.g., name, address, provider and tax identification numbers, etc.), whether the provider is currently under investigation by a government agency or contractor, a full description of the nature of the matter being disclosed, the type of health care provider implicated and any provider billing numbers associated with the matter being disclosed, the reasons why the provider believes that a violation of law may have occurred, and a certification regarding the truthfulness of the submission.[2]

To ensure that providers conduct a timely internal investigation of the potential misconduct, the Open Letter states that the provider must be able to complete its investigation and damages assessment within three months of acceptance into the SDP. Under the SDP, providers are expected to submit a detailed report to the OIG demonstrating that the potentially fraudulent conduct has been thoroughly reviewed, including a discussion of the nature and extent of the improper or illegal practice (e.g., the potential causes of the incident or practice, the period in which the incident or practice occurred, and the corporate officials and departments involved in the matter) and the organization's discovery and response to the matter (e.g., how the incident or practice was identified, the steps used by the entity to investigate the

matter, and any disciplinary action taken against corporate officials, employees, and agents as a result of the investigation). The provider is also expected to conduct an internal financial review of the problematic incident or practice in order to calculate its impact on federal health care programs. Because all of this must be completed within three months of the initial disclosure, providers should have completed their internal investigations and financial reviews at the time of the disclosure or be prepared to dedicate sufficient resources to these efforts to ensure that they are completed within three months of the disclosure.

The OIG has streamlined its internal process for reviewing and resolving the SDP submissions, which presumably means that providers who comply with the Open Letter should expect to have their disclosures resolved more quickly than in the past. This should make the SDP more appealing to providers who are looking for a quick resolution to their disclosure.

The Open Letter also adds a potential benefit to a self-disclosure: the avoidance of a CIA or CCA. In order to receive this benefit, providers must make a complete and informative disclosure, quickly respond to OIG requests for further information, and conduct an accurate audit. The OIG interprets compliance with the foregoing as evidence that the provider has implemented effective compliance measures, thus rendering a CIA or CCA unnecessary.

Although the OIG does not generally impose CIAs on providers who make self-disclosures,[3] the Open Letter provides an additional assurance to providers that good-faith disclosures will not result in CIAs. CIAs typically last five years and require providers to implement a comprehensive compliance program, submit various reports to the OIG, retain (at significant expense to the organization) an independent review organization to audit and review the provider's claims, and agree to certain stipulated penalties for violations of the CIA. CCAs are less onerous, but still require providers to certify that they will operate their compliance programs for a period of years and provide for stipulated penalties. Knowing that disclosures will generally not result in CIAs or CCAs should make the SDP a more appealing option for providers and may encourage more internal auditing and monitoring as a result.

Certain practical considerations

The Open Letter's revisions and clarifications to the SDP make it a more attractive mechanism for disclosing potential wrongdoings; however, potential issues regarding the SDP still persist. The Open Letter emphasizes that the OIG expects "full cooperation" from providers and that providers must "timely respond to OIG's request for additional information." One practical issue is whether the OIG will require the provider to waive the attorney-client privilege in connection with the SDP. In the original 1998 SDP publication,[4] the OIG observed that it "must have access to all audit work papers and other supporting documents without the assertion of privileges or limitations on the information produced." However, the OIG also stated that "[i]n the normal course of verification, the OIG will not request production of written communications subject to the attorney-client privilege." It is unclear whether there is an expectation under the Open Letter that providers will be more willing to waive the attorney-client privilege. In any event, compliance officers and legal counsel who conduct internal investigations should be mindful that portions of the investigation may ultimately be provided to the OIG if the provider makes a self-disclosure. The 1998 SDP publication noted that the OIG will discuss with the provider's counsel ways to obtain access to information without the need for the provider to waive the attorney-client privilege, and counsel for the provider may want to consider contacting the OIG in this regard.[5]

The Open Letter also emphasizes that only potentially fraudulent conduct involving federal health care programs should be disclosed through the SDP. Billing errors and overpayments should be submitted directly to the claims processing entity. Sometimes the line between simple billing mistakes and potential fraud is a blurry one, particularly when one considers that the Federal False Claims Act contains a "reckless disregard" standard.[6] As a result, providers should consider consulting their compliance departments and/or inside or outside legal counsel when potential billing issues arise, to help evaluate whether fraud could potentially be involved in the billing error. Matters that are considered by the provider to be simple billing mistakes and disclosed to the claims processing entity as such may ultimately be referred to the OIG (outside of the SDP process) by the claims-processing entity if it believes that potential misconduct occurred.

In connection with a disclosure, providers should be aware that a disclosure regarding one particular aspect of an arrangement or a transaction may lead to the OIG investigating other issues that involve the same arrangement or transaction. For example, a provider that discloses a below-fair-market-value physician lease arrangement should ensure, as part of its internal investigation of the arrangement, that other aspects of the arrangement and other arrangements with the physician comply with applicable law. The OIG will not necessarily limit its review to the specific issue disclosed by the provider, which the OIG acknowledged in the 1998 SDP publication: "Matters uncovered during the verification process, which are outside of the scope

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of the matter disclosed to the OIG, may be treated as new matters outside of the Provider Self-Disclosure Protocol."[7]

Finally, it is important for providers to remember that disclosures to the OIG under the SDP do not prevent the OIG from referring the matter to the Department of Justice or other enforcement bodies for additional investigation and potential penalties and/or prosecution. However, a provider's use of the SDP and cooperation with the OIG would potentially be a mitigating factor in the OIG's recommendations to other enforcement bodies.

Conclusion

A well-designed compliance program may, from time to time, uncover compliance problems that potentially require disclosure to the government. When potentially fraudulent conduct is identified, compliance officers should consult with inside or outside counsel to determine whether the organization should take advantage of the SDP. Providers that make a good faith effort to conduct a thorough internal investigation of the potentially fraudulent conduct and quantify the financial impact to federal health care programs will likely have their disclosures resolved more quickly by the OIG and without the imposition of a CIA or CCA. ■

1 The April 15, 2008 Open Letter may be found on the OIG's website at http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf. Inspector General Daniel R. Levinson announced the issuance of the Open Letter at the HCCA conference in New Orleans on April 15, 2008.
2 63 Fed. Reg. 58,399, 58,401 (Oct. 30, 1998).
3 An "Open Letter to Health Care Providers" issued by the OIG on April 24, 2006 indicated that CIAs had only been required in 27 of 136 self-disclosures that were resolved with monetary settlements as of that date. Department of Health & Human Services, Office of Inspector General, An Open Letter to Health Care Providers (April 24, 2006).
4 63 Fed. Reg. 58,399 (Oct. 30, 1998).
5 63 Fed. Reg. 58,399, 58,403 (Oct. 30, 1998).
6 31 U.S.C. §§ 3729-3733.
7 63 Fed. Reg. 58,399, 58,403 (Oct. 30, 1998).

Fair market value support required: Physicians in administrative roles

By Jen Johnson, CFA

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Placing physicians in paid positions for administrative roles requires great care, because failure to set compensation at fair market value (FMV) could result in criminal and/or civil penalties based on health care fraud and abuse laws. If an agreement between a physician and health care organization is audited by federal or state health care authorities, the analytical process and documentation to justify that the payment is FMV will be essential in defending the compensation level. This article discusses the growth of these positions and what organizations should consider when determining how to ensure that an arrangement meets the FMV requirements.

Growth in administrative roles

The American College of Physician Executives reports membership is up 12% for the first quarter of 2008, over 2007 figures. In addition, they have seen management/leadership training courses grow 5% to 7% over the past two years. The growth of administrative roles for physicians has been spurred by a demand from both physicians and health care facilities. The newest generation of physicians is not as tolerable of the hours physicians kept in the past, and many are looking to administrative roles to achieve a better work-life balance.

In addition, new publicity surrounding safety and quality issues has made health care organizations more accountable for quality care. As transparency becomes increasingly important, administrative functions required to implement and monitor quality metrics will increase. The Joint Commission has also demonstrated its recognition of this need by recently publishing 2009 requirements related to medical staff leadership. Because quality initiatives are typically managed by physician leaders, the transparency trend should continue to feed the growth of physicians in administrative roles.

Determining FMV

The challenge of determining FMV for these positions is that there is little market data and guidance for physicians in administrative roles. This topic was specifically addressed in the most recent Stark II, Phase III update. When Phase III was released, it eliminated a safe harbor that determined a FMV hourly rate for physicians in either clinical or administrative roles. Compliance officers, attorneys, and analysts were forced to rethink their FMV approach. Phase III did provide some very vague guidance to determining administrative compensation. The language included in the new regulations stated:

> A Fair Market Value hourly rate may be used to compensate physicians for both administrative and clinical work, provided that the rate paid for clinical work is

Fair Market Value for the clinical work performed and the rate paid for administrative work is Fair Market Value for the administrative work performed. We note that the Fair Market Value of administrative services may differ from the Fair Market Value of clinical services. (Stark II, Phase III, FR Vol. 72, No. 171)

Based on these latest guidelines, health care organizations must carefully examine the list of services the physician will provide, preferably by reviewing the subject agreement, to best determine FMV compensation for administrative roles. Using this information allows health care organizations to make a supportable decision regarding what market data on which to base compensation by asking two questions:

1. Is a physician required for this service?
2. Is the physician's specialty required for this service?

If the answer to both is yes, it makes sense to turn to market data for clinical compensation, such as nationally recognized surveys for physician compensation, because the physician would be using his or her expertise in performing these administrative services. Regulatory guidance also suggests that health care organizations should maintain time records, due to the part-time nature of these agreements. Allowable payments are often not enough to keep health care organizations in the clear of possible legal scrutiny; these organizations must also prove that the payments are supportable through documentation.

If the answer is no, look to other market salary data for titles that better reflect the services the physician will provide, such as chief medical officer or quality assurance director. In some of the more unique arrangements, such as co-management agreements whereby physicians and non-physicians team up to manage a facility or department, health care organizations can base the FMV on the cost approach, which requires the valuator to build-up the cost of the service and include an appropriate mark-up.

Documentation, documentation, documentation

A key factor in being compliant with health care regulations is to document the methodologies used in determining FMV. A review of past OIG audit reports determined that it is important to document anything and everything reported to a federal program. In many instances, the OIG found that certain costs reported on Medicare cost reports are allowable, but not supportable. This indicates that even if the intentions and reasons for payments reported are sound, if there is improper documentation, the costs may not be supportable, which may disqualify certain cost items. Similar conclusions have been found by review of medical director arrangements, whereby the medical director performed allowable duties, but without time records; these services and associated hours were considered unsupportable by the OIG.

Be careful before proceeding. If health care organizations are not careful in determining FMV compensation, they could draw the scrutiny of federal and state regulatory authorities, which may start to pay more attention to these arrangements because of their growth and FMV challenges. Recent OIG enforcement activity has included hefty financial verdicts and imprisonment for both hospital CEOs and physicians. The critical components to compliance include understanding the services provided, documenting the hours spent on the services, and following the regulations surrounding health care valuations. ■

This purpose of this article is to provide insight to valuation guidelines related to FMV. It should not be construed as legal advice.

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Hospitals hit hard in recent government enforcement actions

By Gary W. Herschman and Robert J. Senska III

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Recently, the OIG and other federal law enforcement agencies brought a host of enforcement actions against health care providers for alleged violations of the Stark law, the Anti-kickback Statute (AKS), and the False Claims Act (FCA).

This flurry of enforcement activity provides a sobering reminder to all hospitals and physicians of the need to structure their arrangements to comply with these laws and of the consequences of non-compliance.

Set forth below is a brief summary of some recent enforcement actions and settlements, as well as certain practical recommendations to keep in mind in order to protect your hospital against similar enforcement actions.

Hospital pays $1.9 million to settle Stark law violations

A Texas hospital agreed to pay approximately $1.9 million to settle allegations that it violated the Stark law and the FCA. Among other things, the government alleged that the hospital received federal Medicare and Medicaid reimbursement for orthopedic items and services for patients that were referred to the hospital by a physician group that utilized space owned by the hospital without paying rent.

Generally, the Stark law permits physicians to rent office space from hospitals as long as there is a written lease signed by the parties and the rental payment is fair market value. Notably, the settlement resulted from the hospital's self-disclosure to the OIG following its discovery of the improper lease arrangement during an internal compliance audit.

HealthSouth and physicians settle with OIG for $14.9 million

HealthSouth Corp., the nation's largest provider of inpatient rehabilitation services, and two affiliated physicians settled allegations that they violated the Stark law, the AKS and the FCA.

The government claimed that HealthSouth and the physicians had entered into improper "sweetheart deals" pursuant to which the physicians were illegally compensated to induce patient referrals for HealthSouth services. Specifically, the government alleged that the doctors were receiving payments above fair market value pursuant to "sham" medical director agreements with HealthSouth, and as such, it was improper for the physicians to refer patients to HealthSouth.

In bringing the action, the government commented that it will not tolerate hidden financial agreements between health care providers which may influence where patients receive treatment and what treatment is received. In addition to the hefty fines, HealthSouth was required to amend its Corporate Integrity Agreement.

Federal court awards $4.7 million for Stark law violation

A federal court in Louisiana recently ruled that a home health agency and its owner violated the Stark law and the FCA and ordered them to pay $4.7 million in damages and fines.

The government presented evidence that the home health agency and its owner billed Medicare for services furnished pursuant to prohibited physician referral arrangements. The court concluded that the defendants entered into sham "advisory services agreements" with several physicians under which the physicians were paid by the defendants but did not perform any actual services, other than referring patients to the home health agency.

The home health agency and its owner created fake physician service logs, listing services which the physicians never actually performed or had already provided as part of caring for their patients. These were not, in fact, "advisory services" for the agency. The court also found that the defendants had submitted false cost certifications to Medicare for unperformed physician services.

Practical guidance

In light of these developments, hospitals may wish to consider the following recommendations in structuring and monitoring their arrangements with physicians:

- **Document all arrangements with physicians.** All arrangements involving payments by hospitals to physicians for professional services, medical director duties, or other services, or pursuant to which hospitals provide services, space, equipment or anything of value to physicians, should be memorialized in a written agreement which satisfies the requirements of a Stark law exception.
- **Document fair market value.** It is exceedingly important that all of the terms of the arrangement are commercially reasonable and that all payments are fair market value. In this regard, it is advisable to obtain a writ-

ten analysis from an independent health care consultant which verifies that the payments are fair market value for the items/services provided. If this is not feasible, the hospital should maintain a record of all relevant information (i.e., regional market data and figures from comparable arrangements) upon which it relied to determine the payments.

- **Monitor and review all physician agreements.** Hospitals should periodically review all of their physician agreements (preferably on an annual basis) to ensure that they conform with current Stark regulations. Hospitals should also confirm that physicians are properly performing all required services. If physicians are not performing their duties under the contracts, the payments may not be fair market value.

One way to monitor performance of services under contracts is to require each physician to complete and submit bona fide service logs that document all of the services performed by the physician under the agreement during a specified time period (e.g., each month). Hospital managers should carefully review and verify the logs.

Although ongoing review by a hospital of its various physician agreements can be time consuming, given the health care regulatory environment, it is a critical prophylactic measure.

Such reviews may not only be an opportunity to ensure compliance with the Stark law and the AKS, but may also be an opportunity to ensure that the hospital is meeting The Joint Commission's new leadership standard, which requires hospitals to closely monitor patient care, treatment, and services provided through contracts. ■

The views and opinions expressed in this article are those of the authors and do not necessarily reflect those of Sills Cummis & Gross PC.

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New York State Medicaid Work Plan: A sign of the times?

By Heather O'Shea, Esq. and Keri Tonn, Esq.

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On April 18, 2008, New York's Office of the Medicaid Inspector General (OMIG) issued a detailed Work Plan (the Work Plan) specific to the state's Medicaid program.[1] New York is the first state to publish an individual state Work Plan of such a detailed and comprehensive nature. Given the obligations imposed by the Deficit Reduction Act of 2005, it is likely that many states will take notice, possibly even follow New York's lead, and perhaps even use the Work Plan as a model. Consequently, compliance officers, regardless of the state in which they are located, should review the Work Plan and consider incorporating applicable focus areas into their organization's audit plans and risk assessments.

Overview of the New York Work Plan

Through its Work Plan, OMIG has provided a detailed description, often with the supporting authority, of the specific areas of review of the Medicaid program for state fiscal year 2008-2009 (April through March). The Work Plan is ambitious, wide-ranging, and will require technical expertise to execute. The state apparently recognizes this fact and has earmarked funds for up to 750 staff and has set aside additional resources for investments in technology. Additionally, the New York Medicaid Inspector General has announced his intentions to collaborate with other state agencies to carry out the work; nine agencies (including the Attorney General's Medicaid Fraud Control Unit, and 13 counties that are participating in OMIG demonstration projects) are specifically identified in the Work Plan. This type of interagency collaboration has traditionally been more common on the federal level.

There are similarities between the New York Work Plan and that of the Department of Health and Human Services, OIG annual Work Plan, including the general format and certain focus areas, but providers and suppliers should know that this is not the "same old, same old." The New York Work Plan identifies a number of new target areas that OMIG intends to scrutinize. Perhaps the most significant new focus area is managed care. The Work Plan lists more than 20 specific areas related to Medicaid managed care that OMIG intends to review. Some of the focus areas include payments for deceased enrollees, payments for enrollees who moved out of state, stop loss payments, and improper crossover/duplicate payments. OMIG also intends to review data matches where there is no encounter data for newborns, but where Medicaid has paid monthly capitation payments. This review will focus on identifying incorrect payments and addressing quality-of-care issues.

Some other areas in the Work Plan focus on laboratory services, physicians' prescription ordering practices, and pharmacy providers. OMIG will review Medicaid payments for some independent laboratories. OMIG plans to review a sample of claims to determine whether the tests were ordered, that the results were available, and that the laboratory billed in accordance with applicable regulations. Specifically, OMIG will review the claims to ensure that there was no inappropriate bundling.

OMIG will also audit physicians who have ordered high volumes of controlled substances that are covered by Medicaid. In connection with this review, OMIG intends to conduct a chart review to determine if documentation supports medical necessity.

The pharmacy review will focus on claims information and comparing that documentation to the actual prescriptions. In addition, OMIG will conduct a review of selected out-of-state pharmacies that bill New York State Medicaid to determine whether the pharmacies are properly dispensing and delivering medications. In connection with the pharmacy reviews, OMIG also intends to verify the licenses of all ordering providers in an effort to detect fraudulent practices, such as stolen provider ID numbers, unlicensed physicians, and excluded providers who prescribe drugs.

The New York Work Plan also devotes attention to the usual targets. Five audit areas are applicable to hospitals. OMIG will:

- Perform reviews designed to detect providers that are upcoding.
- Examine ambulatory surgical services to determine whether the services were provided in the appropriate setting. One focus of this review is to determine whether the service

was provided in an ambulatory surgery setting because of patient safety reasons and the administration of anesthesia.

- Review patient billing records to determine whether any claims were improperly submitted to medical assistance programs that should have been submitted to another payor, because Medicaid is the payor of last resort.
- Look at Disproportionate Share Hospital (DSH) payments. OMIG will review trends in hospitals' claims for DSH payments, and it will conduct a review of records relating to uncompensated care at selected hospitals to determine whether the DSH payments were appropriately claimed and paid.
- Review hospital-based physician compensation to detect duplicate payments for direct patient care services and administrative services.

Implications for the future

The Deficit Reduction Act of 2005 made it official; the New York Work Plan makes it clear: Medicaid enforcement is a top priority for federal and state regulators. This is understandable, given that the Medicaid program is the largest health insurance program in the United States and provides coverage to approximately 44 million people in low-income families and 14 million elderly and disabled people.[2]

What does this mean for providers and suppliers? The obvious answer is that there will be a heightened level of focus on providers and suppliers through potentially duplicative, but most certainly, additional audits. One way that providers and suppliers will see this play out is with the Payment Error Rate Measure (PERM) program, a federal initiative to determine national payment error rates for the Medicaid program. As part of the PERM program, the Centers for Medicare and Medicaid Services uses contractors to review medical records and to perform statistical calculations of Medicaid, the State Children's Health Insurance Program, and managed care claims. For participating states, the PERM review takes place every three years. As explained in the Work Plan, OMIG intends to use PERM samples to collect additional information that the PERM program does not require, but which OMIG might use to identify other possible areas of fraud, waste, and abuse in the New York Medicaid program. OMIG will also use the PERM model to perform continuous random sampling of Medicaid claims between the three-year cycles.

Regardless of whether other states follow New York's lead with a similarly detailed plan, the Work Plan demonstrates the direction of regulatory enforcement methods. First, federal and state regulators are going to be relying more and more on data mining in their efforts to detect fraud and abuse. Data mining provides auditors with an efficient way to extract and detect specific billing practices. With data mining, providers may not even know the government is auditing them, because the review occurs off-site with previously submitted information. Consequently, compliance officers should maintain systems and protocols to ensure that the data being submitted to the government is accurate.

Second, medical necessity reviews are becoming the norm, and not just quality improvement organizations conduct them. Clinical expertise is needed to effectively review medical records; however, as evidenced by concerns raised in the Recovery Audit Contractor reviews, the auditors may not always possess this background. Compliance officers should continue to conduct reviews of medical record documentation to ensure that the services provided are appropriately documented. Although this is not a new area, it should be a priority.

Finally, state Corporate Integrity Agreements are likely to become commonplace.

As announced in the Work Plan, providers and suppliers can expect OMIG to require a Corporate Integrity Agreement as part of any settlement with the state of New York's Medicaid program. Given the focus on Medicaid enforcement, providers and suppliers should expect other states to do the same.

What should compliance officers do now?

New York has taken significant steps to be a leader in its Medicaid enforcement efforts with the development of the Work Plan and through OMIG. The New York Work Plan is yet another sign that Medicaid compliance demands the same level of attention that providers and suppliers have been dedicating to Medicare. Whether or not other states follow with a similarly detailed plan, the Work Plan provides a preview of what states may deem important focus areas in Medicaid enforcement. Compliance officers, regardless of their state of residence, should review the Work Plan, evaluate the identified focus areas, and consider incorporating applicable items into their organization's compliance work plan and auditing and risk assessment tools. The steps that compliance officers take now can better prepare their organizations for the future of Medicaid enforcement activities.

1 Available at http://www.omig.state.ny.us/data/images/stories//omig_workplan2008_2009v2.pdf.
2 Kaiser Family Foundation, Kaiser Commission on Medicaid Facts, State Fiscal Conditions & Medicaid 1 (2007). Available at http://www.kff.org/medicaid/upload/7580-02.pdf

ASK LEADERSHIP

JOHN FALCETANO

John asks the leadership your questions

Editor's note: John Falcetano is Chief Audit/Compliance Officer for University Health Systems of Eastern Carolina and a long-time member of HCCA. This column has been created to give members the opportunity to submit their questions by e-mail to jfalcetano@suddenlink.net and have John contact members of HCCA leadership for their response.

QUESTION:

Can you use ICD-9 procedure codes on hospital outpatient claims?

The answer below was provided by John C. Falcetano, MA, CHC, CIA

According to CMS, the answer the answer is no. CMS provides the following information on their Website.

ICD-9-CM procedure codes were named as the HIPAA standard code set for inpatient hospital procedures. The ICD-9-CM procedure codes were not named a HIPAA standard for procedures in other settings, such as hospital outpatient services or other types of ambulatory services. Hospitals may capture the ICD-9-CM procedure codes for internally tracking or monitoring hospital outpatient services; but when conducting standard transactions, hospitals must use HCPCS codes to report outpatient services at the service line level and the claim level, if the situation applies. Even though an ICD-9-CM procedure code qualifier is available, in addition to a HCPCS code qualifier, at the "situational" claim level segment, the Transactions and Code Sets regulation states that ICD-9-CM procedure codes is the adopted standard code set for hospital inpatient services. ■

ICD-9-CM = International Classification of Diseases 9th Edition Clinical Modification
HIPAA = Health Insurance Portability and Accountability Act of 1996
HCPCS = Healthcare Common Procedure Coding System

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Erythropoiesis-stimulating agents: Regulatory update

By Julia Moreau, RN, MBA; Victor Shutack; and Karen Delbridge, MT (ASCP)

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Epoetin alfa (Epogen® and Procrit®) and darbepoetin alfa (Aranesp®) are erythropoiesis-stimulating agents (ESAs) used to treat anemia in patients with end-stage renal disease (ESRD), people receiving zidovudine to treat HIV, and people receiving chemotherapy for some types of cancers.[1] These drugs work by signaling the bone marrow to make more red blood cells and are used in the hope of limiting the number of blood transfusions that the patient will receive.

Recently this class of drugs has come under more intense scrutiny by government agencies and medical groups due to safety issues regarding dosages prescribed, as well as the cost of these drugs.

- March 9, 2007 - The US Food and Drug Administration (FDA) issued a public health advisory outlining new safety information as the result of recently completed studies that described an increased risk of death, blood clots, strokes, and heart attacks in patients who have chronic kidney failure when these drugs were given at higher than recommended doses. The FDA recommended that a black box warning be placed on drug packaging.[2]
- March 21, 2007 - The House Committee on Energy and Commerce issued letters to the drug manufacturers, Amgen and Johnson & Johnson, urging them to suspend direct-to-consumer marketing until the FDA has completed its investigation.[3]
- April 18, 2007 – *The Journal of the American Medical Association* reported on a study that stated for-profit dialysis facilities administer about 3,300 units per week more epoetin alfa per patient than non-profit dialysis facilities, regardless of patient anemia status. The study authors report that the 2004 reimbursement rate of $10 per 1,000 unit of epoetin alpha corresponds to $1,700 per year greater expenses per patient.[4]
- June 26, 2007 – The House Committee on Ways and Means conducted a hearing on Ensuring Kidney Patients Receive Safe and Appropriate Anemia Management Care. The purpose of this meeting was to hear oral testimony from invited witnesses to gain a better understanding of dosing of ESAs, variations in utilization of ESAs across providers, and reimbursement issues.[5]
- July 30, 2007 – CMS issued a National Coverage Determination policy for the administration of epoetin alfa for non-ESRD patients.[6]
- January 11, 2008 – CMS issued Transmittal 1412 requiring the reporting of hematorcrit and hemoglobin levels on all claims for the administration of ESAs, implementation of new modifiers for non-ESRD indications, and reporting of hemoglobin and hematocrit levels on all non-ESRD, non-ESA claims that request payment for anti-anemia drugs.[7]

Medicare requirements for end stage renal disease patients

Currently, epoetin alfa and darbepoetin alfa are covered under the Part B benefit for the treatment of anemia in ESRD patients who are on dialysis. ERSD patients who have been receiving epoetin/darbepoetin alfa therapy should have a hematocrit between 30% and 36%. Renal dialysis facilities are required to report hematocrit or hemoglobin levels on claims submitted to the Fiscal Intermediary (FI) for Medicare patients who receive erythropoietin products.[8]

Medicare implemented a national claims monitoring policy for epoetin alfa administration in renal dialysis facilities for services provided after April 1, 2006. Providers are expected to maintain a patient hematocrit level between 30% and 36%; however, due to the variability in response to treatment, Medicare will not monitor the hematocrit until it reaches 39.0%. Medicare has modified the specific requirements over time, and as of October 1, 2006, CMS requires that the -GS modifier be reported on in-facility claims when the dose of epoetin alfa was reduced and maintained in response to a hematocrit or hemoglobin level. In the initial version of the requirement, an automatic 25% reduction in payment was applied if the -GS modifier was not on the claim, but the updated definition allows for some flexibility due to changes in dosing required during the monthly billing

Continued on page 58

 ...continued from page 57

cycle. Medicare Publication 100-4 section 60.4 reminds providers that CMS expects that as the hematocrit approaches 36.0% (hemoglobin 12.0g/dL), a dosage reduction will occur. The excess dosage is not considered to be medically necessary, and renal facilities may not bill Medicare beneficiaries for the payment reduction unless an Advance Beneficiary Notice is obtained prior to administration of the drug. Medicare contractors may review medical records to assure appropriate dose reductions are applied and maintained and hematological target ranges are maintained.[9]

Beginning in January 1, 2008, renal dialysis facilities will be required to change their methodology for reporting epoetin alfa use. Prior to January 1, 2008, epoetin alfa was paid according to the total number of units reported on the claim next to value code 68. After January 1, epoetin alfa will be billed for each administration on a separate line item indicating the date of service for each administration. The units reported on the claim line for epoetin alfa will be multiplied by the total units as defined by the Healthcare Common Procedural Coding System (HCPCS) code to reflect the dosage per administration. The -GS modifier should be reported on the line item(s) that represent an administration of epoetin alfa at the reduced dosage following reporting instructions as indicated above. No payment reductions will result when the -GS modifier is present on the claim.[10]

Both the Office of the Inspector General (OIG) 2007 and 2008 Work Plans include plans for the OIG to review claims for epoetin alfa billing by dialysis facilities to identify if the epoetin alfa was billed in accordance with Medicare's requirements.[11, 12]

Medicare requirements for Non-ESRD patients

On July 30, 2007, a National Coverage Determination (NCD) went into effect for the administration of epoetin/darbepoetin alfa for non-ERSD patients. CMS will cover epoetin alfa administration for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia in patients with specified clinical conditions. CMS has identified eight conditions in non-ERSD patients where they will not cover epoetin alfa treatment. For these eight conditions, treatment with epoetin alfa is not considered medically necessary.[6]

Effective January 1, 2008 and with an implementation date of April 7, 2008, CMS will require that all claims for non-ESRD patients receiving ESAs have the most recent hematocrit or hemoglobin level on the claim, just as it does for ESRD patients. They will also require that one of three modifiers be appended to the level II HCPCS code for the ESA to indicate the reason for the drug administration. These modifiers are EA – ESA, anemia, chemo induced, EB – ESA, anemia, radio-induced, and EC – ESA, non-chemo/radio. If ESAs are administered for more than one of the indicated therapies, they should be reported as separate lines on the claim with the appropriate modifier. Lastly, all claims for the administration of Part B anti-anemia drugs other than ESAs used in the treatment of cancer that are not self administered will require the most recent hematocrit or hemoglobin on the claim.[7]

Recommendations for health care providers

Health care providers should establish policies and procedures related to the ongoing monitoring and management of hematocrit levels to effectively manage the administration of ESAs. Clinicians involved in the management of the patient's anemia should meet periodically to perform a detailed review of the patient's clinical status and response to these drugs in order to recommend the most medically appropriate measures to initiate. The team must include the patient's treating physician who is ultimately responsible for ordering of services for the patient. The team should ensure that the patient's care plans and clinical records include the rationale for the current ESA dosages, factors that may be affecting the ESA response, and the plan for any dosage changes are fully documented in the medical record. These activities should be performed on an ongoing basis.

For ESRD patients whose hemoglobin levels start to approach the target range (12 g/dL or a hematocrit of approximately 36%), physicians and the anemia management team should closely monitor the patient's laboratory, clinical, and medication administration data. Maintaining the patient's hemoglobin in the target range is often difficult and blood levels are prone to fluctuations. This is due to factors related to the patient's constantly changing environment and condition. Some patients may respond more strongly to the ESA dosage and some will require higher doses to achieve the same response. For example, infections are known to lower hemoglobin and ESA responsiveness, but iron supplementation will help increase both. Thus, the physician and the anemia management team must monitor hemoglobin and adjust ESA doses as needed with the goal of keeping the patient's hemoglobin level in the target range for as much time as possible. These temporary hemoglobin fluctuations are generally understood in nephrology and have been described in multiple publications.[13]

In addition, patients who are receiving epoetin alfa doses greater than 10,000 to 12,000 units three times per week should be closely monitored and the rationale for any dosage increases above that level should be clearly documented in the patient's medical record.

Some dialysis facilities rely on an anemia management nurse, working from a physician approved protocol or algorithm, to make weekly or monthly ESA dosage adjustments. ESRD facilities utilizing these protocols should conduct periodic reviews of the Anemia Management Medication Protocols or Algorithms to determine if they comply with regulatory guidance and the latest industry recommendations. The medical director, other physicians, and members of the anemia management team should be involved in this review.

If it is determined that it is clinically appropriate to maintain a hematocrit close to or above 39.0%, then it is the patient's treating physician's responsibility to document the rationale for maintaining a high hemoglobin level. This can include an attestation statement from the ordering physician, indicating the clinical or environmental conditions that substantiate the increased blood hemoglobin levels, such as congestive heart failure, obstructive lung disease, or those living at high elevations.[14]

When clinically monitoring the patient's hemoglobin levels, it is important to be concerned with the billing and regulatory requirements that impact reimbursement. For dialysis patients, in order for appropriate inclusion of the -GS modifier on the claim, there must be clear lines of communication between the dialysis facility and the individuals responsible for billing. In addition, the process of appropriately adding the modifiers to the claims, once established, needs to be audited and monitored on an ongoing basis. This includes a comparison of hematocrit levels across all patients and a periodic medical record to claims review with a focus on ESA utilization for patients whose hematocrit levels exceed 39.0%.

In conclusion, with all the regulatory changes and concerns regarding the safety of these drugs, providers should proactively develop policies, tools, and systems for monitoring hematocrit levels within the FDA approved target range. Assessing current anemia management protocols to validate that they meet the latest regulatory and clinical requirements will assist with billing compliance and decrease the adverse risk to patients. ■

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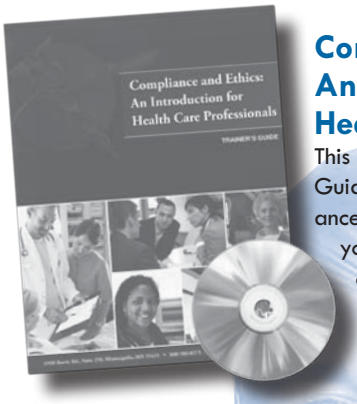

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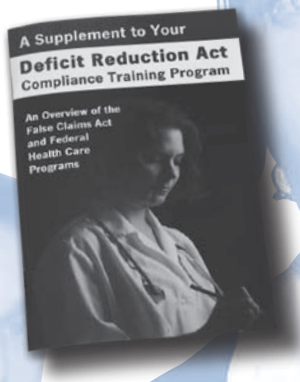

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This 19-minute video plus 10 participant handbooks offer an in-depth review of the HIPAA Privacy Rule. Viewers will learn the importance of protecting patient privacy and confidentiality, including the use and disclosure of protected health information; patient consent and authorization; administrative requirements, and more.

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The physics of health care compliance in the medical device sector

By Andrew Leven, JD

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Popular phrases often reflect prevailing ideas. In this article we assess how two of those ideas – "problems" and "challenges" – have diminished the viability of health care compliance (HCC), and then generally propose a way to move that function forward.

Broadly speaking, problems are obstacles. Some are fairly easy to handle, others difficult, and not a few are insurmountable. At their core, though, hard problems suggest hard solutions. They evoke images of rolled up sleeves, less than satisfactory compromises, and toil. Challenges, by contrast, are not problems at all. They are opportunities.

In today's corporate culture, the clear expectation is that opportunities are to be embraced. And the medical device and diagnostics sector is currently hip deep in them. Indeed, this mindset is so frequently voiced that one is hard pressed to attend a company meeting or read an internal memorandum that does not invoke it.

That subtle repositioning of obstacles as opportunities reflects a world view that, it will be argued, poses a fundamental problem for the HCC officer. Because the demands that HCC places on medical device companies are not opportunities; they are obstacles, and to pretend otherwise—to position HCC as something that it is not—is to build a program to fail.

Gravity

One way to understand this argument is through the lens of physics. We all know that if you jump off a ladder, it really doesn't matter whether or not you intended to fly. There is gravity, and then the ground.

Industry, too, is governed by certain rigid rules that form the larger environment in which HCC operates. One is that in highly competitive, cutting-edge markets, a company's revenues must exceed expenses on a go forward, continuous, and accelerating basis. If not, then the company stagnates, bonuses are cut, key employees look for the exits, and the organization begins to falter.

That dynamic has some important, positive benefits for the business of medical devices, but it also defines the internal balance of power in most device companies. When a corporation's continued viability hinges on meeting (or exceeding) a 12-month business plan, employees on the revenue side of the ledger are valued more than those on the expense side. That is, every department is important, but sales and marketing are more important, and this unvarnished reality informs virtually every significant business decision that a company makes.

Other rules of physics speak to career progression. In a moment of unguarded candor, most corporate leaders will tell you that the hardest part of business is not creating initiatives, but the internal struggle that precedes them. And this struggle is fought out against an unforgiving backdrop: Every employee at a company (but one) works for, and has to please, a boss who decides what they do, how much they make, when they are promoted, and whether they remain employed—meaning that intellect certainly matters, but relationships can matter more. Bosses change. High priority projects sometimes aren't. A colleague is "up," then he is "down," and understanding who is headed where counts, because being tied too closely to a leader on the way out can end a career.

Then there are the rules of market development. Disruptive technologies create wholly new markets, which are then consolidated and segmented. As a market matures, differences among competing products gradually become more nuanced and then almost invisible, leaving competitors locked in trench warfare, battling over significant customers.

In the device sector, the combatants' ammunition of choice in these battles is key opinion leaders (KOLs). Why? Because in a maturing market, companies increase sales by either reaching new doctors, expanding product usage to new patient populations, or both. One established pathway for doing so is clinical trials, another is continuing medical education (CME), and in each of them KOLs predominate, either at participating clinical sites for trials or as CME faculty lecturers. KOLs also write much of the most impactful medical literature, serve on the editorial boards of key journals, sit on many FDA panels, and train other physicians on devices. For these reasons, competition among device

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companies for KOLs is not only widespread, but also routine.

Effective compliance programs—and their ripples

Numerous articles describe the elements of an effective health care compliance program and suggest ways to translate them into internal company processes and procedures. It is worth recalling, though, that these elements are not, and were never intended to be, industry friendly. Conceptually, they are derived from the United States Sentencing Commission, which offered up "effective" compliance programs as an opportunity for law breaking companies to reduce their criminal sentences.[1] The existence (or absence) of an effective compliance program is also a factor that every federal prosecutor must consider before deciding whether to charge a company criminally.[2] Compliance was further delineated, given its now familiar form, and specifically applied to industry by the Office of Inspector General (OIG), Department of Health and Human Service (HHS) in May of 2003.[3]

Plainly, then, these elements, which are at the core of every HCC program, were not written by the home team, and it shows. Take, for example, the first OIG element – that companies implement policies to "address specific areas of fraud and abuse, such as . . . sales and marketing practices"[4] that provide "anything of value" to health care professionals with the intent to reward, or induce, product purchases.[5] This practice is prohibited under the Federal Anti-kickback Statute (AKS). In pertinent part, AKS provides that: whoever knowingly and willfully pays or offers to pay a person any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, for the purpose of inducing that person to purchase or order any good or item for which payment may be made under a federal health care program is guilty of a felony punishable by a fine of not more than $25,000, five years imprisonment, or both.[6] Doctors who solicit remuneration from industry with the same improper purpose also face criminal liability under the AKS.[7] Two civil sanctions (i.e., a civil money penalty and/or exclusion from federal health care programs) are also available when the Secretary of Health and Human Services determines that a doctor, health care facility, or company has violated the AKS.[8]

To avoid AKS liability, companies are advised by the OIG to "identify any remunerative relationship between itself . . . and persons or entities in a position to generate federal health care business" and then "determine whether any one purpose of the remuneration may be to induce or reward the referral or recommendation of business . . ." (emphasis in the original) because "a lawful purpose will not legitimize a payment that also has an unlawful purpose."[9]

The broad language of the AKS has been narrowed through the promulgation of "safe harbors," which are set forth in the Code of Federal Regulations and generally referenced by the OIG. Those safe harbors list certain objective criteria that, if followed, render the likelihood of prosecution remote. They do not, however, permit activity undertaken with an improper purpose. So, for example, a consulting agreement that meets each of the relevant safe harbor criteria is nevertheless wholly unprotected if intended to induce the consultant to buy more product, or reward him for past purchases.

The clear import of the OIG Guidance (when read with the criminal statutes it references) is apparent. Industry is not permitted to compete over physician relationships, and must instead compete solely on the quality, capability, and price of their products.

The impact on the device sector of this law enforcement-driven paradigm is quite significant. In a typical market, only one company has a genuinely superior product, and in many device market segments it can be argued that there is no "best" product at all. In truth, most device companies can (and do) aggressively compete on products. But to grow, or even simply to maintain market share, many also feel compelled to continue competing for physician relationships.

How, then, does the OIG Guidance match up against underlying business dynamics? Consider these hypothetical scenarios.

Scenario one. A KOL and frequent user of the company's products is paid $80,000 a year in consulting and speaker fees. To Sales and Marketing, he is a strategic, valued asset that helps drive numbers. HCC sees a risk that has to be assessed. And the KOL, who is used to making (and being right about) life and death decisions every day, expects to be accommodated. HCC can live with paying this KOL because he actually does the work, is particularly well-qualified to do it, and is being compensated at something approximating fair market value for his trouble. But there is an important regional conference in Thailand. The company needs the KOL to speak there for an hour, requiring three days out of the office at $4,000 per day, plus meals, accommodations, and an $11,000 business class ticket, which the KOL has already booked. HCC raises the flag – "Wait, we need a written justification. Why this rate, and why this doctor?" which leads immediately to a struggle between the affected company functions. Not over HCC, but over numbers and power. The company needs the KOL, and they need him happy. E-mails start to fly. "We have got to pay this doctor!!!" exclaims one. "Get it done!!" demands another. "Otherwise he will punish us," laments a third.

Scenario two. A significant customer asks a sales rep to provide an education grant to her hospital, noting that five competitors approach her every week to detail products that, with minor technical differences, provide the same patient benefit. The doctor then voices her personal commitment to physician education, and states that she will choose to support device companies that share her values. If the rep (or company) can't demonstrate that shared commitment, then she will place her business elsewhere. "Why," the sales rep wants to know, "can't we support this doctor?"

Scenario three. The company's president meets a physician affiliated with a nationally known research facility, who is in a position to influence customers. At dinner, the physician asks the president to support an upcoming CME conference, and the president verbally commits to a $50,000 CME grant. There is no tie to, or discussion of, product sales, but also no mention of the conference agenda, topic coverage, CME faculty, or how the company's grant money will be used. This leaves the company unable to document (or even articulate) an acceptable business purpose for what may well have otherwise been a perfectly legitimate use of funds, if it had been approved using objective HCC criteria. "But," the company president explains, in response to a very delicately worded HCC inquiry, "the research facility is nationally known. They are helping patients. And this doctor is a friend to the company."

The point here is not to hammer out nuanced answers to what are undoubtedly familiar fact patterns. It is about identifying differing worldviews, sources of internal conflict, damage control, and damage.

The HCC officer focuses on the one purpose rule, unhelpful internal e-mails, and a repeated—almost reflexive—circumvention of the core processes that he is being paid to enforce and feels (quietly) pressured to ignore. Sales and marketing leaders see numbers, targets, market share, competitors, and four fiscal quarters until the ax starts to fall. The sales rep believes that he is being prevented from supporting his customers, thus placing him at an unfair competitive disadvantage. The company president is troubled by what he views as unwanted (and unwarranted) interference in a routine exercise in public relations. And all of them are right.

In this regard, a March 2007 PricewaterhouseCoopers survey about the medical device sector's implementation of the AdvaMed Code is telling.[10] Fully 82% of respondents believed AdvaMed had "no negative impact" on their company's financial results, and an additional 10% felt that compliance actually had a beneficial financial effect.[11] Yet 76% of these same survey respondents rated "customer expectations" as one of the three top HCC implementation challenges. A clear majority (75%) said "their companies had received resistance from customers in striving to comply with the AdvaMed Code." Substantially more than half (61%) identified "lack of management support or inadequate resources (which can be a reflection of management support)" as one of the "biggest challenges to implementing effective monitoring controls."[12] And all of the respondents who actually articulated these perceptions and contradictions were HCC officers. The PricewaterhouseCoopers survey "did not capture the views of senior management on compliance issues,"[13] or, apparently, those of anyone on the commercial side of the business.[14]

Tone at the top

This fundamental disconnect (and the significant compliance vulnerabilities that it creates) is not a challenge. It is a problem that, unsurprisingly, very few device companies have genuinely engaged. What we see instead are a plethora of internally generated HCC policies, communicated through "challenge-based" internal messaging. HCC, employees are told, is a "competitive advantage," a "business partner," an undefined form of "legal insurance," or some vague combination of the three. All of which is a highly problematic foundation upon which to predicate deep organizational change, because it creates expectations that HCC cannot meet.

Trying to sell HCC as "a competitive advantage" is a nonstarter because, as noted earlier, the policies it requires represent a decisive shift in many companies' basic (and proven) business model. For those companies that need physician relationships to grow revenue, this shift is quite unwelcome, at least in the short-term, which is the very time frame that virtually all device companies must live in.

Similarly, HCC as "legal insurance" presupposes a relationship between actions and consequences that frequently does not exist. Government cases against industry are almost always thinly staffed (usually, by a single agent, a single prosecutor and, perhaps one paralegal), often involve a warehouse full of documents, and can take years to bring to closure. As a result, they are not undertaken lightly, and are rarely (if ever) the direct result of a focused proactive law enforcement initiative. The government does flag broad trends and then generally allocate a modicum of additional prosecutorial resources to address them, but criminal cases are not made with resources. They are made with leads from witnesses and cooperators—be they whistleblowers, a physician with a cocaine addiction, a competitor, a referral from another agency, or a disgruntled divorcee whose ex-spouse is in the industry.

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These real-world constraints mean that most of the government's criminal HCC investigations are not built on a careful, informed assessment of which company is the worst actor. Rather, they often hinge on such episodic, case-specific circumstances as whether (1) a credible company insider, victim, or witness savvy enough to understand (and gather) solid, relevant evidence of corporate wrongdoing (2) connects with a law enforcement agent that has the time and skill to work an anti-kickback case, (3) who knows a similarly situated prosecutor who is willing to venture into an industry that he really doesn't understand. These factors do line-up, but usually by happenstance, and largely independent of the relative seriousness of a particular company's actual misconduct. This is not to say that the degree of misconduct or, at least, its pervasiveness, plays no role in the law enforcement environment. Generally speaking, the more a company violates the law, the more people know about it. Because each individual with knowledge is a potential prosecutorial lead, serial corporate law breakers are more likely to be discovered and investigated than sporadic ones. That relationship is, however, essentially numerical, not qualitative.

In effect, the "legal insurance" motif asks senior executives with a two-to-three-year corporate life expectancy to risk further shortening it by curtailing revenue growth in response to an inherently unpredictable external threat that may never be realized.

Lastly, positioning HCC as a "business partner" to help the company navigate choppy legal waters actually describes a result – not a process. Most HCC officers wear several hats, including those of investigator and enforcer. Because the internal corporate environment is driven to a significant degree by personal relationships, this puts the HCC function at a distinct disadvantage unless the company already follows the rules. When compliance is not widely adhered to, the HCC function must play the self-defeating role of having to either (1) routinely try to stop commercial initiatives, or (2) internally investigate the same business leaders to whom he/she has been tasked with providing business advice. And however necessary that role may be, it is not partnering. In that sense, HCC as a "business partner" is less a pathway to creating a mature compliance culture than it is a measure of whether that culture currently exists within an organization.

Indeed, one could argue that in companies where a mature compliance culture does not exist, HCC is often perceived as a perplexing, expensive, and ultimately unwelcome enigma. Most business leaders expect every cylinder of the company's operations to contribute to or support revenue growth, and not to interfere with basic customer relationships. In an environment passively hostile or indifferent to compliance, HCC rules around sales and marketing practices are therefore likely to be viewed as divorced from business reality, and further undermined by reference to the inevitable differences in the compliance practices of competing companies in the same sector. Inconsistencies in approach are inherent in HCC because that function's role is to opine on highly nuanced, fact-specific situations that are often gray. Different companies also differ in their commitment to compliance. And, as in any other function, it is not uncommon for HCC decisions to be rendered based on imperfect and incomplete information.

This confluence of circumstances, in turn, strongly suggests that few, if any, of the commercial rank and file are going to spontaneously advocate for rigorous compliance programs. Rather, it seems clear that HCC is a top down process that will only gain cultural acceptance when a company's leadership requires that acceptance to occur.

The most direct way to achieve such acceptance is for the company president to mandate (and actually enforce) it, with all that suggests in terms of business planning, marketing programs, grant making activities, sales rep detailing, internal investigations, and consistent, transparent discipline. It is, in fact, possible in a corporate hierarchy to force the round peg of HCC into the square hole of prevailing business practices.

The sustainability of this approach is, however, open to question. How, for example, can a company president be persuaded to profoundly alter the way the company generates revenue, and will such changes endure after that individual and her leadership team depart?

Customers as targets

An answer to these questions, or at least the beginnings of one, is suggested by a basic human dynamic. When a trial lawyer wants to win, he first identifies what the jurors, as decision-makers, care about, and then organizes his case around those themes. Having identified the commercial leadership as the decision-makers in the device world, it follows that their focus is on what generates revenue—that is, the customer.

Logic dictates that if customers did not mind HCC, or at least did not punish companies for deploying it, then the commercial side would be much more willing to genuinely accept the changed business practices that HCC requires. Yet, no sustained effort has, so far, been made by the leading device companies to shape their customers' view of compliance. (Sporadic efforts have been made

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by individual companies to educate doctors about HCC rules. We speak here, however, of a sustained effort, which is generally described in greater detail below.) In an industry where even minor product alterations are calibrated against intensely researched customer perceptions, HCC policies that directly impact customers have been widely implemented without engaging customers in those changes.

Why this has occurred in particular companies can be disputed, but its logical consequences cannot. Absent a better alignment of customer expectations with industry practice, many device companies will remain poised on the compliance fence—saddled with HCC policies they felt compelled to adopt, but are unwilling (and effectively unable) to implement – and therefore vulnerable to any but the most casual government scrutiny.

A detailed analysis of what the effort to drive that alignment might look like is beyond the scope of this article. The basic strategic approach required, though, seems apparent. For HCC to take root internally, device companies need to remodel the external landscape. Physicians should be a compliance target, and shaping their perceptions about HCC should be a purposeful company goal.

In undertaking this effort, companies should be guided by the fact that HCC is not a product, and will not drive growth. HCC is instead a set of rules that any number of physicians may find irksome and unnecessary. But, doctors are also people. Most people are more likely to tolerate rules that they understand as rational and will resist opaque rules that are unilaterally imposed.

Fundamentally then, HCC should be explained to a company's customers by organizing it around a context and themes that physicians can relate to. The purpose is not, it should be emphasized, to create HCC converts, but instead to neutralize, or at least diminish, customer resistance by making sense, together, of why their relationships with industry are the subject of HCC rules, and how those relationships can (and should) be modified so that they can continue.

For example, many doctors reject the notion that industry support influences their treatment decisions. But, health care is a four legged stool, not a pedestal. Besides physicians, there are also the government, industry, and patients, each of whom brings different perspectives to bear. Even those doctors who ignore (or are unaware of) government and industry pronouncements presumably still do care about the perceptions of their patients, and that concern presents a contextual touch point for conversations about HCC that the device industry needs to have with its customers.

Under this "patient perceptions" approach, that conversation could be built around questions like "How do physicians think patients would react if they knew that their doctor received several thousand dollars a year (or more) in free meals, gifts, training, and office supplies from the same company that sells the device being prescribed?" and "Do physicians believe that a set of strict professional and legal rules, designed to assure that this situation plays no role in treatment decisions, would reduce any resulting patient anxiety?" In this regard, it bears mention that the Pharma, AdvaMed, and AMA codes speak primarily to the "reasonability" of particular expenditures by industry on doctors (not the aggregate amount of support given), that a growing number of state laws do (or soon will) require those amounts to be publicly disclosed, and that several major device companies have told Congress that they will make information about CME grant recipients publicly available on the Web.[15]

Another context for explaining compliance thematically is to discuss medicine as a profession. Doctors are used to, and comfortable with, canons of ethics that define their obligations to patients. The underlying purpose of HCC is to direct health care spending to products that help patients the most, at the least cost. Given this purpose, it is plausible (and, indeed, correct) to characterize HCC as a more complex, but valid, application of existing professional canons to a doctor's selection of one device over another for use in patients.

Other themes may resonate more strongly with customers and provide better platforms for shaping their perceptions about HCC than the two highlighted here. Any theme that is deployed must, however, be built around issues actually faced by the audiences being addressed and demonstrate HCC's basic viability, or it will have little traction.

Breaking ground

Serious initiatives require serious efforts, and this one will require more than a CME program, some PowerPoint slides, and a few articles. We speak instead of a sustained initiative to effectively stake out HCC as an issue of physician ethics, which will necessarily involve a prolonged, mutually supporting effort by industry, medical societies, and medical schools. For industry, viable support pathways include conferences, advisory boards, CME grants, focus groups, and speakers bureaus resourced at levels commensurate with a program that is viewed as a core commercial imperative.

Those pathways are expensive, but so is the unforgiving enforcement environment, which has imposed significant, uninsurable costs on the device sector; most recently, $311,000,000 in fines levied against several

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orthopedic companies at the conclusion of a multi-year criminal investigation.[16]

Building this initiative at the company level would employ the same basic approach used to conceptualize, resource, and implement other authentic customer focused programs. That is:

1. identify the problem;
2. gather data on, and understand existing customer perceptions;
3. clearly articulate a strategic goal;
4. devise tactics, assign tasks, and set a timeline for reaching them;
5. impose accountability; and
6. measure progress against relevant metrics.

This process is a very familiar one to most leading device companies, all of whom are well positioned to execute all manner of strategic and tactical objectives. In the HCC context, though, steps (1) through (3) may best be facilitated by structured, formal input from a third-party, particularly in those organizations that have stalled on the "challenge based" HCC model.

The reason for looking to an "outsider" in those situations is because it is very difficult to change minds that have already been made up, and even harder to do so when the putative change agents are themselves stakeholders in the original decision-making process. A third-party facilitator carries no baggage, risks no intra-company relationships, and (if he/she is sufficiently compelling) provides organizational cover for taking a new and different direction. The specific details of the facilitator's presentation must, of course, tie back to the particular organization being addressed. But in every organization the key audience will be the commercial leadership, and it is critically important to organize whatever information is presented around their expectations, as to both form and substance. This suggests that any third-party facilitator needs to do two things: (1) understand a company's products, competitors, business model, and the current state of their compliance program; and (2) be able to frankly articulate both the problems faced and a viable, customer-focused pathway for improvement. Many organizations may also want the third-party's HCC program assessment and suggested improvements to enjoy the attorney-client privilege, which may be available when the facilitator is an attorney conducting the analysis to provide legal advice. In those instances, an outside law firm should be engaged as the facilitator.

Conclusion

One idea that everyone in industry can coalesce around is the value of connecting with customers. As applied to HCC, that idea broadly offers a fact-based, intellectually honest strategy that targets, and is organized around, the commercial side's core activities and concerns. In particular, proactively engaging physicians does bring them closer to the business. Reshaping physicians' negative perceptions about HCC will set a better table for building an enduring culture of compliance within device companies. And, once established, that culture should help protect revenue by reducing legal risk.

Hard problems are never easy, but this one need not be insurmountable. To solve it, companies need to accept that HCC is a very difficult, multi-faceted obstacle, and then do the hard work of overcoming it. The time has come to embark on that process. ■

1 See, e.g., 18 USCA Section 8C2.5(f)(Culpability Score) (1991 ed.). See 18 USCA Chapter 8, Historical Notes to 2004 Amendments.
2 December 12, 2006 Memorandum of Kevin McNulty, Deputy Attorney General, United States Department of Justice, Principles of Federal Prosecution of Business Organizations.
3 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Register 23731 (May 5, 2003) (OIG Guidance). Though directed specifically at pharmaceutical companies, the OIG Guidance plainly indicates that it also applies to medical device and diagnostic companies, Id. at pg. 23742, fn. 5, and that expansion has been accepted by industry. See, e.g., Rapp, Kristine, New Times, New Ethical Standards (MX November/December 2003) (noting OIG's contention that the Advamed Code should explicitly refer to the OIG Guidance); Roche Diagnostics Corporation Description of Compliance Program and Declaration Pursuant to Cal. Health and Safety Code Section 199402(e) (2005) (declaring that Roche's compliance program for devices is "in accordance with" the OIG Guidance).
4 OIG Guidance, pgs. 23732, 23733.
5 OIG Guidance, pg. 23734.
6 42 U.S.C.A. Section 1320a-7b(b)(2).
7 Id. at Section 7b(b)(1).
8 See 42 U.S.C.A. Section 1320a-7a (a)(7).
9 OIG Guidance, pg. 23734 and 23737.
10 Challenges of Complying With the AdvaMed Code (Analysis of the Medical Technology Industry – Benchmarking Survey) by PricewaterhouseCoopers, King & Spalding, LLP, and Compliance-Alliance, LLC (March 2007) Available at: http://www.pwc.com/extweb/pwcpublications.nsf/docid/046115D77D5EA5338525732A007759C0. Accessed April 9, 2008.
11 Id. at page 5.
12 Id. at pages 9 and 10.
13 Id. at page 10.
14 See Id. at page 14 (describing all survey respondents as "compliance professionals") .
15 15 Freking, Kevin, Drug Companies to Reveal Grant Practices (April 11, 2008) Available at: http://apnews.excite.com/article/20080411/D8VVQ0D00.html. Acessed April 11, 2008.
16 16 See Trotta, Elizabeth, Feds, Medical Device Makers, Settle Corporate Fraud Case (September 27, 2007) Available at: http://www.thestreet.com/story/10381767/1/feds-medical-device-makers-settle-corporate-fraud-case.html. Accessed April 9, 2008.

Modified CEU Quiz

Beginning with the July issue of Compliance Today, readers will notice a change to the CEU quiz. The quiz will still have four questions, but the objectives and questions will be taken from more than one article in each issue. The change was made to put the time requirements more in line with other qualifying activities for obtaining one CEU. By drawing questions from more than one article, we hope to provide a more well-rounded learning experience.

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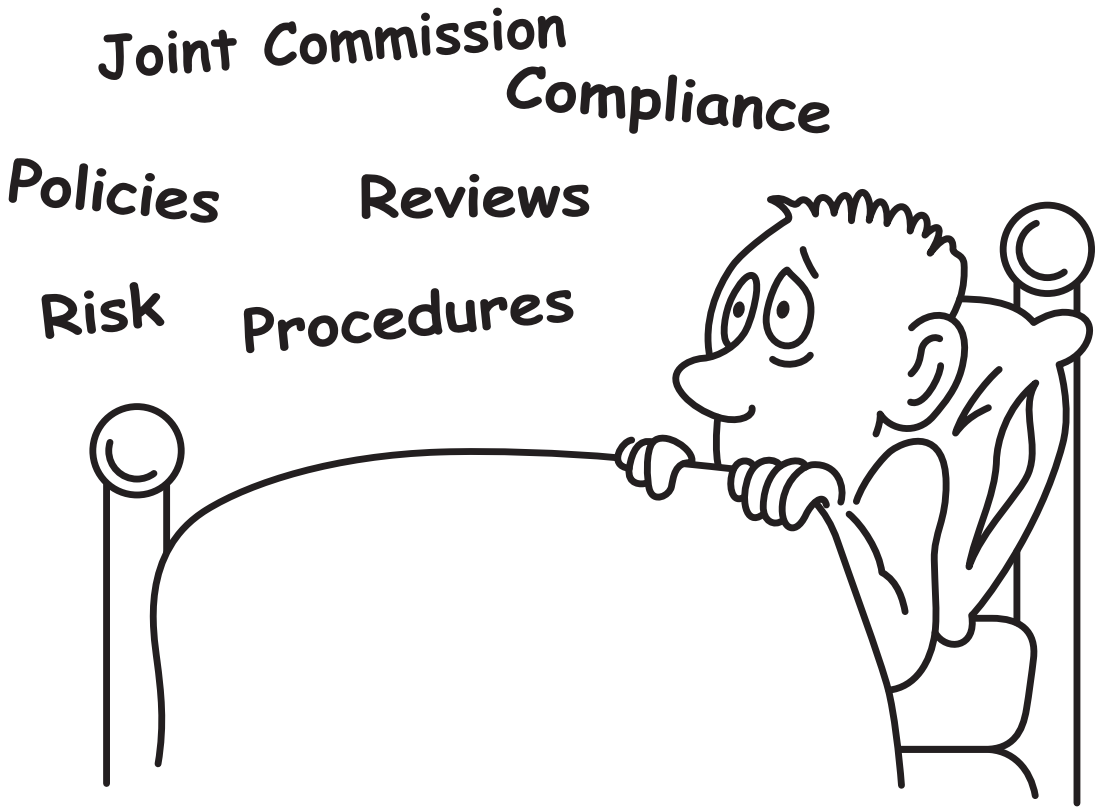

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The Fraud & Compliance Conference is jointly sponsored by the Health Care Compliance Association (HCCA) and the American Health Lawyers Association (AHLA). It will include an explicit designation of a session as "compliance focused" or "legally focused." The Planning Committee has included enough sessions in each designation that an individual could attend all "compliance" sessions or all "legal" sessions for the entire program. Yet an attendee also has the option of selecting a diversity of sessions and networking with an expanded group of individuals. The Fraud and Compliance Forum has the benefit of combining the quality of HCCA and AHLA sessions with the expanded networking power of a combined program.

HCCA and AHLA are going green! Attendees will receive electronic access to the course materials prior to the program as well as an electronic version of the materials at the program. Attendees will not, however, automatically receive a binder. If you would like to purchase a binder for $45, please indicate that on the registration form.

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