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Meet

Dee Warrington

Corporate Compliance and Risk Management Officer for LifeMasters Supported SelfCare, Inc.

PAGE 14

Medicare compliance: We found a witch!

PAGE 6

Feature Focus:

Disclosure of Financial Relationships Report: Preparing for increased scrutiny

PAGE 34

Also:

HIPAA Security Rule and the telecommuter

PAGE 53

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INSIDE

Letter from the Leadership

By Rory Jaffe, MD, MBA, CHC
HCCA President

HCCA starts LinkedIn group

I joined LinkedIn, a social network for professionals, about two years ago, when UC Davis business school announced to its alumni that there was now an alumni group on the LinkedIn site. I filled out the profile form, linked up to a few people I knew, then sat back and pretty much ignored the whole thing. I just could not figure out any use for the site, other than to collect connections—it felt like baseball card collecting.

Time passed, and then I found myself looking for a new job. I quickly learned that looking for job listings is almost a hopeless task. It would take a full-time effort just to scan the thousands of web sites and hundreds of thousands of job listings. And then, I'd have no way of really knowing what the job was like, and my prospective employer would have to guess about what Rory was like.

It was only then that I understood the virtues of networking. I had only two good sources of job information—friends and headhunters. And I usually found out about the good headhunters from friends.

Social networking suddenly made more sense. It is a wonderful way to get reliable and useful information about jobs and about prospective employees. And when you add not only your friends, but also friends of your friends to your social network, the multiplier effect greatly extends your ability to obtain reliable information. I have 52 direct connections on LinkedIn so far. But when you add in their connections—that is, friends of friends—the number soars to over 2700. That's over 2700 people who may know about jobs and can provide prospective employers with reliable information about me.

But one of the weaknesses of LinkedIn is the same problem I had when originally looking for job listings. There are over 20 million people on LinkedIn. How do I sort through all that to find the people I know? LinkedIn groups help. LinkedIn groups allow people with similar interests or backgrounds to readily find each other.

We started the HCCA LinkedIn group for that reason. Current members of HCCA can join the group and then easily find other HCCA members to connect with, and network for jobs, advice, or simply to commiserate. And compliance officers tend to have lots of reasons to commiserate with each other. I encourage you to explore the benefits of networking with other HCCA members through our LinkedIn group. Just make sure you record the same email address with LinkedIn as you do with HCCA—that's how we verify membership.

To join HCCA LinkedIn group: **http://www.linkedin.com/e/gis/83345/1D396A6BC45A**

By the time you read this, I hope to have found a job, but in case not, consider this a shameless example of networking—contact me if you know of some interesting opportunities! ■

Relationships Matter

Your professional relationships are key to your professional success.

Want more networking opportunities? HCCA has set up a LinkedIn group for our members. LinkedIn is the "Facebook" for professionals. You can join for free and set up your professional profile online, then network with colleagues and classmates. You can join the group by visiting this link: **http://www.linkedin.com/e/gis/83345/1D396A6BC45A**

How can LinkedIn help me?

LinkedIn is a place to find and leverage professional opportunities, now and throughout your career. LinkedIn enables you to:

- Present yourself and your professional capabilities
- Find and reconnect with colleagues and classmates
- Leverage powerful tools to find and reach the people you need
- Build a powerful network of trusted professionals
- Discover professional relationships and opportunities
- Tap into inside connections and information
- Get the edge that gives you competitive advantage

There are already 20 million professionals in the LinkedIn Network and that number is growing fast. Whether you seek a job, a hire, a reference, a sales lead, an expert, or an inside connection at one of 50,000 companies, LinkedIn is an irreplaceable resource for building your professional relationships and achieving your goals.

Highlights of Medicare's new Prior Determination Rule

By Cindy Shields

Editor's note: Cindy Shields is Compliance & Privacy Officer with MCBS, LLC, in Augusta GA. She may be reached by telephone at 706/667-7406 or by e-mail at CindyShields@mcbs.com.

Medicare has a new Final Rule effective March 24, 2008 that provides prior determination for certain items and services. (Federal Register, Vol. 73, No. 36, Friday, February 22, 2008, Rules and Regulations, Pages 9672 to 9679.)

If a service or item has a Local Coverage Determination (LCD) or National Coverage Determination (NCD), the patient's condition must meet certain criteria (such as diagnosis) in order for Medicare to consider the service or item medically necessary for that patient and pay for the service or item. If the patient's condition does not meet the criteria outlined in the LCD or NCD, the physician needs to furnish the patient with an Advance Beneficiary Notice (ABN) to inform the patient that Medicare will probably not pay for the item or service; and have the patient either choose to have it and pay for it, or choose to decline the item or service. If the physician does not get a signed ABN and provides the service, the physician will probably not be paid by Medicare and will not be permitted to bill the patient. In this scenario, a patient might decline a medically necessary service because he/she does not want the financial liability, but it may have been a situation where Medicare would have paid after all. (It might have meant an appeal, but it would have eventually been paid by Medicare.)

To provide a greater certainty to a patient and physician of whether a service will be covered by Medicare, section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the HHS Secretary to establish a prior determination process for certain physicians' services. The Secretary has done this by adding section (d) to 42 CFR 410.20. Detailed instructions will be issued to the Carriers via the Medicare manual.

Those eligible to request a prior determination are (a) the physician, if he/she is participating or accepts assignment and has received the patient's consent to make the request; (b) the patient, if the physician has presented the patient with an ABN. Only certain services or items will be eligible for prior determinations. These services were chosen because they are the most expensive physicians' services included in the Medicare Physician Fee Schedule (MPFS), are performed at least 50 times annually, and include plastic and dental surgeries costing at least $1,000 (not including adjustment for location). The eligible services or items are those found (on the date of the request) specifically listed (CPT code and description) on the Website of the Medicare Carrier that has jurisdiction where the services are to be rendered. CMS may require documentation to accompany the request. The Carrier has to respond within 45 days of the date of the request. Obviously, these are for services not urgently needed.

If the Carrier believes the LCD or NCD has sufficiently specific, reasonable, and necessary criteria that addresses the particular clinical indication for the procedure for which the prior determination is requested, the Carrier will send a copy of the LCD or NCD to the requestor, along with an explanation that the LCD or NCD serves as the prior determination and that no further determination will be made. Other possible written responses to the request include (a) the service is covered; (b) the service is not covered and the reason; or (c) the carrier lacks sufficient information to make the determination and the additional information that is needed. No matter the response, the beneficiary still has the right to receive the service and have a claim submitted.

An ABN should be provided if the beneficiary wants the procedure and (1) the prior determination confirms non-coverage; (2) a decision could not be made because requested information was not received; or (3) the decision on the prior determination has not yet been received. An ABN is unnecessary if the prior determination is favorable.

These prior determinations are not subject to administrative appeal or judicial review. Not seeking a prior determination will not be taken into account in an administrative or judicial review for a claim. Once a patient is provided with the service, a prior determination cannot be obtained. ■

Medicare compliance: We found a witch!

By Mark A. Bonanno

Editor's note: This article was written prior to April 15, 2008, when the U.S. Department of Health and Human Services Inspector General issued an Open Letter to Providers. Please note that the April 15 Open Letter to Providers explains that the OIG has streamlined its internal process for resolving these cases. In turn, the OIG will expect providers to complete their disclosure and damages assessment within three months from the time of acceptance into the Self Disclosure Protocol and expect full cooperation from disclosing providers during the verification of the matter disclosed.

According to the Open Letter, providers who disclose in good faith, fully cooperate with OIG, and provide requested information in a timely manner will generally not be required to enter into Corporate Integrity or Certification of Compliance Agreements with OIG.

Mark Bonanno is an Oregon-based attorney in private practice. He provides business and compliance legal services to clients in the health care industry, and may be reached by email at mab@healthlawoffice.com.

In a comedic scene in the 1975 movie *Monty Python and the Holy Grail*, a group of villagers accused a woman of being an evil witch and wanted to burn her at the stake. Acting out of fear, the villagers dressed up the woman like a witch by putting witch-like clothes on her, a witch-like hat, and a witch-like nose, just before bringing her to the knight who oversaw the village. During an on-the-spot trial, the knight ordered her to be placed on a large set of suspect weighing scales located in the village center. She weighed the same as a duck, and was therefore, judged to be a witch. As the legal logic went, a duck floats and so does wood. Witches, apparently, are made of wood, so if the woman weighed the same as a duck, she must be made of wood, and therefore, (you guessed it) she must be a witch. The woman never had a chance at a fair trial – at least one that she could have afforded.

What does this movie scene have to do with Medicare compliance? Very little, but it is a humorous story to lead off about a not-so-funny scenario in health care today. Like the poor woman in the *Holy Grail*, individuals may be accused and judged guilty of Medicare fraud by colleagues who may be acting out of fear and misinformation regarding fraud and false claims. If the individual eventually is brought before a government official, the private accusation that preceded any official public evaluation, creates a difficult—if not impossible—task of resolving the actual legal issues correctly.

The purpose of this article is to explain a procedure known as the Provider Self-Disclosure Protocol; highlight the difference between fraud, false claims, and overpayments; and discuss a hypothetical scenario that is similar to the scene from the *Holy Grail*. Afterward, some practical guidance is offered for organizations and individuals caught up in the confusing world of health care billing investigations.

So how would a health care provider, such as a physician, become threatened with the proverbial burning at the stake, like the woman in the movie from 1975? To start to answer that question, we have to go back in time again, but only to 1998.

The protocol

Shortly after the federal government's expansion of health care anti-fraud initiatives arising out of a program known as Operation Restore Trust[1] and the beefed-up anti-fraud provisions in the Health Insurance Portability and Accountability Act of 1996[2] (HIPAA), the Department of Health and Human Services Office of Inspector General (OIG) issued guidance on a new Provider Self-Disclosure Protocol in 1998 (Protocol).[3] The published intent of the Protocol was to facilitate the resolution of matters that potentially violate federal law and not to address matters involving overpayments or errors that should be brought to the attention of the Carrier or Fiscal Intermediary (that is, the insurance company hired to process claims for the federal government).[4] The Protocol set forth procedures for providers to follow in submitting their written disclosures of the matters, including a statement about why the provider believes federal law may have been violated.[5]

On its surface, the Protocol sounded nice and protective. And, in certain situations, it probably would be nice and protective. Nevertheless, what was missing from the Protocol was a roadmap of how voluntary disclosures would be evaluated by the OIG. In fact, the OIG specifically stated that it would not be bound by any findings made by the provider, and it was not obligated to resolve the matter in any particular manner.[6]

Another significant problem was that the discretion to file under the Protocol was left to the provider, whether it was a larger health care entity or an individual. Such an approach set up the potential consequence that health care organizations like hospitals would act akin to federal prosecutors and judges in both pointing a finger at an alleged perpetrator and assessing whether fraud may have occurred in their institutions. In that scenario, where a larger corporate entity attempted to scapegoat an individual, the use of the Protocol might

end up being abusive and devastating for both parties, especially in situations where the alleged fraud or false claims could be explained rationally as billing mistakes or even a negligent understanding of the billing rules.

If the Protocol is rushed to as a defensive tool for a larger entity, it could end up being a trap for the unwary. In fact, one piece of information that should be discussed more openly at seminars is the potential result that once providers file under the Protocol, they tend to box themselves into monetary settlements that start at roughly two times the amount of the alleged damages. Why? The answer is almost a "just because" answer, and it is tied back to the underlying legal basis for the Protocol.

When a provider files its disclosure, the OIG General Counsel's Office assumes that the provider, not necessarily someone who works for the provider, is admitting it may have violated federal law, namely the False Claims Act and other federal statutes, such as the Civil Monetary Penalties Law where the penalty for violations can be double or triple the amount of the actual damages.[7] Further, what the effect of any admission made under the Protocol does is subject the provider to the whim of the OIG in assessing its full range of penalties, which could include exclusion from participation in the federal health care programs.[8] And, exclusion—the true hammer of the OIG—is potentially a business or career-ending threat.

Fraud, False Claims, and Overpayments

Given that backdrop, we need to review some federal laws and the legal meaning of the words "fraud," "false claims," and "overpayments."

Fraud. Probably due to highly publicized, multi-million dollar settlements and government press releases about health care fraud perpetrators going to jail, there may be a perception that any improper payment in health care is a crime. That is a false perception. In fact, the government acknowledges:

> [T]here appear to be significant misunderstandings within the physician community regarding the critical differences between what the Government views as innocent "erroneous" claims on the one hand and "fraudulent" (intentionally or recklessly false) health care claims on the other. Some physicians feel that Federal law enforcement agencies have maligned medical professionals, in part, by a perceived focus on innocent billing errors. These physicians are under the impression that innocent billing errors can subject them to civil penalties, or even jail. These impressions are mistaken.[9]

Such an acknowledgement might provide some comfort to the vast majority of providers who just do their work, submit bills for services through a complex insurance-based payment system, and hope they got the rules right, but the impression that tripping up—just once—can lead to serious problems is not unfounded.

Many federal statutes criminalize bad conduct in the health care industry.[10] For most of the statutes, however, the state of mind a person or corporate entity must possess is that they knew what they were doing was wrong and they purposefully went ahead and did it anyway. In other words, someone actually is plotting and scheming about a way to steal money from the government. Does that really happen? Yes, fraud happens. But, do most health care providers intentionally set out to bilk the federal government? Doubtful.

Government prosecutors will state publicly that ignorance of billing rules is no defense or that the rules are clear simply because they are published on the Internet, but that is one view of the world. If a billing rule takes not only legal counsel but highly trained billing experts to figure it out, something is not quite right with the rule. Are billing rules complicated? Sometimes they are, and sometimes they are a moving target.

The federal Anti-kickback Statute is an example.[11] That law generally makes it a crime to bribe providers for their referrals. The actual language of the statute encompasses not only offers or payments for referrals but also solicitation or receipt of any remuneration for those referrals. Remuneration is a broad concept and includes anything of value, not just cash.[12] Potential application of the law is extremely broad. As the joke goes at seminars, "Are free pizzas to physicians at a hospital function illegal?" And, the lawyerly response is: "Potentially, if they are intended as an inducement for those physicians to refer their Medicare or Medicaid patients." While that is meant as a light-hearted anecdote, the law does affect many financial arrangements in health care.

Given the potential for endless application, the OIG promulgated a series of regulatory exceptions known as "safe harbors."[13] If a transaction follows an applicable safe harbor, it should be protected from prosecution. If a transaction comes close to a safe harbor, however, but is slightly off one or more elements, it is not necessarily illegal, but it will not get safe harbor protection. In addition to safe harbors, the OIG issues periodic "advisory opinions" to requestors, asking if their particular arrangement will be prosecuted as a kickback.[14] The answer only applies to the requestor, but the OIG makes the opinions available for public review. As such, advisory opinions further refine the OIG's stance on particular arrangements. Therefore, knowing precisely which transactions work, and which do not, is by no means

Continued on page 9

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crystal clear. There are lawyers that devote much of their entire practice to understanding and advising clients about the kickback and other health care fraud and abuse laws.

The point here is that compliance with Medicare rules can be a highly complex process. For that very reason alone, most billing problems of the average health care provider are not fraud, but something far less criminal.

False claims. The main statute federal prosecutors use to enforce health care billing issues is the civil version of the federal False Claims Act.[15] The nice thing about the statute from the government's perspective is that it not only provides for increased monetary damages (up to triple the amount of the overpayments), but a separate monetary penalty of up to $10,000 for each claim that is declared to be improperly filed.[16] In short, seemingly minor billing problems quickly can be turned into big dollar cases under this statute.

For example, a former in-house lawyer for a health care company was sued under the statute in 2007.[17] The lawyer apparently had signed two pieces of paper (known as certifications) that were required to be filed with the OIG and stated that to the best of her knowledge, her company was in compliance with federal law.[18] The government later found out that the company had potential Stark Law violations that, if proved, would have amounted to about $18 million in overpayments. Federal prosecutors filed a False Claims Act suit against the lawyer as an individual, arguing that her signing those two pieces of paper caused 70,000 false claims to be presented to the Medicare program. As a result, the total monetary penalty she faced was $754 million (or $18 million times 3 = $54 million … plus 70,000 claims times $10,000 per claim = $700 million). This an unusual case and novel legal theory for the government, but the point is that the False Claims Act is a powerful and fear-instilling tool in the anti-fraud arena.

The other danger for health care providers is that the statute permits folks with knowledge about potential false claims to bring whistleblower or *qui tam* lawsuits against the provider as though they were federal prosecutors.[19] For their role in the case, the whistleblower (known legally as a relator) could receive around 25% from any monetary judgment or settlement.[20] Typical whistleblowers might include a billing clerk or compliance officer who knows that many claims are not being filed properly or not being refunded if overpayments are detected.

This introduction to the False Claims Act probably sounds dreadful. In light of that dread, a question that gets asked frequently by health care providers is whether all claims submitted to Medicare that result in overpayments are false claims. The answer is an emphatic "no." A true false claim is one that you sort of had to know was false. In legal jargon, to be found guilty of filing false claims, the person either "actually knew" about, "deliberately ignored," or "recklessly disregarded" the falsity of the claim.[21]

What is "knew" or "knowingly"? The accused person must have actual knowledge that the information being presented to the government is false. Generally, this standard means that the person must be more than negligent in their understanding.[22]

What is deliberate ignorance? Well, think about a person who digs a hole in the sand, puts their head in it, and covers up their head, but somehow manages to go about their merry business of filing complex health care claims.[23]

What is reckless disregard? Here, think about a medical office manager who was told by a Medicare Carrier staff person to obtain proper billing numbers for the office providers, even though that meant more paperwork, but that manager went ahead and billed without proper numbers because the paperwork was too burdensome to do right away.[24]

In short, the main thing to take away from these legal terms is that the False Claims Act requires something more than mere negligence on the provider's part in the submission of Medicare claims.

Another more legally complex issue under the False Claims Act is the concept of causation or who actually caused false claims to be submitted for payment.[25] If you are treating a Medicare patient, deciding what codes to put on the claim form, filing out the claim form, and putting the paperwork in the mail (or rather, hitting the send button on the computer), in all likelihood and legally, you caused that claim to be submitted to the federal government. You are potentially on the hook for false claim liability if you knew the billing code you put on the claim form was a level or two higher than the level of service you knew you provided to the patient.

If, however, you work as an employee in a clinic and you treated a patient, filled out paperwork on the services provided, gave that paperwork to a billing staff person who is employed at the clinic, and waited for your salary-based paycheck to be direct-deposited into your bank account, there is a open-ended legal question about whether you caused that claim to be submitted to the government. Notably, that claim was not prepared by you, you may not have seen the actual coding put on the claim, the coding could have been changed by someone other than you, the claim was submitted by the clinic, and the list goes on. In short, causation can be a legal gray area.[26]

Continued on page 11

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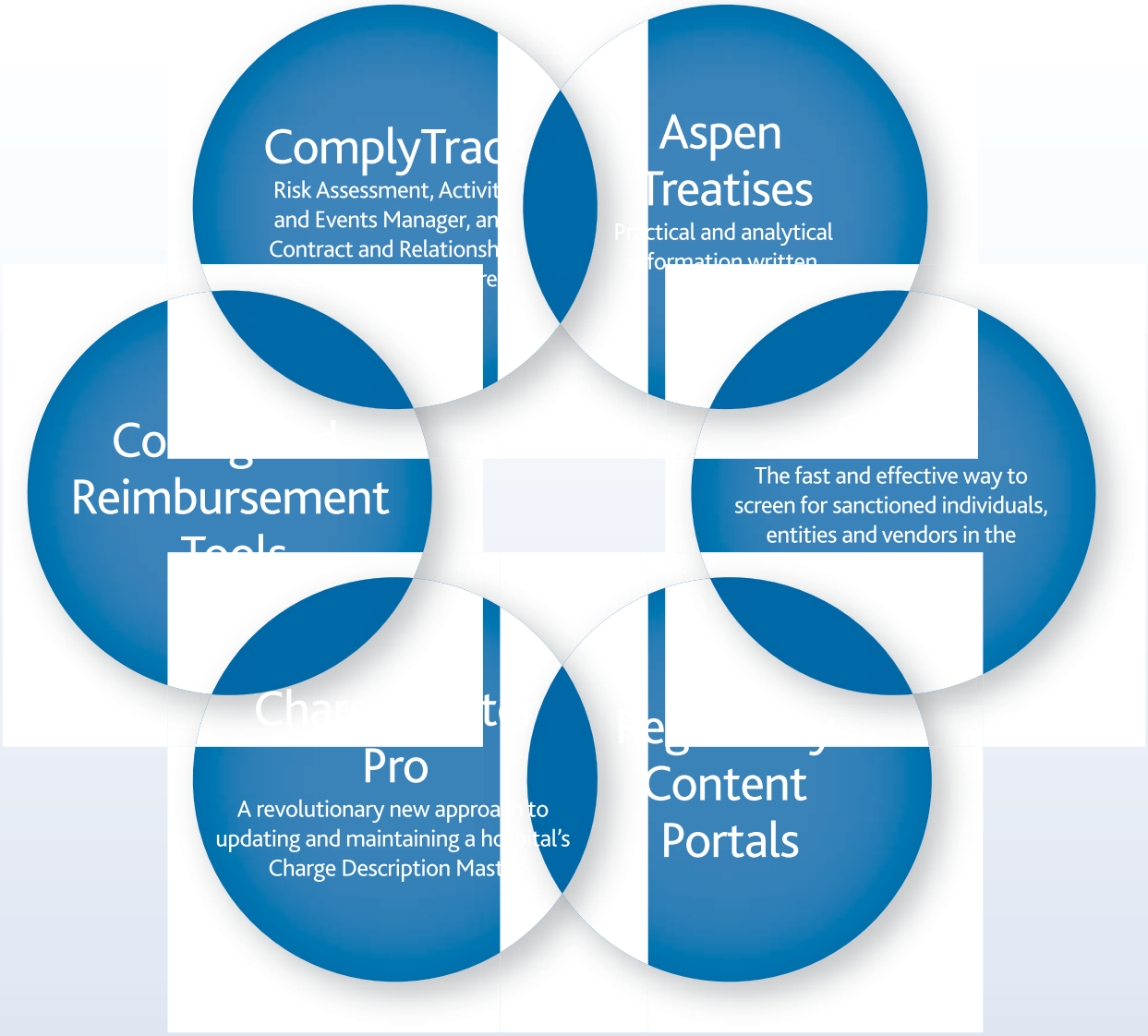

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Those are some nuances about the False Claims Act. The take home message: Overpayments are not always false claims.

Overpayments. If you have billing problems, you hope they are overpayments. In a legal sense, overpayments are payments that result from mistakes in claim processing. Notably, overpayments could even be the result of negligence in how your claims are processed. For further explanation, let us turn to the actual words of the OIG.

Periodically, the OIG issues compliance guidance for various organizations involved in health care claims submission, such as hospitals, third-party billing companies, and physicians. In 2000, the OIG issued guidance for individual and small group physician practices.[27] Specifically, the OIG stated this about erroneous claims that could lead to overpayments:

> [U]nder the law, physicians are not subject to criminal, civil or administrative penalties for innocent errors, or even negligence. The Government's primary enforcement tool, the civil False Claims Act, covers only offenses that are committed with actual knowledge of the falsity of the claim, reckless disregard, or deliberate ignorance of the falsity of the claim. The False Claims Act does not encompass mistakes, errors, or negligence. The OIG is very mindful of the difference between innocent errors ("erroneous claims") on one hand, and reckless or intentional conduct ("fraudulent claims") on the other. For criminal penalties, the standard is even higher—criminal intent to defraud must be proved beyond a reasonable doubt.
>
> [E]ven ethical physicians (and their staffs) make billing mistakes and errors through inadvertence or negligence. When physicians discover that their billing errors, honest mistakes, or negligence result in erroneous claims, the physician practice should return the funds erroneously claimed, but without penalties. In other words, absent a violation of a civil, criminal or administrative law, erroneous claims result only in the return of funds claimed in error.[28]

Not much more really needs to be said. Overpayments happen. Someone even may have been negligent in allowing overpayments to happen. None of that should amount to fraud or false claims liability.

To review, the problem with using words like "fraud" or "false claims" in health care is that those words mean something, and therefore, the words should not be used in a careless manner. Too often, billing staff, administrators, consultants, and even legal counsel engage in the "oh, my goodness" panic response when bad billing issues are first discovered. That initial response sets the wrong tone in an organization and makes it very difficult to resolve matters correctly and sanely.

The private sector must stop thinking "crime" and "fraud" when billing issues are first detected. That accusation is for the government to make. Instead, the private sector must focus on correctly identifying the issue (which is the most difficult part of any internal investigation) and appropriately developing a corrective action plan.

With the legal jargon explained a bit more, we still need a better understanding of how the Protocol works.

The Village and Dr. Goodwitch

Perhaps an example will help, so we will look at Village Surgical Group, PC (the Village), a professional corporation that operates as a unified group practice made up of a large number of physicians, let's say 25 surgeons.

Dr. Ima Goodwitch is one of the surgeons. She is a Type A personality, in the hospital at 6:00 a.m., booked for procedures and patient visits all day, and leaves the hospital in the early evening. Like a lawyer, Dr. Goodwitch believes if she works all day, she should be billing all day. She is good at recording her work day, but she has a loose understanding of coding from what was learned long ago in her early training. Nevertheless, she is prompt with her paperwork and turns it all over to the in-house administrative staff back at the Village so she can put it out of her mind. The Village gathers the paperwork and turns it over to a third-party billing company that prepares and processes the claims. All billings go out under the Village's tax identification and group number, but Dr. Goodwitch is paid basically on an "eat what you kill" basis, with a percentage retained for the billing company and the Village administration. This is a fairly common scenario so far.

One day, however, the Village administrator creates a new policy that all Village surgeons will be subject to retrospective claim reviews as part of a brand new compliance plan (the Plan). A retrospective review means that claims already have been processed and payment has been received by the group. In contrast, a prospective review would look at claims that have been coded by the provider but are awaiting submission for payment. If problems are detected in a prospective review, the claims could be corrected prior to submission to avoid potential overpayment situations. According to published OIG recommendations, a sample of five claims will be reviewed and critiqued annually.[29] On paper, this policy does not sound too burdensome and should be fairly benign. The surgeons think nothing of it, approve the Plan, and let the administrator get to work.

Continued on page 56

Teachable moments: How a local disaster provided a HIPAA training opportunity

By Darrell W. Contreras, Esq, CHC

Editor's note: Darrell Contreras is the Chief Compliance Officer at Lakeland Regional Medical Center in Lakeland, Florida. He may be reached by telephone at 863/687-1155 or by e-mail at Darrell.Contreras@lrmc.com.

On Wednesday morning, January 9, 2008, more than 70 vehicles collided on Interstate 4, approximately 30 miles southwest of Orlando, Florida. The cause of the collision was low visibility from a mixture of fog and smoke from a nearby brush fire. As a result of this crash, Lakeland Regional Medical Center, the regional trauma center, was put on a "Code 2 alert", meaning that the hospital, which was already experiencing a very high census, had to prepare to receive additional seriously injured patients.

With fluid motion, the hospital activated its emergency response plan and made arrangements to receive an unknown number of patients. Remarkably, to the credit of the staff, operations appeared to run so smoothly that an outside observer would likely never have known anything was out of the ordinary. As events unfolded and details began to emerge, it was apparent that there were some fatalities and scores of injuries.

The timing of this tragedy coincided with our efforts to publish and promote the "Three HIPAA Rules"— an approach to providing guidance to caregivers on how to evaluate HIPAA issues. Simply put, the rules are:

1. Is using or disclosing this patient information in the best interest of the patient? If yes, then the "best interest" reason must be documented. If no, then the information may not be used.
2. Do I need to use, disclose, or access this patient information, whether verbal, paper, or electronic, to do my job? If "yes", then the information may be used, disclosed, or accessed. If "no", then the information may not be used.
3. Protect your password—log off your workstation when you walk away.

These rules are not intended to be exhaustive and are used only to guide caregivers towards identifying whether they need to seek additional guidance (e.g., call the Compliance Officer).

This tragedy presented the opportunity to apply these rules in a real-time situation. In any event that receives national media attention, there are always two concerns for protecting the privacy of the patients brought to the hospital: (1) people giving out information to unauthorized people; and (2) unauthorized people, including staff, viewing the patient files. Not too long ago, these concerns were faced by a hospital in New Jersey after actor George Clooney was involved in a motorcycle accident. Though Clooney's injuries were minor, the event received national media attention and resulted in several hospital employees being suspended without pay for inappropriately accessing Clooney's medical information. Knowing that similar public interest and curiosity could occur here, it was important to act quickly to provide "just-in-time" education and guidance.

At Lakeland Regional Medical Center, e-mail is used as a communication medium to provide updates during alert situations, like this, to members of the management team. A timely e-mail from Public Relations helped to address the first concern about providing information to unauthorized people by reminding all staff to direct media inquiries to the Public Relations department. To address the second concern about unauthorized people viewing patient records, a follow-up e-mail was sent to all members of the management team with the heading, "This is a Friendly HIPAA Reminder."

The "Friendly HIPAA Reminder" began with a request: "Please talk with your staff today about only accessing patient files and records that are needed to take care of their patients" and the correlation between this request and the I-4 disaster. The message also included a "Friendly HIPAA Reminder" that routine audits of patient accesses are conducted, noting that we wanted to avoid problems of inappropriate access. At that point, the stage was set to remind employees about Rule 2 of the "3 HIPAA Rules" that applied to this situation:

> If there are any questions regarding what is appropriate access, please refer to this rule:
>
> Do I need to access or use this patient information, whether verbal (talking about the patient to others), paper (the patient's chart), or electronic (the patient's records and information on the computer) TO DO MY JOB? If the answer is "Yes", then it is okay to access or use the patient information. If the answer is "No", then do not access, use, discuss, or review the information.

Were the e-mail reminders effective? The best way to gauge whether the reminder was an effective measure to address the "curiosity factor" is to do an audit. Audit results validated that there appeared to be no inappropriate

access to any I-4 accident patient files. In addition, several members of the management team expressed their appreciation at having the "just-in-time" reminder that provided their staff with precisely the guidance needed.

The best gauge that we had regarding whether the e-mail from Public Relations was effective came later that evening from a local news report. Local news media reported that they had made several attempts to call the hospital to obtain information about patients. The report lamented that they were not given any patient information because of "the hospital's privacy practices." The reminders worked!

Under the HIPAA Privacy Regulations, there is, of course, some information that can be provided to the public and the media without infringing upon the privacy rights of patients. In this case, however, the Public Relations department worked behind the scenes with the patients prior to the media requests to determine whether they wanted information released; the patients declined, resulting in the media's report of being unable to obtain patient information. Although good media relationships are important, in the eyes of a public that is increasingly more concerned about privacy, it is better for the hospital to be perceived as one that will not give out patient information instead of as a place where people can call and be given any and all details about a patient. As such, the media report represented a HIPAA success in the constant battle to protect patient privacy and presented another teachable moment.

Once again, the e-mail distribution mechanism was chosen to announce the success with the subject line: "HIPAA, HIPAA, HOORAY!" The e-mail asked management to take the time to thank their staff "for their continued commitment to patient privacy." However, as noted above, it is important to provide clarification about when it is appropriate and not appropriate to give out information. To address this, the e-mail message reiterated Rule 1 of the "Three HIPAA Rules": Is using or disclosing this patient information in the best interest of the patient? The e-mail message continued with the reassurance that if there is any discomfort or question about whether the rule applies, that it is okay to ask for help.

In a little more than 24 hours, this tragedy provided the opportunity to provide HIPAA

Continued on page 25

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01/08

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.

10TH Annual Survey CORRECTION:

A correction has been made to the Compliance Officer Salary Q 51c in the 10th Annual Survey on page 26. The correct information is:

Q51. Annual base salary of the Compliance Officer, By Total Revenue of the Health Care Organization

- $100 million = $82,418
- $100 to $299 million = $96,390
- $300 to $599 million = $104,471
- $600 million or more = $118,591

Link to Corrected 10th Annual Survey: http://www.hcca-info.org/survey10

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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:

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feature article

Meet Dee Warrington

Corporate Compliance and Risk Management Officer and Chief Privacy Officer for LifeMasters Supported SelfCare, Inc.

Editor's note: HCCA Board Member Jennifer O'Brien conducted this interview with Dee Warrington in April 2008. Ms. Warrington may be reached by telephone at 757/337-0693 or by e-mail at dwarrington@lifemasters.com.

JO: Tell us a little bit about your background and what brought you to your current role as a compliance professional.

DW: At LifeMasters Supported SelfCare, Inc. (LifeMasters), I am responsible for the day-to-day operations of the compliance, enterprise-wide risk management, and privacy programs. I have been working with LifeMasters since 2005, when the company began providing disease management programs and services to the Medicare/Medicaid markets and began to create and formalize its voluntary compliance program. I have been working in healthcare for 12 years, primarily in operations or what I refer to as "the trenches." Prior to my current position at LifeMasters, I have held various positions within the healthcare industry. I served as the privacy officer at a healthcare technology organization and held other positions with Aetna and WellPoint in the areas of contract compliance and quality management. I have an undergraduate degree in business, and I am currently pursuing a Graduate Certificate in Health Care Compliance at the George Washington University.

JO: Tell us about LifeMasters and the services it provides.

DW: LifeMasters (www.lifemasters.com) is a disease management company with a primary focus on delivering disease management solutions that improve health outcomes while significantly reducing costs. The company was founded in 1994 by David E. Goodman, MD, a Harvard-trained physician with the vision of creating a coordinated approach to preventive care for chronic illness, rather than simply managing the condition. Since its founding, LifeMasters has been focused on one mission: to empower individuals living with chronic diseases to achieve optimal health. Almost 14 years later, LifeMasters is one of the largest and most widely recognized disease management providers in the nation. LifeMasters offers programs for individuals with, but not limited to, asthma, diabetes, cancer, congestive heart failure (CHF), coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD) hypertension, depression, diabetes, and metabolic syndrome. LifeMasters' programs are holistically focused, offer support for co-morbidities, and facilitate lifestyle changes such as smoking cessation and weight loss.

LifeMasters services over 600,000 participants from six locations and has over 1,000 employees. Our clients include some of the nation's leading health plans, employers, retirement systems, and governmental organizations.

JO: You position includes accountability for compliance, risk management and privacy. Do you differentiate between the roles, and if so how?

DW: I try not to differentiate between the roles, but since I am still 'integrating', it is hard not to differentiate. I am striving for a program that fully-integrates all three disciplines: compliance, enterprise-wide risk management, and privacy. The compliance program is in place; however, we are still integrating the enterprise-wide risk management and privacy program. I inherited the privacy program as of January 2008. Like every other compliance officer, I am figuring out what is best for our culture and how to utilize the program that works best for us.

JO: What are you seeing as factors that are pushing disease management organizations to develop more formal and substantive compliance programs?

DW: For stand-alone disease management organizations, like LifeMasters, there are three primary factors: (1) client contract requirements, (2) NCQA/URAC [National Committee for Quality Assurance/Utilization Review Accreditation Committee] accreditation requirements, and (3) DMAA [Disease Management Association of America] compliance program guidance. I think more importantly, for LifeMasters, we see the benefits of implementing a voluntary compliance program. We relied on the published compliance program guidance issued by the OIG/HHS for the various sectors of the health care industry when developing our compliance program.

JO: What are some of the unique compliance challenges that you face working in disease management?

DW: The hot topics right now in disease management are with the health and wellness component:

- HIPAA's non-discrimination and wellness rules
- HIPAA's privacy requirements
- The American With Disabilities Act
- COBRA health care continuation requirements
- Tax withholding and reporting requirements

The rules do not prevent the establishment of disease management and health and wellness programs. The rules simply create hurdles which require sufficient knowledge in order to effectively navigate around or over such hurdles. Thus, the challenge is identifying the issues so that risks can be avoided and/or mitigated.

JO: What are the biggest compliance risk areas for your organization?

DW: Participant status and billing are two of the biggest compliance risk areas. We bill by participant status; therefore, it is vital that our participant status requirements are fully understood (the participant is in the right status at the right time) and we have effective internal monitoring in place.

JO: You are Chair of the Compliance Committee for the DMAA: The Care Continuum Alliance. Tell us about the DMAA and some of the compliance challenges you are working to address.

DW: DMAA represents more than 200 corporate and individual stakeholders, including wellness, disease and care management organizations, pharmaceutical manufacturers and benefits managers, health information technology innovators, biotechnology innovators, employers, physicians, nurses and other health care professionals, and researchers and academicians. DMAA convenes all stakeholders who provide services along the care continuum toward the goal of population health improvement. These care continuum services include strategies such as health and wellness promotion, disease management, and care coordination.

The biggest challenge we have addressed is regarding the need to bring more states under the Nurse Licensure Compact (NLC). Disease management programs offered by DMAA member organizations frequently employ nurse advice lines, tele-nursing call centers, home health and long-distance patient monitoring, hospital follow-up care, and disaster mobilization. It is critical that nurses who cross state lines are able to comply with state licensure laws. The increased mobility of the nursing workforce further underscores the need for licensure reciprocity laws.

Other challenges are related to establishing best practices and guidelines in the high risk areas of community outreach, longitudinal

record maintenance and transfer of patient records, and in the care coordination of highly sensitive confidentiality issues such as abuse, minor consent, and mental health.

Also, the compliance committee is addressing the fundamentals, such as developing and publishing voluntary compliance program guidance for disease management organizations, and is currently working on a code of conduct toolkit.

JO: What have you found to be the most valuable type of information in your day-to-day work?

DW: Being involved and in-touch with the frontline and middle management who are responsible for the day-to-day operations. When I interact with and listen to them, I am able to identify issues that my area may need to weigh in on or I have identified as potential risk(s) that need to be addressed. I make myself available by annually visiting our six locations and by participating in operational committees and workgroups.

JO: In your opinion, what is the most important component of a compliance program?

DW: I feel all the components are important in order to have an effective compliance program; however, if I were to choose one, I

Continued on page 18

would choose leadership support; without it you are not going to have an effective or robust program. You will end up frustrated and struggle to get any kind of attention. To be effective, the program must have full support from the board and management.

JO: What have you found to be the single biggest challenge in your role and how have you overcome it?

DW: The biggest challenge is coordinating our activities with other functional areas and their activities. It is easy for them to view compliance and risk management as yet another program that is going to impede them from doing what they want to do. It has been a slow process, but the staff is beginning to see the value in our function and is coming to us on a regular basis as a resource. This allows us to do what we do best, which is to give them the information they need to help them make better business decisions.

JO: What types of resources have you found to be valuable as you maneuver through the ever increasing regulatory challenges in your day-to-day work?

DW: We use multiple online resources, but nothing can replace the value of attending conferences and seminars hosted by the DMAA, HCCA, HIPAA Summit, and SCCE [Society of Corporate Compliance and Ethics]. Having the opportunity to learn from and network with other compliance professionals is an invaluable resource. Also, we take full advantage of compliance listservs, journals, magazines, and Webcasts. We also rely on our outside counsel, lobbyists, and policy consultants to provide us with regulatory updates.

JO: What recommendations do you have for someone just starting out in compliance and for setting up a compliance program?

DW: I have many recommendations but here are my top five:

1. Roll up your sleeves. Learn the "ins and outs" of the organization. This is where you will find the most interesting problems and risks.
2. Build strong working relationships throughout the organization by being accessible, a good listener, and responsive, as well as one who offers recommendations and solutions.
3. Trust but verify. Do not assume anything or act like everything is a crisis; more than likely, it is not. All you have is your credibility, and you risk losing credibility when you make something bigger than it is. Save the red flag for when you need it, so that the issue gets the attention and support it deserves.
4. Be patient and persistent. Developing and implementing a compliance program is a huge undertaking that requires many resources. You will encounter roadblocks.
5. Maintain your personal integrity and be willing to walk away from any company that is putting your reputation at risk.

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

DW: There is a lot of value in attending the annual HCCA Compliance Institute. The sessions are very diverse and allow you an opportunity to network with other compliance professionals. I like the Industry Immersion tracks because the sessions allow you to learn and share experiences with your peers. At future annual HCCA Compliance Institutes, I would like to see disease management organizations, health and wellness providers, and employer groups recognized as industries and given an opportunity to host Industry Immersion sessions.

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

DW: I visit with my two granddaughters as much as possible, Madyson and Makenna. Madyson is two, and Makenna is 10 months old. Our visits are not too relaxing, but they are very fun! They keep me grounded and remind me of what is truly important in life, which is to "be in the present – not the future – not the past – just the present." ■

Letter from the CEO

Why are we where we are?

We have more opportunities for members to get involved, because of the non-bureaucratic culture of our organization. Most importantly, we are a successful organization because of the talent of our membership.

We have problems and frustrations just like any other organization. However, we don't have the kind of problems that other organizations do. Our problems are associated with our entrepreneurial, fast-paced, risk-oriented approach. We want to get as many people involved as we can. As a result of our 50 compliance conferences, 48 audio conferences, four certifications, two magazines, and a myriad of other activities, we get a lot of people involved. You may see some people whose names come up regularly. Because of the number of things we do, we have to rely on some people to help regularly. The real question is, "How many people get to be involved in our organization compared to other professional organizations?"

Opportunities come from growth and risk. Growth and risk comes from entrepreneurial behavior. If you want to see limited opportunity, join a bureaucratic, constipated, committee-run organization. "No" is the word of the day. Everything has to be approved, overseen, changed, analyzed, and watered down to make sure everyone is happy and on board.

If you count meaningful work, not just superficial, resume stuffing committee assignments, I would put our organization up against any other for generating opportunities for members to get involved. We want more people involved and to do that, we have to keep growing, take risks, move quickly, delegate, and trust. We must also mange and tolerate the challenges associated with that approach.

Other organizations have pre-meeting meetings to discuss who should be invited to meetings. There are meetings to examine all of the political ramifications of the topic to be discussed at the meeting. They discuss who would be offended or not offended by being included or not included. We, on the other hand, think of an idea and take action. We ask someone to get it done. If someone else is offended by not being included, we try to find something for them to do and we get that done too. We have more resources to accommodate all these requests to be involved, because our resources are not tied up in meetings, political discussions, and endless ruminating about ramifications.

We have approximately 150 people writing articles each year. If you count people who promise to write articles, that number mushrooms to well over 300. Approximately 50 people are involved with our certifications annually. With 50 conferences, we have over 750 new speaking opportunities annually. No association anywhere near our size can touch this number. We have approximately 100 people involved in the speaker selection process for our 50 conferences. Approximately 100 people help with the audio conferences annually. Many people are involved in product development, Website content, and a myriad of other projects.

In this article I talk about our very talented, experienced, intelligent membership and our organization's operational culture. As I mentioned, we have our own problems, but in the long run we grow faster, do more, and have more opportunities than other organizations. To create more opportunity, we all can't be involved in every decision. We have to be willing to take risks and make mistakes. We are better off because we often delegate to individuals and trust them, rather than delegating to committees. It's not easy to do it the right way. In this article I discuss why we are the way we are, and the challenges and compromises associated with our approach.

Why are we the largest compliance and ethics organization in the world? I must admit, it is an assumption on my part, that with 6,600 members (5,500 HCCA 1,100 SCCE), we are the largest compliance and ethics professional association in the world. It is the largest I have ever heard of. Nevertheless, we are very successful because we do things differently than others, and we have people who know this profession better than most.

We are where we are because we have a large number of people who know what they are doing. We have people who know the profession and where it's going. They know what is important and what is not. They are not trying to push their own agenda or trying to cash in on the compliance/ethics surge. We also have a system that allows them to be effective. The system or culture we have is unlike many non-profit membership organizations that become bureaucratic, indecisive, and compromising.

Continued on page 21

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!

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The People

Our members, speakers, conference program chairs, authors, our board, and our committee members have practical knowledge of our profession. We have many people making hundreds of good decisions every month. Our people are practical. They get to the point. They know what they are doing because they have lived this profession. They are not caught up in glamorous fringe issues, but rather, they understand the profession at its core. More than anything, they know where this profession is going, because they know where this profession has been, and they know what is important.

Generally speaking, people are not picked to work on projects because of who they are, who they work for, what degree they have, or how much money they are willing to give. Volunteers aren't assigned to tasks because they are the most vocal or most powerful. People are assigned to tasks because they know what they are doing. We have the courage to assign the right task to the right person. Because we put the right people on a project, we have a greater return on investment (ROI). That increased ROI gives us more resources to get more people involved.

This is not always easy. It's often easier to go with the flow and assign tasks to people who insist on working on something. It often easier to pick the person who would be the most upset if they were not chosen. It is also a temptation of many organizations to assign everyone who wants to work on a task to the task. The world is full of people who can't say no and believe more is better. Sometimes more isn't better. Others accomplish tasks through extreme collaboration and by setting up a series of committees. If you work hard enough on anything, you can ruin it and waste resources. There is so much to be done that there is no need to be so inefficient. We try to think about long-term gain as opposed to short-term gain.

There are too many people to mention who exemplify the knowledge of this profession. Just look at the Website, magazine, or brochures. Not only do people know what they are doing, but they come from many different perspectives. They represent the best of the best: compliance and ethics officers, consultants, academics, regulators, risk managers, auditors, certified fraud examiners, outside lawyers, CEOs, vendors, etc. We have specialists in ethics, risk, law, compliance, hotlines, auditing, disclosure, education, etc.

We now have experts from 45 different industries and 12 countries. Collectively, these people have a deep understanding of the profession and all its components. With the aforementioned diversity of thought and experience, we minimize group think. Because we have involvement from many sectors of this profession, we get a balanced and realistic look at the practical implementation of compliance and ethics programs.

Tasks are delegated to a limited number of experts who get input from others, but they are not forced to over-engineer everything to keep people happy. It is difficult for people on the fringe of our profession to keep things simple, because they are inexperienced and/or lost in the details. We delegated tasks to volunteers who get along, are trusted, avoid minutia, and pick a date and finish. Sometimes a project requires attention to minutia or a hard-charging pit bull. It is not often, but we make sure we get the hard chargers, and we back them when the going gets tough.

Our members are experienced. People who know what they are doing can keep projects simple and too the point. People who don't know what they are doing have to include everything they can think of in a project. They do that because they don't know what's really important and can't sort the wheat from the chaff. Our volunteers are not theoretical. Our people want to get it right, but they understand the practical limitations that we have to deal with in the real world. Over the last 12 years we have been very fortunate to have assembled some of the very best compliance and ethics professionals in the business.

The System

We don't do it with a committee when a collaborative and knowledgeable individual will do. We don't write a white paper when a memo will do. Authority, accountability, and responsibility are often delegated to an individual or two, and we trust them. Much more gets done in our system. We get a better result than others do. A great example of this is Debbie Troklus, who runs our certification program. She has a Board, but they don't meet just to meet. They don't meet to think big things and tell others what to do. They get the right people together when they have a specific and a defined task. They hire experts to guide them, and follow their lead. If someone decides they know better and they don't, we don't cave in just because they are powerful, loud, confident, or just to keep the peace.

Joe Murphy shared an old saying with me "Don't let perfection be the hobgoblin of the good." That may apply to professional associations more than any other type of entity. Many people think that if they can make something a little better, it should be changed. Things rarely ever get done on time with that approach. Some things just fall by the wayside altogether, because people get frustrated and tired of the endless additional ideas and change. Some believe most of the important work on a project is accomplished

Continued on page 68

The Federal Sentencing Guidelines: How low can judges and courts go?

By Gabriel L. Imperato, Esq, CHC

Editor's note: Gabriel Imperato is the Managing Partner of the Fort Lauderdale office of Broad and Cassel. He is a member of the Health Care Compliance Association Board of Directors. He can be reached by telephone at 954/745-5223 or by e-mail at gimperato@broadandcassel.com.

Implementing an advisory Federal Sentencing Guidelines system continues to challenge federal judges and alter the landscape in compliance convictions. On January 7, 2008, the US Supreme Court ordered the First Circuit Court of Appeals to reconsider its July 2006 decision in *Thurston v. United States*. The Supreme Court ordered the appellate court to reverse a three-month prison sentence on a former health care executive convicted on a charge of conspiracy to defraud the Medicare program.

This latest chapter in the struggle to understand reasonable sentencing after *United States v. Booker* gives new insight to how federal courts will use the Sentencing Guidelines in future health care fraud cases. These decisions have far-reaching implications for the future application of the United States Federal Sentencing Guidelines to Organizations. Prior to *Booker*, judges would look at how an organization's compliance program measured up to the enhanced compliance requirements called for by the Sentencing Guidelines Amendments of 2004. The Amendments emphasized the need to promote an organizational culture that encourages ethical conduct and exercise due diligence to prevent and detect misconduct.

Since *Booker*, the compliance landscape has changed. The decision in *Booker*, as demonstrated in *Thurston*, makes it unclear whether courts will credit organizations for less-than-complete compliance programs. Now that the Guidelines are advisory, how will courts view the programs that aren't in perfect compliance? These cases underscore the individual and corporate consequences of an ineffective corporate compliance program. The average federal sentence faced by corporate executives had been increasing, but now, the impact of an advisory guidelines scheme has removed the boundaries in sentencing.

The case against Thurston

William Thurston was a senior vice president of Damon Clinical Testing Laboratories, Inc (Damon Labs). Thurston was convicted for his role in a scheme to defraud Medicare and originally was sentenced to three months imprisonment with a recommendation that the term of imprisonment be served in a halfway house. Thurston's sentence was appealed by prosecutors as being too lenient. On two separate occasions, the Supreme Court has turned back this case, based on rulings that the Sentencing Guidelines do not require the district courts to impose sentences within fixed ranges and "lenient" sentences may be upheld when made with proper justifications.

The case against William Thurston was based on the theory that between 1988 and 1993, Damon Labs added a ferritin blood test to LabScan, a panel of blood chemistry tests. The ferritin test had been infrequently ordered by physicians prior to its addition to the LabScan panel. The addition of the ferritin test to the panel was part of a scheme that the government alleged was developed by Thurston and others at Damon Labs in response to a 16% reduction in Medicare fees paid to laboratories in 1987. The government further alleged that Damon Labs concealed the new test, then charged doctors and patients little or no extra fee for the added test. What's more, Damon Labs executives concealed the fact that the company was charging Medicare for the added test. In October 1996, Damon Labs pleaded guilty to conspiracy to defraud Medicare and paid $119 million to the US government in fines and related civil liabilities.

Thurston and former Damon Labs president, Joseph Isola, were indicted on a single count of conspiracy to defraud Medicare by billing for the blood tests determined to be medically unnecessary in most cases. Isola pled no contest to the charge and was sentenced to three years probation along with a $100 special assessment. In December 2001, a jury convicted Thurston of conspiring to defraud Medicare by inducing the unnecessary ordering of the ferritin test. The district court judge's sentencing decision to depart downward more than 16 levels from the Guidelines launched a firestorm.

Background: The Federal Sentencing Guidelines

In 1987, Congress enacted the Sentencing Guidelines which established the US Sentencing Commission, created sentencing guidelines, and made all federal sentences determinate or fixed. Under section 5K2.0(c), a sentence departure could only be based on characteristics or circumstances outlined in the Guidelines. Congress' goal was to diminish disparate treatment of individuals or organizations convicted of a federal offense, including health fraud. Judges could depart from the guidelines, upwards or downwards, but the guidelines instructed judges on whether specific factors could be considered and how much weight they could be given.

In 2003, the Sentencing Commission created

Continued on page 24

amendments to the Guidelines that prohibited and otherwise limited sentencing guidelines departures in a wide variety of cases. In many cases, defendants had come to depend on departures which could be the only means of mitigating sentences. Two years later, the United States Supreme Court released an opinion in *United States v. Booker* in which the Court struck down the mandatory provisions of the Federal Sentencing Guidelines, thereby requiring district courts to focus on the broader range of factors under consideration when imposing sentences and requiring appellate courts to review the sentences for reasonableness. What the Supreme Court's decision means to health care executives and compliance officers who face indictments on fraud charges is that their sentences were no longer bound by or limited to the range defined in the Guidelines.

When Senior District Judge Edward Harrington decided to reduce Thurston's sentence several steps away from the Guidelines, a litany of appeals followed. The federal courts would need to decide what deference the Guidelines should have in Thurston's case.

The tug of war over Thurston's sentence

A 1998 indictment charged Thurston and other former Damon executives with conspiracy to defraud the United States and the Health Care Financing Administration. Thurston was convicted. Under the Federal Sentencing Guidelines, Thurston's sentence should have been between 63 and 78 months; the sentence would then be capped at 60 months based on the statutory maximum imposed under 18 U.S.C. § 371 (the statute governing conspiracy to defraud United States). At Thurston's first sentencing hearing in 2002, the government demanded the maximum sentence, but the district court imposed a sentence of three months—with a recommendation that the term of imprisonment be served in a halfway house—and three months home detention followed by two years probation. Judge Harrington's decision to grant a downward departure was based on his assessment of Thurston's good works and the disparity between his and Isola's sentences.

Thurston appealed the conviction and the Department of Justice (DOJ) appealed the sentence. The government argued that Thurston should have received 60 months, the statutory maximum. Prosecutors complained that the sentence—a departure of more than 16 levels from the Guidelines—went too far.

The First Circuit court rejected both bases for departure, vacated the sentence, and remanded the case for the district court to impose the statutory maximum of five years. First, the appellate court found that while a "good works," departure is permitted under the Guidelines, it is generally discouraged and allowed only when such works are exceptional. The court found that Thurston's works were not extraordinary and that the district court should not have used them as a basis for departure. Next, the court stated that in the First Circuit, judges may not depart downward based on a need to "equalize sentencing outcomes for similarly situated co-defendants, without more." The court of appeals found that the obligatory "more" was lacking and ordered Thurston be resentenced.

Thurston appealed again, taking his case to the Supreme Court of the United States in 2004, and in January 2005, the Court reversed the appeals court ruling in light of *United States v. Booker*. The Court ordered that Thurston be resentenced using the Guidelines in an advisory capacity.

A second district court judge reinstated the three-month sentence stating that a five-year sentence would engender public disrespect for the legal system. The DOJ appealed a second time, asking the First Circuit to reinstate the five-year term. Again, the First Circuit ruled that a three-month sentence as too lenient when the sentence recommended for the crime was 60 months. The court of appeals once more vacated the sentence, this time with instructions not to sentence Thurston to less than 36 months. The government appealed yet again.

In the meantime, the Supreme Court decided a case styled *Gall v. United States* (2007) in which the Court considered a downward departure that granted the petitioner probation when his co-conspirators received sentences of nearly three years. In *Gall*, the district court judge based the departure on the petitioner's voluntary withdrawal from the conspiracy leading to the convictions, as well as Gall's post-offense conduct (which included finishing school and getting a job). The appellate court found the 100% variation was not supported by the necessary "more" required for such a departure. Here, as was the case in *Booker,* the Supreme Court considered the degree of deference commanded by the now-advisory Guidelines. The Court concluded that a district court judge must, when departing from the guidelines, explain the appropriateness of an unusually lenient (or harsh, as the case may require) sentence with sufficient justifications. The Court then added that appellate courts may consider the extent of deviation from the Guidelines, but could not require extraordinary circumstances or employ a rigid mathematical formula when determining the strength of the justification for a specific sentence.

The government appeal reached the Supreme Court and in January 2008, the Court vacated the appeals court judgment, and remanded that case for further consideration in light of *Gall.* At press time, there were no

further filings in this case. This ruling seems to establish *Booker* and *Gall* as the bookends in determining whether and how courts can depart upward or downward from the Sentencing Guidelines.

Federal courts continue to seek appropriate sentences for the most serious Medicare fraud offenders. In view of the new standards following *Booker* and *Gall*, as they relate to departures from the Guidelines, and this new decision ordering the First Circuit to review its decision, it will become less likely that white collar convictions will result in by-the-book sentencing.

As more cases and appeals are decided post-*Booker* and post-*Gall*, uncertainties regarding sentencing will be necessarily be resolved. What also becomes less clear is how the courts will judge compliance programs that do not exactly meet the 2004 Amendment enhancements. The courts will no longer use the seven criteria as hard-and-fast rules. The lack of certainty asks organizations, and individuals, to consider what the limits for judges and sentences will be in this new era of compliance; and thereby, whether their efforts at compliance are enough to fit within the new boundaries. ■

Teachable moments: *...continued from page 13*

training without detracting from staff efforts to care for patients. By promoting these three rules, a majority of the HIPAA situations that our caregivers face on a daily basis can be addressed. Moreover, the rules were provided in the context of a real-time situation that made it easier for them to understand how the rules apply to their daily lives. Lastly, because of the news report, staff were able to see these teachable moments in a successful and positive light. The response from the staff and the successful experience serve as further encouragement to always look for teachable moments, even in the face of tragedy. ■

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Inserted in this issue of **Compliance Today** is a quiz related to the article: "Medicare compliance: We found a witch!" by Mark A. Bonanno beginning on page 6.

To obtain your CEUs, take the quiz and print your name at the top of the form. Fax it to Liz Hergert at 952/988-0146, or mail it to Liz's attention at HCCA, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Questions? Please call Liz Hergert at 888/580-8373.

Compliance Today readers taking the CEU quiz have ONE YEAR from the published date of the CEU article to submit their completed quiz.

Medicare outpatient rehabilitation service compliance

By J. Trent Casper, MPT, CHC

Editor's Note: Trent Casper is a Senior Compliance Consultant with Intermountain Healthcare in Salt Lake City, Utah. He can be contacted by e-mail at trent.casper@intermountainmail.org or by phone at 801/442-1501.

Rehabilitation services for Medicare beneficiaries are essentially those procedures and treatments rendered by, or under the oversight of, physical therapists (PT), occupational therapists (OT), and speech-language pathologists. The needs addressed by rehabilitation therapists are diverse, but are most readily classified as related to orthopedic, neurological, or medical conditions. Orthopedic concerns may include trauma-related injuries to ligaments, muscles and joints, low back and other painful conditions, and post-surgical care. Rehabilitation involves restoring function through strength training, range of motion and other exercises, and through use of physical modalities such as heat, cold, and electricity to address pain. Neurological conditions may result from strokes, tumors, or other disease processes that result in deficits in communication, cognition, memory, muscle strength and coordination, and motor control. Therapy professionals focus on improving functional independence in persons with these needs through a variety of training and retraining techniques, and through patient and caregiver education. Therapy professionals also participate in the treatment of medical-related conditions that lead to weakness, loss of function, difficulty swallowing, non-healing wounds, etc.

Rehabilitation professionals provide services to Medicare beneficiaries in a variety of settings (e.g., inpatient hospital acute medical floors and intensive rehabilitation units, outpatient hospital and private practice clinics, skilled nursing facilities, etc). The focus of this article will be on the unique compliance concerns related to providing therapy in an outpatient setting.

The volume of outpatient rehabilitation care provided to Medicare beneficiaries is considerable at this time, and is sure to grow as the average age of the American population continues to increase.

Rehabilitation services compliance concerns

Certain idiosyncrasies in how outpatient rehabilitation services are provided and charged to Medicare present some unique compliance concerns.

Serial billing

One element is the fact that rehab treatments are typically provided over several visits encompassing weeks, or even months, in cases of serious need. This requires charge accumulation and serial billing to Medicare and repeated filing of Medicare secondary payer forms to meet Medicare billing requirements. Failure to have a process in place that adequately addresses these billing needs can lead to payment denial and/or payment delay.

Physician certification

As a condition of payment for outpatient rehab services, Medicare requires that therapy patients are under the care of a physician or non-physician practitioner (NPP), if allowed by state regulation, at the time that therapy was received by the patient. In conjunction with this oversight, rehab services must be provided according to a plan of care (POC) established by a physician, an NPP or a licensed therapist. This POC is required in order to bill Medicare, must be specific to the patient's needs, and must be certified by date and signature of the physician or NPP.

The certification process has historically been a 30-day time period for outpatient rehab services. The 2008 Medicare Physician's Fee Schedule Final Rule extended the certification period up to 90 days. This extension in the time period is viewed as significant paperwork relief by rehabilitation therapists and was effective as of January 1, 2008. If these all-important certification forms are not appropriately signed and dated by physicians/NPPs, the service provider is at risk for receiving a non-appealable technical denial by Medicare for all therapy services provided during that certification period. Most physicians and NPPs review, sign, and return the forms promptly, but there are those who do not, thereby leaving the rehabilitation professional at risk for denial of payment due to a process over which they have limited control.

Personnel

Therapy to Medicare beneficiaries in an outpatient setting must be provided by, or under the oversight of, a licensed therapist. In the case of OTs and PTs, Medicare allows therapist assistants to also provide patient care. In hospital and rehabilitation agency settings, general supervision of the assistant is required, meaning a licensed therapist is available for consultation, but does not need to be on the premises. In my home state of Utah, for example, therapist assistants can render care according to a POC established by a therapist with on-sight supervision by the therapist required every 6th visit or every 30 days, whichever is less. This allows therapist

assistants to work in a home health environment, providing care in consultation with the therapist, but without immediate oversight of the therapist. In private practice settings, Medicare requires direct, in-the-suite supervision of the assistant by the therapist.

Certain state licensing acts also allow participation of on-the-job trained physical therapy aides in providing therapy. Medicare does not recognize care provided by aides to be skilled, and is therefore never billable. This condition results in a compliance risk and must be managed. The therapist has the responsibility to ensure that appropriate supervision is provided at all times for care to Medicare beneficiaries, and that only appropriate personnel provide billable services.

If care is provided to Medicare beneficiaries by assistants without the necessary oversight, no claim should be filed. This situation requires that patients are scheduled appropriately, so that care can be delivered according to Medicare's requirements by the appropriate personnel.

Medical necessity

Therapy must be considered "medically necessary" to be paid by Medicare. This concept is described in the Medicare on-line manuals as, "the patient's condition will improve significantly in a reasonable (and generally predictable) period of time" and relates to the patient receiving care that is adequately complex to require the skills of a therapist. This concept often does not lend itself to a black-and-white interpretation.

As driven, compassionate professionals whose job it is to assist persons with difficult conditions that cause pain or loss of function, therapists provide care over a number of visits and become well acquainted with patients and their family members. They are aware of the patient's and the family's goals and expectations, which in most cases are for the patient to return to a full level of premorbid function. These full recovery goals may or may not be realistic. That being said, therapists and therapist assistants face pressure from the patient and their family members, at least initially, to achieve this level of progress. Therapists are confronted with staying fully aware of the payment conditions of Medicare, trying to motivate and educate patient and family members, and being clear in their own minds regarding the patient's initial and ongoing rehabilitation potential. This decision-making process may be complicated further by the fact that if the patient does not fully recover, he or she may no longer be able to reside in their home independently. This reality is very difficult for the patient, but also for their loved ones who may lack the resources to care for the patient alone, pay for care to be provided by others, or pay for the patient to reside in a care facility.

In going through this rehabilitation process, therapists must decide when care is truly restorative or when it more appropriately becomes compensatory. Though both types of care can be appropriate and billable to Medicare, the clinician must meet the challenge of deciding when to shift to more compensatory training and education of the patient and caregiver, while not diminishing the hopes or motivation of the patient to continue in their recovery process. Eventually, the time comes to discharge the patient when there may be a glimmer of hope for a more complete recovery. The therapist may struggle when, at some level, the determining factor in the discharge appears to be money. Effectuating the discharge can therefore be a difficult moral and ethical decision at times.

Determining medical necessity is also difficult for therapists in that they can help all patients in some way. Patients can always improve their function or ability in some way with additional strength, flexibility, or motor control; all core variables that therapists are trained to enhance. The therapist must successfully determine when services meet the medical necessity conditions of a payer contract and when care is more appropriately delivered as a private pay service.

Documentation and charging

Therapists must clearly document each date of therapy service to justify charges and to enhance the quality of the care provided. Given that therapy is delivered over a series of treatment visits, therapists can see the effects of their treatments and modify them to optimize patient outcomes. Daily documentation serves as a simple, but vital, quality improvement tool.

Therapy documentation also serves as the receipt to the payer of services provided. Submitted charge codes are linked to specific Current Procedural Terminology (CPT) codes in the Charge Description Master of the provider. Documentation in the therapy record must show that services provided met procedural and time definitions of these charge codes.

The majority of CPT codes charged by rehabilitation clinicians, in particular OTs and PTs, are based on a 15-minute treatment unit. The number of units that can be charged in a treatment session is defined by the total time a patient received therapy. This is a required documentation element by Medicare, which has published guidelines for how this time is to be documented. On average, 15 minutes of therapy will be provided for each unit charged. The guideline is:

- For 8 through 22 minutes, charge 1 unit
- For 23 through 37 minutes, charge 2 units
- For 38 through 52 minutes, charge 3 units
- For 53 through 67 minutes, charge 4 units, etc.

Continued on page 29

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Additionally time must be adequately documented to show that specific charges are correct. If a total of 55 minutes of therapy was received by a patient, 4 units of timed codes could be charged. If 30 minutes were spent in a procedure, say therapeutic exercise, and 25 minutes were spent in a different procedure, 2 units of each code could be charged. This awareness of time and the volume of each service to charge are important to Medicare, given that some therapy procedures are reimbursed at higher rates than others. Therapists must be sure to document enough detail in the therapy record to justify charges and to avoid any potential "upcoding" in Medicare's view. This documentation of time is also very important to clarify the volume of charges submitted when timed procedures are charged in the same treatment session as untimed procedures. Given that a single unit is all that can be billed for an untimed treatment procedure, Medicare wants the assurance that the number of timed units charged is justified. Therefore, therapists are wise, in these circumstances, to document the time spent, not only in timed services, but also in untimed services, to allow verification of the charges.

Rehabilitation services present one other compliance challenge when considering appropriate charge coding. At times, the same treatment can be charged with different codes depending on the clinician's intention in using the procedure. For example, climbing stairs is a treatment commonly used in a therapy setting. For a patient with lower extremity weakness, climbing stairs can be a nice strengthening exercise. Medical record documentation should reflect that stair climbing was a strengthening activity and the code 97110, therapeutic exercise, should be charged for strengthening. For someone who lacks the skills to safely navigate stairs on their own, the clinician will actually educate and train the patient on how to climb the stairs. This meets the definition of the code 97116, gait training, and this is what should be adequately documented and charged. For a patient who lacks balance and the stairs are used as a positioning guide to enhance weight bearing and balance on a single leg, the documentation should reflect this emphasis on neuromuscular reeducation and CPT code 97112 should be charged.

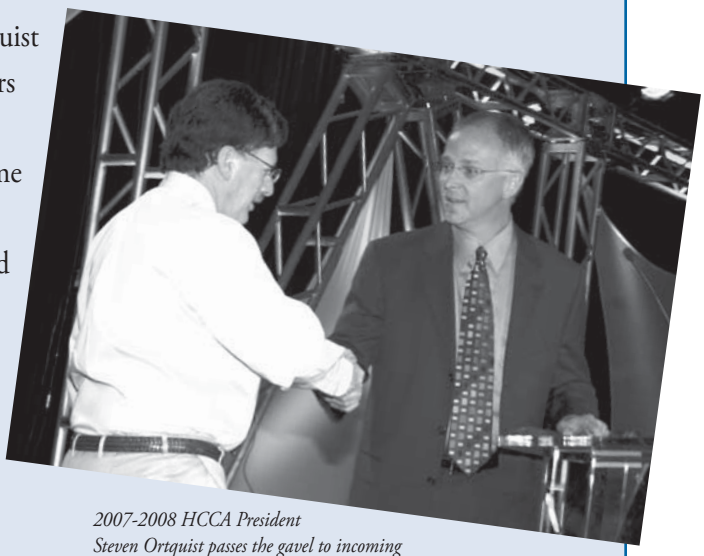
In light of the fact that outpatient rehab services are typically charged by clinicians whose interest centers on therapist inputs and patient responses, rather than by coding and billing professionals whose interest centers on claims and the necessary documentation support, it is evident that some compliance risk may be inherent in the process.

Improving the process of compliance

Perhaps the most important way to improve the rehab services compliance process is to make it a team process. This includes bridging any disconnect that exists between therapy clinicians and hospital patient account services (PAS) personnel. While each depends on the other for submitting therapy claims, the typical interaction between PAS and rehab service personnel is limited to rehab personnel providing a daily charge ticket to PAS for the therapy claim. Rehab clinicians may not have first hand knowledge of what charges are actually going out on a claim, and PAS personnel have no knowledge that a claim is supported by medical record documentation. Rehab service administrators must engender a relationship with the PAS person assigned to enter their claims and should encourage rehab service personnel to better understand the charge/claim process. Administrators must also ensure that clinicians understand the importance of timely and accurate documentation, accurate charge ticket completion, and the need to cooperate in providing any information (e.g., occurrence codes, etc.) that may be required by PAS to submit an accurate therapy claim. ■

HCCA Thanks Steve Ortquist and Welcomes Rory Jaffe

We thank Steve Ortquist for the countless hours he contributed to HCCA during his time as President (May 2007- May 2008) and we extend our best wishes Rory Jaffe as he begins his term as HCCA President! Good Luck Rory!



2007-2008 HCCA President Steven Ortquist passes the gavel to incoming HCCA President Rory Jaffe, MD

Practical tips for dealing with Pharma reps

By Teresa Bivens, CPC, CHC

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Many interactions with pharmaceutical companies and their representatives are beneficial to the medical profession, but others have come under close scrutiny by governmental agencies and the public. In the past, lavish gifts, expensive trips, discounts, and free samples were the normal expectations of medical providers, starting when they were residents or medical students. Now providers have become wary on what they should and should not do when it comes to dealing with pharmaceutical companies.

What started this trend? The settlement that seemed to have focused governmental scrutiny on pharmaceutical companies was the TAP Pharmaceuticals settlement of October 3, 2001. TAP Pharmaceuticals was accused of giving physicians kickbacks and bribes for prescribing the prostate cancer drug Lupron. Several other large pharmaceutical settlements quickly followed. After the Office of Inspector General (OIG) identified potential risks in relationships among purchasers and their agents, physicians, and sales representatives in influencing referrals and prescribing patterns, it published draft guidance for the pharmaceutical industry on October 3, 2002. The final guidance was presented on May 5, 2003. The Executive Committee of the Pharmaceutical Research and Manufacturers of America (PhRMA) developed a marketing code to govern the pharmaceutical industry relationships. The code, which took effect July 1, 2002, is nicknamed "the PhRMA Code." The PhRMA Code and the OIG guidance give compliance officers and medical providers clear guidelines on how to interact with the pharmaceutical industry.

So, what is allowed and not allowed under the PhRMA Code? In short, the following interactions are permitted under the code:

- Informational presentations accompanied by occasional meals.
- Financial support given directly to sponsors of continuing medical education (CME) or third-party conferences.
- Occasional gifts, if they primarily benefit patients and are valued under $100 (this includes practice-related gifts of pens, notepads etc.).
- Funding to allow healthcare professionals-in-training to attend major educational, scientific, or policy making meetings (selection by institution).
- Reasonable compensation and reimbursement for travel, lodging, and meal expenses for bona fide consultants.
- Product samples for patient use in accordance with the Prescription Drug Marketing Act are acceptable.

What interactions are not allowed under the PhRMA code? Anything provided or offered to a healthcare professional in exchange for prescribing or for a commitment to continue prescribing products is not permitted.

Some examples of what is not allowed under the PhRMA code are:

- Entertainment and recreational events – golf, spa, football tickets, etc.
- "Dine and dash" programs ("take-out" meals in the absence of a company representative).
- Inclusion of a spouse or guest in sponsored meals and/or receptions.
- Individual financial support for third-party conference attendees.
- Cash and/or cash equivalents (i.e., gift certificates), except as compensation for bona fide consulting.
- Honoraria, travel, or lodging expense to non-faculty and non-consulting meeting attendees.
- Gifts that are not practice related or do not benefit patients.
- Items intended for personal benefit (i.e., floral arrangements, artwork, music CDs, etc.).
- Token consulting or advisory arrangements used to justify compensation for travel, lodging, and other out-of-pocket expenses.
- Inducements. Anything that makes the physician feel obligated.

If it makes you pause to consider if it is allowable, it probably isn't!

An excellent tool to educate physicians and/or staff on what is allowable and what is not is to consolidate the PhRMA Code information into a grid with practical examples (see Table 1). Large entities and academic centers may want to perform a pharma audit survey to determine any areas of risk. Follow-up education for physicians and staff is always appropriate. Entities should draft policies to address interactions with pharmaceutical representatives and establish internal guidelines for "nominal" value, "occasional" meals, etc., using the OIG Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals as references.

The American Medical Association (AMA) Web

site offers excellent online educational lessons regarding physician professionalism and gifts to physicians from industry at www.ama-assn.org.

What if a medical provider is offered an inappropriate gift? The OIG Guidance, the PhRMA code (minimum standards) and any internal policies and procedures on gifts should be examined and appropriate action taken. The issue should be raised with the manufacturer or contact the FDA MedWatch Program at 1-900-FDA-1088 or www.accessdata.fda.gov/scripts/medwatch/.

The provider should remember that most interactions with the pharmaceutical industry are beneficial to the medical profession and their patients. But, with the increased governmental scrutiny on the pharmaceutical industry, medical professionals need to carefully consider their interactions with pharmaceutical representatives. Even though most "gifts" given to physicians from pharmaceutical representatives are of nominal value and only used to help the physician to remember the product name, there is a clear connection between the provider's obligatory feelings for receiving a gift and the gift giver. Each physician should carefully consider their interactions with pharmaceutical industry representatives and make decisions based on the guidances available and sound ethical principles. ■

For a more extensive table of what is - and is not - allowed, please contact the author.

Pertinent Points in the PhRMA Code

Example	Caveats
Informational presentations by industry reps and others who speak on behalf of a company may provide valuable scientific and educational benefit. Occasional meals may be offered as long as they are modest (as judged by local standards) and occur in a venue and manner conducive to informational communication.	■ The primary reason for attending is to learn something that will ultimately benefit patients ■ The food is not used as an inducement for attendance
Continuing medical education or third-party scientific/educational conferences or professional meetings can contribute to the improvement of patient care, and therefore, financial support from companies is permissible. All subsidies must be given to the conference sponsor and can be used to reduce the overall conference registration fee for all attendees. Financial assistance for scholarships or other educational funds to permit healthcare professionals in training to attend carefully selected educational conferences may be offered. The selection of those who receive the funds must be made by the academic or training institution.	■ Giving a subsidy directly to an individual may be viewed as an inappropriate cash gift. ■ Including an attendee's spouse or guest is not appropriate ■ Providing entertainment and/or recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is not allowed ■ The costs of travel, lodging, and personal expenses must be paid by the individual attendee
Consultants who provide services must have a written contract that outlines the service provided, basis for payment, and a legitimate need for the services	■ Reasonable reimbursement for travel, lodging, and meals is permitted ■ The venue and circumstances must be conducive to the consulting services provided ■ The selection of consultants must be directly related to the identified purpose, and the number of retainees must be reasonable

ANYTHING provided or offered in exchange for prescribing or a commitment to continue to prescribing is not allowed

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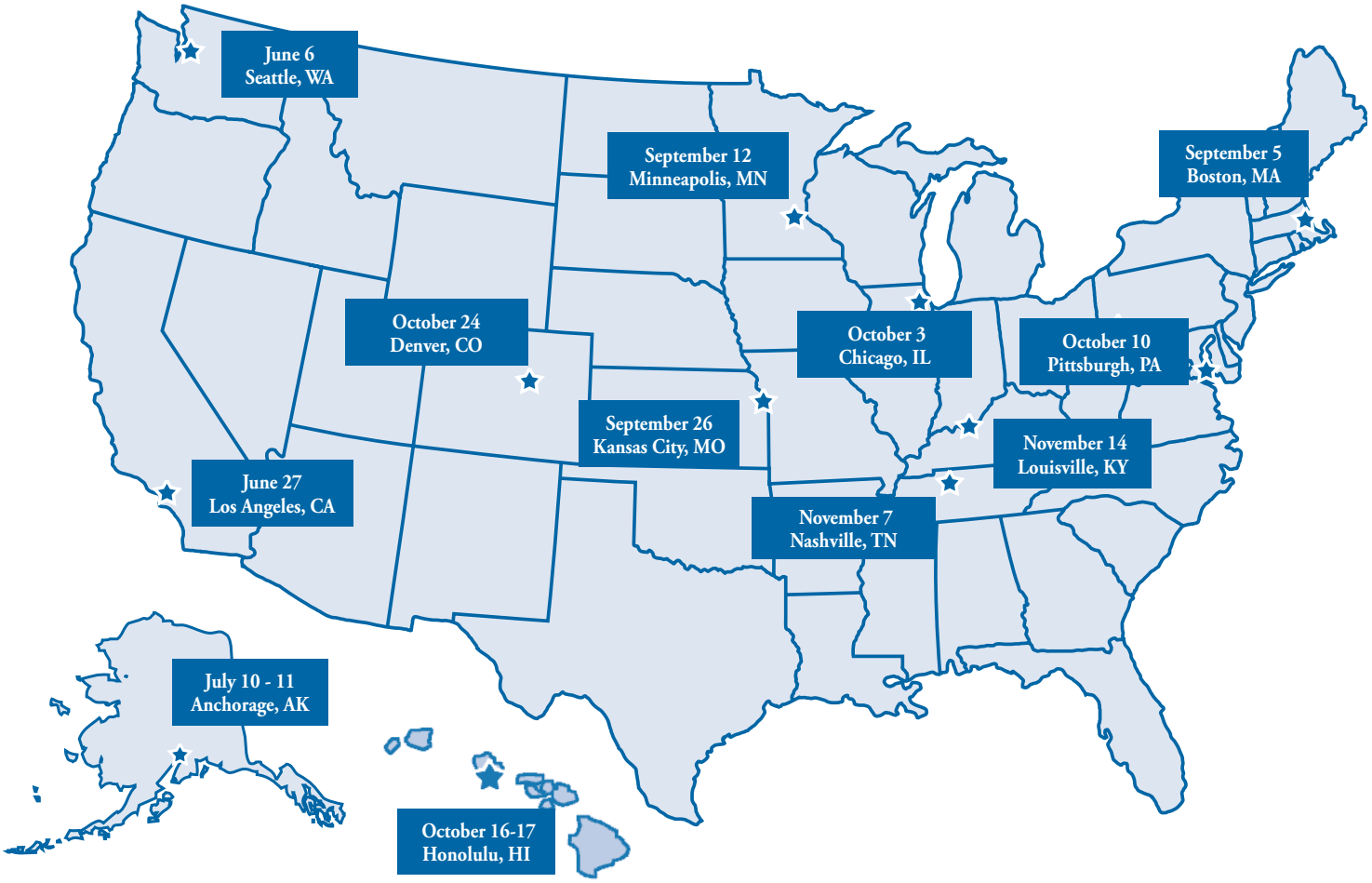

feature focus

Disclosure of Financial Relationships Report

Preparing for increased scrutiny on hospital/physician arrangements

By Leonard J. Henzke, John N. Fink, and Darin E. Libby

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Would all your deals with physicians pass regulatory scrutiny? The Centers for Medicare and Medicaid Services (CMS) want to know, and they are in the process of developing a regular disclosure process to obtain information on hospital/physician relationships.

CMS has made the review of financial arrangements between physicians and hospitals a top focus area in an effort to determine whether relationships are compliant with the physician self-referral statute and other regulations.[1] CMS had planned to distribute a revised mandatory disclosure survey, the Disclosure of Financial Relationships Report (DFRR), to 500 hospitals in late 2007. However, in the final stages of releasing the survey, CMS was unable to obtain approval from the Office of Management and Budget and has elected to further evaluate how the instrument may be modified to accomplish the intended goals. The contents of the final version and the timing of its actual distribution are not known, but CMS's intent to require hospitals to reveal the details of their physician financial arrangements is apparent.

What is the status of the DFRR?

As part of the investigation to address issues regarding physician investment in specialty hospitals, CMS developed the DFRR to collect information to analyze any ownership and investment interest or compensation arrangement between each of the hospitals and the physicians.

With the issuance of the 2009 IPPS Proposed Rule, CMS has postponed the release of the DFRR and is now posing a set of questions to a number of hospitals to determine whether modifications are appropriate. Currently, CMS is soliciting comments on the DFRR process, including:

- Should the collections effort be recurring?
- Should the timeline to complete the DFRR be extended beyond 60 days?
- Should the instrument be directed to all hospitals?
- Should hospitals be required to send periodic updates after they have completed the survey?

It is widely believed that CMS will modify the survey instrument as a standard reporting tool for all Medicare participants, and that it will use the data collected from the DFRR to analyze hospitals' compliance with Stark. Thus, hospitals will be required to disclose terms and demonstrate that adequate supporting documentation exists for their financial relationships with physicians. This article explores CMS's proposed reporting requirement and outlines what hospitals should do to ensure compliance of physician arrangements with applicable laws.

Specifically, the DFRR is an eight-sheet spreadsheet file, which took a sample of hospitals an average of 31 hours of staff time to complete, according to CMS. In the first six worksheets, the DFRR captures general hospital information and information about individuals who have direct and indirect ownership in the hospital, including payments made to the hospital by direct and indirect owners and changes to each owner's equity position during 2006. Only hospitals with physician ownership will need to respond. The remaining two worksheets, however, will require all surveyed hospitals to disclose terms of compensation arrangements with physicians, including call coverage, medical director arrangements, recruiting support, rental agreements, and other compensation paid to physicians. CMS believes that the information sought should already be maintained by hospitals in an organized manner during the normal course of business activities, something many hospitals lack.

What should you do?

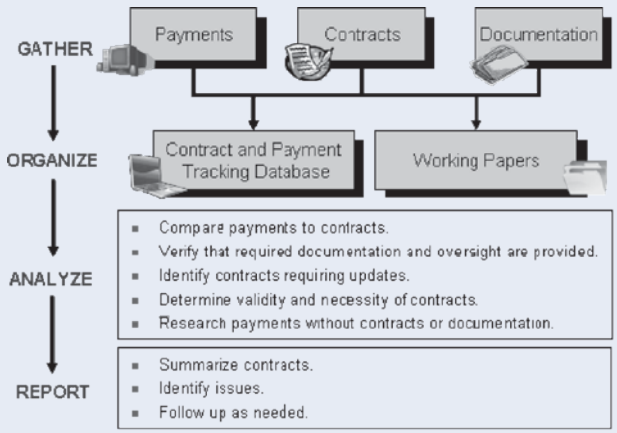
Although the specific details of the DFRR are being reconsidered and it is uncertain whether the survey tool will be issued, CMS is expected to increase its scrutiny of hospital/physician financial relationships in the coming months and years. Therefore, compliance officers and other administrators will need to take the steps necessary to ensure (1) that they implement contract management tools and processes to gain control of monitoring physician financial arrangements, and (2) that their current and future relationships adhere to fair market value (FMV) principles. The remainder of this article provides tips for meeting both of these goals.

Getting control of your physician arrangement

Hospitals maintain financial arrangements with physicians to serve a variety of purposes. Arrangements include contracts for recruitment, call coverage, medical directorships, professional services, management services, property leases, and equity joint ventures. A typical hospital may have hundreds of these arrangements and management of them may occur in disparate areas of the hospital.

Rather than gathering only the information required to respond to the DFRR, hospitals should use this initiative as an opportunity to gather, organize, and evaluate all payments and supporting documentation of agreements made between the hospital and physicians. By auditing all physician payments, hospitals will be able to ensure that their physician arrangements are compliant with relevant laws. They will then be positioned to implement policies and procedures that enable centralized management and control of physician arrangements.

Hospitals should consider the following steps to conduct a thorough audit of existing hospital/physician financial arrangements. The figure below summarizes an efficient, yet thorough process to assemble and analyze hospital/physician arrangements.



Auditing hospital/physician arrangements

Step 1 – Develop assessment tools

The primary audit tools are (1) a payment tracking database and (2) checklists for each type of physician payment. The payment tracking database will be used to organize the key terms of each arrangement and match payments to their corresponding contracts. Fields within the database should include contract terms, such as service obligations, payment calculations, and repayment provisions. Elements of legal guidelines and requirements should also be included in the database, as directed by legal counsel. A robust contract management system would be helpful in this regard.

A checklist should exist for each type of physician arrangement to identify elements required in each contract. For example, a recruitment contract should contain a community need assessment, documentation on meeting relocation requirements, FMV opinion on financial support, etc. The checklist should identify each of these elements and provide a reference to ensure all supporting documentation is in place. These and other requirements should be identified by legal counsel so that contracts may be evaluated relative to their inclusion of key items.

Step 2 –Organize contracts, payments, and documentation

Every contract, payment, and the relevant documentation should be assembled to allow efficient and thorough analysis. Contracts should be organized by type of arrangement and payments should be downloaded from the check registry of the general ledger and organized in the payment tracking database. Documentation of contracts will include supporting material, such as community need assessments or FMV studies. Documentation of payments will include timesheets and invoices from physicians.

Step 3 – Analyze contracts and payments

During this step, contracts are evaluated against the checklists and payments are compared to the terms of each contract. Tasks to be completed include:

- Comparing payments to contracts,
- Verifying that required documentation and oversight are provided,
- Identifying contracts that require updates,
- Determining validity and necessity of contracts, and
- Researching payments that do not have corresponding documentation.

Continued on page 36

 ...continued from page 35

Depending on the ability of the payment tracking database, payments may be matched to their contract automatically. Payments that do not tie to a contract are then flagged for manual investigation.

Step 4 – Summarize findings and conduct follow-up

During the course of the audit, a wide variety of issues may be identified and obvious problems may include:

- Payments for which no contract exists or for contracts that have expired,
- Contracts with terms that no longer comply with Stark,
- Failure to meet contract terms,
- Payments that are inconsistent with contract terms,
- Recruitment arrangements without community physician need assessments, and
- Contracts that lack FMV documentation and/or a third-party opinion.

Less-obvious problems may also become apparent, such as:

- A physician may be compensated through several different contracts such that his/her total work effort would require greater than 1.0 full-time equivalent (FTE).
- Call coverage and/or medical directorship rates may differ for the same specialty.
- Different methodologies may be used to document fair market rental rates for subleased space in medical office space owned or leased by the hospital.

Adhering to FMV principles

As noted above, one of the major concerns identified through the audit process is whether FMV documentation or a third-party opinion exists for those contracts that require it and whether consistent methodologies are followed to document FMV. If your organization lacks FMV documentation, you may be at risk as CMS increases its scrutiny. The following section reviews potential methodologies for determining FMV in each of the major types of hospital/physician financial relationship categories.

Section 411 of the Code of Federal Regulations and Section 1877 of the Social Security Act generally define FMV as "the value in an arm's-length transaction, consistent with general market value." Another definition of FMV, based on the Internal Revenue Service Revenue Ruling 59-60, characterizes FMV as "the price at which the property would change hands between a willing buyer and a willing seller when the former is not under any compulsion to buy and the latter is not under any compulsion to sell, both parties having reasonable knowledge of relevant facts." Given the breadth and complexity of hospital/physician financial arrangements, these definitions provide hospital administrators with little guidance regarding (1) whether to pay physicians for their services, and (2) if payment is warranted, how much to pay.

Hospital-based specialty agreements

The growing frequency of stipends for hospital-based specialists is rooted in the characteristics of these services. In general, anesthesiologists, emergency medicine physicians, hospitalists, intensivists, and pathologists spend all of their professional time in the hospital and have limited ability to work harder to increase their incomes; whereas surgeons or office-based practitioners can increase their incomes through more efficient scheduling, improved marketing, or by keeping longer office hours. Hospital-based specialists are generally subject to the hospital's overall patient activity level; therefore, these groups have become more aggressive in demanding stipends for providing guaranteed levels of coverage.

The stipend the hospital provides should not enable the physicians to earn incomes that exceed FMV standards; therefore, the analysis should entail:

- Determining the number of physician FTEs required to staff the hospital. (Some groups will frequently utilize more physicians than are needed to provide coverage, and the group's definition of an FTE needs to correspond closely to benchmarks for hours worked in a year.)
- Outlining the income necessary to sustain the required FTEs at market levels of income.
- Calculating the shortfall, if any, between revenues and funds necessary to maintain market incomes.

Call coverage. The provision of payments for previously uncompensated call coverage duties has exploded nationwide. National benchmarks for call coverage stipends are in short supply, and the complex nature of these arrangements, which can involve many different payment mechanisms, makes true apples-to-apples comparisons difficult. Further, the Office of Inspector General's (OIG's) recent Advisory Opinion No. 07-10 regarding call coverage provides important guidance to hospitals that are paying or considering paying for call.[2]

In general, any solution should encompass a review of call burden and market conditions, and should not merely pay the physicians who complain the loudest or refer the most patients to the hospital. Such a review should incorporate:

- Reviewing call burden data pertaining to emergency department admissions, telephone calls, and other relevant metrics.
- Determining which specialties are most burdened by call.
- Setting payment rates according to call coverage burden.

Medical Directorships. The new Stark Phase III regulations eliminated the "safe harbor" outlined in the Phase II regulations previously issued, which makes determining FMV for these positions more difficult. In general, administrators should look to compensate these positions at median benchmark rates; Medical Group Management Association, American Medical Group Association, and Sullivan, Cotter and Associates, Inc. provide universally respected surveys. Utilizing a blended average of these survey medians closely parallels the now-defunct safe harbor. In some cases, administrators find that they cannot fill medical directorships at median benchmark compensation levels. As a result, they often seek legal counsel's input when entering this "gray area." In these cases, an outside opinion may be necessary to clarify appropriate medical directorship payment rates, because FMV can often be influenced by a geographical shortage of specialists or the need for unique qualifications required for the medical director role. In any case, legal counsel is well advised to back up the gray area with a solid third-party FMV opinion.

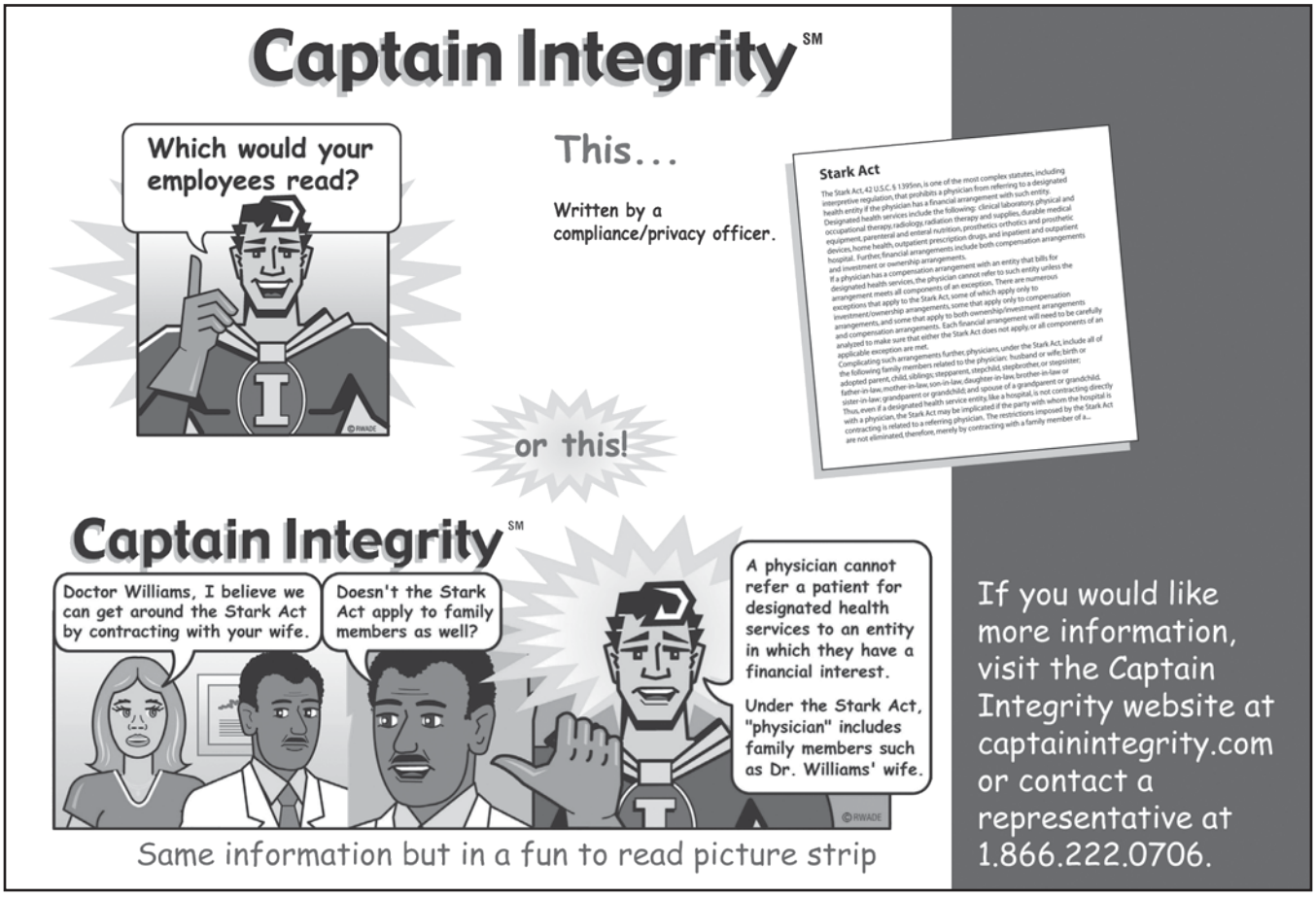
Service Agreements. Physicians are facing declining incomes in many specialties, including oncology and cardiac surgery, due to changes in practice patterns and government reimbursement. As a result, they are seeking to partner with hospitals to enhance services provided to patients and increase reimbursement. Administrators are increasingly pushing the limits of FMV in these arrangements, and need to ensure that payments (which are often productivity-based) are within appropriate benchmarks.

Key Takeaways

Many hospitals can benefit from improved management of their physician arrangements. Compliance officers and hospital legal counsel need to take the steps necessary to organize contracts and collect supporting documentation, promote routine monitoring of compliance with contract terms, and ensure that contracts comply with the ever-changing regulatory requirements. Investing in contract management tools will enable more efficient auditing and reporting and save resources in the long run. Further, seeking a third-party opinion to determine FMV for a hospital/physician financial arrangement provides additional safeguards to ensuring arrangements are appropriate. The penalties for noncompliance are real, and implementing the appropriate steps can protect you from greater CMS scrutiny. ■

1 Section 5006 of the Deficit Reduction Act of 2005 (DRA) required CMS to consider the issue of annual disclosure of information pertaining to physician ownership and investment interest in specialty hospitals. Pursuant to 42 CFR Section 411.361, CMS stated that it will require hospitals to provide it with information on a periodic basis concerning their ownership and investment interests and compensation arrangements with physicians.

2 Leonard J. Henzke and Steve Messinger "Solutions to Emergency Department Call Coverage Issues: Guidance for Payment Solutions," Compliance Today, January 2008.



Navigating Neverland for coded data reporting

By Rita A. Scichilone, MHSA, RHIA, CCS, CCS-P, CHC

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Patient safety is a critical part of a compliance professional's work each day. There are events in health care that are termed "inexcusable errors," "preventable mistakes," and frequently, "never events." An item-by-item list was developed in 2002 by the National Quality Forum (NQF) at the request of the federal government, following release of the well-known Institute of Medicine (IOM) report "To Err is Human." The list was updated in 2006.[1] The Centers for Medicare and Medicaid Services (CMS) provides a current list on their Web site (www.cms.hhs.gov) as well. Stories involving the fictional character Peter Pan describe Neverland as a place where wishes and dreams come true. Health care providers would love to imagine such a place where serious patient safety issues never occur and patients who spend time in hospitals do not acquire undesirable conditions following their admission.

Those who pay for care are increasingly applying the "never" label to reimbursement for medical errors which, according to accepted standards, should not happen. Ethical imperatives arise along with the compliance risks associated with provision health care services that result in these undesirable outcomes. Hospitals are stepping up and by policy are not charging for selected NQF-defined never events. Nationally, nearly 1,300 hospitals have indicated they will waive all directly associated costs, based on a survey conducted by the Leap Frog Group.[2] CMS published a rule in August 2007, effective in October 2008, that denies payment for eight hospital-acquired conditions; five of them are on the NQF lists.

From an ethical viewpoint, not billing for these conditions seems like the right thing to do, but wait a minute… Does this mean that health care providers don't report or index the codes for any of the conditions normally assigned an ICD-9-CM code? Should coders never assign the ICD-9-CM Classification System E codes available for designation of "Misadventures to Patients during Surgical and Medical Care"?

A great deal of anxiety occurs about public reporting of medical errors, although selected states require reporting to advance a culture of quality and commitment to patient safety. There may be so much angst that executives require coding professionals to omit codes for "present on admission" or "one of the never events" and this situation represents an ethical dilemma for the compliance office and the knowledgeable workers who are tasked with coded data management for providers.

Although physicians generally agree that medical errors should be reported to their hospitals, many of them do not actually do it, according to a University of Iowa recent survey.[3] The discrepancy between attitude (belief that error reporting can improve quality of care) and action (admitting an error occurred) was notable. Coding for hospitals depends on physician documentation to provide the source for encoded data for indexing, storage, and required reporting. When physicians provide clinical data appropriate for reporting according to code set conventions and official guidelines, coding professionals have an ethical obligation to assign codes to fully classify and represent the care provided. Compliance professionals have an obligation to watch for systematic suppression of evidence that increases legal risk.

The Health Care Compliance Association (HCCA) provides a code of ethics for compliance professionals' behavior [4] and the American Health Information Management Association's "Standards of Ethical Coding"[5] provides guidance for coding professionals to follow. Taken together, these documents provide help for creating a coded data compliance plan that addresses the dilemma of health record documentation, coding, and reporting of adverse patient outcomes.

Excerpt from the HCCA Code of Ethics for Health Care Compliance Professionals (HCCPs) (from Principle 1, Obligations to the Public section):

> R1.2 HCCPs shall take such steps as are necessary to prevent misconduct by their employing organizations.

Excerpt from AHIMA Standards of Ethical Coding (Ten Standards):

> 6. Coding professionals should not change codes or the narratives of codes on the billing abstract so that meanings are misrepresented. Diagnoses or procedures should not be inappropriately included or excluded because payment or insurance policy coverage requirements will be affected. When individual payer policies conflict with official coding rules and guidelines, these policies should be obtained in writing whenever possible. Reasonable efforts should be made to educate the payer on proper coding practices in order to influence a change in the payer's policy.

The ethical concepts from these two highly respected organizations complement each other. Organizational leadership may pressure staff to suppress reporting of coded data that represents

adverse outcomes, a "never event," or a condition that developed while receiving care (e.g., infection, fall with injury). This may occur in a situation where code assignments are tightly linked to the billing process when, in fact, the diagnosis and procedure codes assigned are often used for other purposes, such as disease and procedure/operation indices for data retrieval, disease registries, and other reasons specific to the setting. Failure to report codes expressed in health records could be interpreted to be misrepresentation of facts. Information retrieval of events that suggest that quality and safety standards are not being achieved is critical, because the coded data facilitates analysis and trending for identification and improvement as part of any patient safety program.

Compliance professionals must take a leadership role in creating a culture for ethical behavior. The health record that documents events in a clear fashion is the best defense against allegations of poor quality care or reckless disregard for patient safety procedures. Coding professionals will translate the clinical data captured in the health record by assigning clinical codes used in information transfer. Compliance professionals and health information management (HIM)/coding professionals and compliance professionals share common goals. Two of the most important are: (1) reporting data with integrity and accuracy, and (2) upholding an obligation to refuse to participate in or conceal unethical practices.[6] Emerging issues created by increased scrutiny and accountability for quality care must be addressed in effective compliance plans, policies, and procedures. Data quality can be improved with the use of a standard workflow and performance benchmarking.[7]

With Compliance and HIM working together, the following elements should be added to existing compliance guidance related to coded data work-process flows:

1. Implementation and use of a policy for encoding clinical conditions documented in health records according to official code set guidelines and regulatory reporting requirements. Examples of inclusion: adverse reactions to medication, "never events" as described in documents from authoritative sources, and complications that occur because of the care process.
2. System configuration and functionality must allow for capture and storage of all encoded data separate from the claims data used in the billing process. This functionality ensures that clinical data is captured for trending and analysis when a provider chooses to not charge the patient for care.
3. Building a culture of transparency and openness is required to enable trending and problem solving among health care providers, patients, and payers that results in better patient safety records.
4. Reporting of present on admission (POA) indicators for CMS, the Compliance office must confirm monitoring of the use of the "U" indicator to evaluate inadequate or inappropriate documentation patterns. For more information about the CMS requirements go to http://www.cms.hhs.gov/HospitalAcqCond and then click on Educational Resource. After April 1, 2008, Inpatient Prospective Payment System (IPPS) hospitals will have their claims returned if the claims are submitted without the proper POA indicator(s) included. Payment will be impacted beginning in October, 2008.
5. Clinical code assignments should not be impacted when a medical error happens during an episode of care. Diagnosis and procedure codes must be assigned and based on the facts available in the resource documentation found in the patient's health record. Failure to withhold any information in the regular course of business could be interpreted as misrepresentation.
6. Establishing a standard workflow with built-in data integrity checks and improvement feedback loops helps to prevent omissions in reporting that increase compliance risk.
7. Consistency of coding is an important element within a compliance program to ensure that reporting of conditions is reliable. This is accomplished by monitoring and evaluation that compares code selection and reporting between coders as well as comparison to standards.
8. Compliance guidance for coding staff and clinicians should include periodic training requirements for documentation and code assignment processing. This should include a clear understanding of the need to report all conditions within the scope of existing national guidelines and state requirements for reporting.

Today the term "Neverland" may be used to describe an ideal place similar to the fictional place pushed up from the ground by using the power of imagination. The ideal place in health care service delivery is quality care free from significant medical errors and serious preventable adverse events. Navigation to this ideal destination in health care event encoding is accomplished by the guidance systems outlined in compliance documents, planning, and program administrators paying attention to emerging quality reporting issues. Performance measurements and reporting are definitely necessary to meet the patient safety goals ahead. In addition to following regulations and applicable laws, all providers should follow ethical principles and decision making to prevent any suppression of codes for reporting, just to remove charges. ■

1 Serious Reportable Events in Healthcare 2006: A Consensus Report" http://www.qualityforum.org/pdf/reports/sre/txsreexecsummarypublic.pdf and retrieved April 7, 2008
2 O'Reilly, Kevin B." "No Pay for "never event" Errors Becoming Standard", from amednews.com http://www.ama-assn.org/amednews/2008/01/07/prsc0107.htm and retrieved March 3, 2008.
3 University of Iowa Press Release "Medical Error Report by Doctors to Hospitals Seems Underused" (January 15, 2008) http://news-releases.uiowa.edu/2008/january/011508medical_errors.html retrieved March 3, 2008.
4 HCCA Code of Ethics http://www.hcca-info.org and retrieved from Code of Ethics on March 3, 2008.
5 AHIMA Standards of Ethical Coding http://www.ahima.org/infocenter/guidelines/standards.asp retrieved on March 3, 2008.
6 Harman, Laurinda, Editor; Ethical Challenges in the Management of Health Information, Second Edition (2006) Jones and Bartlett,
7 Wilson, Donna et al, "A New Focus on Process and Measure", Journal of the American Health Information Management Association Vol, 79/3. (March 2008).

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Quality in long-term care: A board of directors' dashboard

By Jennifer O'Brien and Katie Arnholt

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On December 6, 2007, close to 50 long-term care professionals and government representatives participated in a government-industry roundtable in Washington DC to discuss and share best practices relating to the improvement of boards of directors' oversight of quality of care. The event was co-sponsored by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) and the Health Care Compliance Association (HCCA). The participants gained new insights into the opportunities created by, and the challenges to, enhancing board of director involvement in the oversight of the quality of resident care. The objective of the collaboration was to share ideas and perspectives; one of the goals was to identify items to include on a "quality-of-care dashboard" that could be used as a tool for boards of directors of long-term care organizations.

We were fortunate to be among the roundtable participants, who represented a wide-spectrum of long-term care organizations and professionals, including not-for-profit and for-profit organizations, multi-facility and single facility organizations, nationally and locally based organizations, clinicians, administrators, compliance officers, outside and corporate counsel, monitors involved in OIG quality-of-care Corporate Integrate Agreements, and OIG representatives. We found the experience rewarding and educational. The roundtable was a success, in large part, because there was an environment in which participants seemed to feel comfortable openly sharing their opinions and ideas. The variety of the participants' professional experience meant that they had unique insights to share, and that they could learn from one another's perspectives. In this article, we will discuss the contents of the Report on the OIG and HCCA Roundtable on Long-Term Care Board of Directors' Oversight of Quality of Care (Roundtable Report)[1] and share what we took away from the roundtable experience.

Dashboards

One of the goals of the roundtable was to identify items that could be included on a quality-of-care dashboard and be offered as a tool for boards of directors of long-term care organizations. A dashboard, like the dashboard in a car, is simply a user interface that organizes and presents information in a way that is easy to read. Increasingly, in the business setting as well as in the health care setting, dashboards are being used to quickly and clearly present key information to management. Management and the board of directors can use that information to gauge the overall health of the organization and as a starting point for further discussion and inquiry. Many businesses that use dashboards include concepts such as red/green/yellow lights, alerts, drill-downs, summaries, charts, and gauges to summarize information. Quality-of-care data can be voluminous and complicated; therefore, a dashboard could be a useful tool for distilling quality data in a way that is easy to read and understand.

There is likely no "one size fits all" quality-of-care dashboard. Rather, such a dashboard should be tailored to the needs and objectives of each individual long-term care organization. A quality-of-care dashboard could be its own free standing dashboard, or quality-of-care items could be situated within a broader dashboard. The message communicated at the roundtable was that a dashboard could be a useful tool and that the purpose of the discussions was to generate ideas for items that could be included on a quality-of-care dashboard, rather than to create a prescriptive set of dashboard measures. As illustrated by the summary of the roundtable discussions below, it seems that simply going through the exercise of creating a tool and other systems and processes for the monitoring and oversight of quality of care, whether a dashboard or some other method, is an important step towards improving the quality of resident care.

The roundtable process

The roundtable consisted of small group breakout discussions that focused on the following topics related to board of director oversight of quality of care:

- **Commitment -** How can boards of directors and organizations demonstrate a commitment to quality?
- **Process -** What processes help long-term care organizations monitor and improve quality of care and help boards of directors oversee quality of care?
- **Outcomes -** What are appropriate outcome measures of quality of care and how

Continued on page 46

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can those measures be effectively utilized?

- **Challenges and opportunities -** What are the challenges and opportunities in using a quality-of-care dashboard?

Representatives from the OIG and HCCA functioned as moderators and scribes for each discussion group and assisted by presenting summaries of the discussions that took place in their respective discussion groups. We participated in the roundtable in these roles: Jenny O'Brien as the moderator of the "process" discussion group and Katie Arnholt as the scribe for the "commitment" discussion group.

Take-aways from the break-out groups

After a full day of discussions, a lot of ideas had been shared, and several themes had emerged. Below are brief discussions of those themes, based on the summaries provided in the Roundtable Report.

A. Observations on commitment to quality

The participants in the "commitment" group discussed various ways in which boards of directors and their organizations can demonstrate a commitment to quality. A consistent theme was that a commitment to quality needs to be communicated and demonstrated from the top, specifically, from the board of directors and management. Some effective ways boards of directors can communicate a commitment to quality include:

- Provide a forum for quality issues – Are quality issues regularly reported to the boards of directors?
- Demonstrate board engagement – Are boards of directors comfortable asking questions necessary for them to understand the information being reported and to determine whether quality issues are being addressed?
- Craft a board mission statement or resolution – Is the commitment to quality expressly stated in the mission statement?
- Evaluate the organization's culture – Has the board of directors evaluated the organization's culture as it relates to quality?
- Demonstrate commitment through structures and processes – Has the organization and its board of directors established quality-related structures and processes and are those structures and processes regularly evaluated?
- Effectively allocate resources – Are the board of directors and management responsive to quality concerns and considering quality in their long-term strategic and capital planning?

B. Observations on quality-related processes

The participants in the "process" group had an in-depth discussion on organizational structures and processes that relate to quality. Included in this discussion was a sharing of the structural tools that the represented organizations use to involve the board in quality improvement efforts and, most importantly, tools used to help boards of directors understand the tracking and measurement of quality. Some effective processes include:

- Provide quality data reports to the board – Regular reporting of quality data from which the board of directors can assess or benchmark quality issues and improvement.
- Develop board expertise/understanding of quality information – Ongoing board of director education on quality issues; such education may be accomplished by forming a subcommittee that is charged with developing an in-depth understanding of and familiarity with quality issues.
- Validate quality reports – Board of director access to experts, internal or external, who can assist in validating and explaining the significance of quality-related information.
- Promote free–flow of information – Management should not be "filtering" out important information or failing to present all the critical facts to the board of directors.
- Coordinate a response to quality issues – Evaluate whether the organization coordinates between medical staff, quality, compliance, and risk management to identify and respond to quality issues in a manner that stresses both compliance with the law and focuses on providing quality care to residents.

A theme in these discussions was that board members should be encouraged and coached to drill down on the quality-related data and ask critical questions. For example, board members should be asking why a quality problem occurred in the first place, as well as what management is doing to fix the problem and prevent it from reoccurring. The more educated and comfortable the board of directors is with quality data, the easier it is to promote active questioning by the board members.

C. Observations on outcome measures

The break-out discussions for the "outcomes" group centered on measurements that could be used to assess an organization's performance on identified quality-of-care issues and that could be highlighted in reports to the board of directors. Participants shared outcome measures currently being used to provide insight into the quality of care and discussed how that outcome information can be utilized to improve performance. Outcome information can be used to detect gaps or problems with the organization's structures and processes. On the other hand, outcome measures can also help an organization see and track improvement. The following categories were consistently identified as valuable measures to consider when developing or designing a quality-of-care dashboard:

- **Survey results –** Includes surveys performed by state survey agencies, such as information regarding deficiencies, fines, and accreditation. Also includes resident and family satisfaction surveys and staff satisfaction surveys,

which can be used to help the organization proactively address quality issues.

- **Resident outcomes and care delivery –** Includes quality indicators and quality measures and can be a good road map for areas that require additional focus and resources.
- **Events reporting –** Includes a summary of events that are required to be reported to the government, which can be used to identify patterns of quality problems.
- **Complaints –** Includes ongoing review and trend reporting of complaints from patients and family members, hotline calls, and staff reporting.
- **Financial indicators –** Includes indicators such as reduced census, high accounts payable, percent of loss time claimed, and denied claims, all of which can be a bellwether for quality-of-care problems.

D. Challenges and opportunities

The discussions in the "challenges and opportunities" breakout group related to broader issues of board member involvement with quality-of-care issues and the use of a quality-of-care dashboard as a tool for attaining the goal of overall improvement in the quality of care provided to residents. In this discussion, the group recognized that there are obstacles and consequences inherent in creating and developing an effective quality-of-care dashboard. Some of these challenges include:

- "One size does not fit all" – Each organization must create a dashboard that fits its specific needs and contains quality indicators that are appropriate for the board of directors' understanding of and familiarity with quality of care.
- Beware of information overload – Consider the appropriate amount and type of quality-of-care information to provide to the board.
- Consider legal liability concerns – Balance the potential legal liability for board members who are truly educated about quality indicators against the board's need for information to effectively exercise its oversight responsibility.
- Scrutinize available quality measures – Be careful to not over-rely on outcome measures. Structure and process issues may be more important than outcomes measures in assessing the quality of resident care.

With challenges come opportunities and some of the benefits of implementing a dashboard include the clear message that the board of directors has set quality as a key priority throughout the organization and that quality is critical to the mission. Quality impacts the success of the organization at every level. A culture of excellent quality of care ultimately leads to excellence and pride in other parts of the organization.

Government-Industry collaboration

Both government and industry participants seemed to agree that the exchange of ideas and sharing of best practices will help move forward the goal for improving the quality of long-term care. As Roy Snell, HCCA's Chief Executive Officer, explained:

> "This is the 5th roundtable partnership with the OIG and it may be one of the most productive and meaningful we have had . . . We believe the outcome of the roundtable discussion will result in greater understanding of how the long-term care industry and the enforcement community can work together and improve the quality of care, as well as improve our compliance systems and procedures."[2]

The OIG and HCCA have indicated that, based on the success of this roundtable, there may be similar roundtable discussions planned in the future. As the Inspector General for HHS explained:

> "Our roundtable discussions shed new light on how the government and long-term care industry can work together to protect the integrity of the long-term care system and improve the quality of care provided to federal health care program beneficiaries . . . . Given the constructive exchange of ideas, OIG is considering additional opportunities for government-industry dialogue on quality of care issues."[3]

Conclusion

Overall, the roundtable appeared to have achieved its objective. It provided the opportunity for professionals from the long-term care industry and government representatives to discuss quality of care from the perspective of board of director involvement in and oversight of quality. Participants shared ideas and gained new insights regarding how to effectively involve and invest board members in quality of care. In addition, participants explored the idea of using a quality-of-care dashboard and generated ideas for items that could be included on such a dashboard. Hopefully, this is just the beginning of similar quality of care-related government-industry collaborations. ■

The views expressed by the authors in this article do not necessarily represent the views of the United States or the Office of Inspector General of the U.S. Department of Health and Human Services.

1 A copy of this report can be found on the HCCA Web site at http://www.hcca-info.org/staticcontent/07OIGRoundtableReport.pdf or on the OIG website at http://www.oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf.
2 January 31, 2008 OIG Press Release available at http://oig.hhs.gov/publications/docs/press/2008/RoundtablePReleaseFINAL01312008.pdf.
3 Id.

The inside story on clinical research billing

By Beau Gostomsky, MBA and Kelly Willenberg, MBA, BSN, RN

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Clinical research is increasingly one of the most heavily regulated "industries" involving numerous federal and state agencies. Investigations and issuances by the Office of Inspector General (OIG) have made research billing compliance a "hot" topic in many institutions across the country and have driven many to investigate their current research billing operations. This introspection has produced startling revelations about the deficiencies and challenges of a complex, multi-stakeholder operation for those compliance, legal, and research administration professionals. Typically, panic ensues as management identifies potential compliance issues from research operations and a general sense of what to do next or how to take control of a compliance risk follows. We address some practical strategies for groups seeking to either develop their research billing operation or evaluate and shore up their existing program.

Developing practical strategies for making a compliant research billing operation practical and effective takes finesse. It involves numerous institutional groups across many unrelated departments, including accounts payable, finance, patient billing, registration, Medical Records, and numerous clinical service providers, as well as the various research team members who conduct the research. It should not come as a surprise to any management or leadership group experienced in multi-departmental initiatives that this can be a Herculean undertaking.

In many instances, the "language" spoken by research clinicians is often very different from that spoken by the financial and patient billing groups, and trying to bring everyone to some kind of operational consensus for a seamless system seems daunting. Additionally, the technology used by the various stakeholders is often specific in focus for each group, and users rarely have the ability to share data back and forth. While it seems obvious that technology is a solution to the flow of research patient and billing information across an institutional system, without a well-planned and robust manual research billing process in place, a technological tool can not make a process compliant in and of itself. Additionally, research billing needs operational oversight, both from a higher-level decision-making aspect as well as an on-the-ground problem-solving team.

At the core, correct research billing is the responsibility of the principal investigator (PI), but most PIs and research team members have little experience with the complexities and regulations that govern billing issues. They do not have a good working knowledge of the institutional systems in play to insure correct billing, if those systems even exist. The varying experience and abilities of research team members also pose challenges to maintaining even the most robust research billing operations with the ever-changing regulations and guidelines that come from the Centers of Medicare and Medicaid Services (CMS). Centralizing the responsibilities for research billing oversight can often solve this kind of issue, if an institution is willing to make the resource investment. Anecdotally, institutions in the past have placed the initial research billing compliance burden on their legal or compliance teams to do an initial inquiry and survey into the existing research billing environment. Based on the findings from that inquiry, an operational process can evolve that takes into account available resources, research volume, and the necessary work needed to create and maintain a compliant system.

The question of additional staffing resources must often focus on the role and responsibilities of that group. Is it only to provide education and training to research teams who will be responsible for creating detailed billing instructions for their research by using sponsor contracts, budgets, grant or foundation awards, and informed consent forms? Does institutional leadership feel that performing a Medicare Coverage Analysis, as a gold-standard for accurately identifying routine care and Medicare coverage for that routine care, is feasible? If so, who has experience, not only to provide that service, but to stay current with changing regulations and be able to integrate those changes in a timely manner? A strong compliance case can be made for centralizing some of these functions as a way to keep control of the information as well as to establish a subject-matter expertise surrounding research billing. A central operation also provides a good opportunity for training and education and provides a detail-oriented group to deal with the specific challenges created from trying to move information to and among various institutional groups. A central operation also

Continued on page 50

provides a "go-to" point for those groups to raise issues and present opportunities for fixing or improving the system.

Integrating current research billing compliance programs with revised CMS policy is ever changing. Centralizing research compliance for a successful research billing program takes full-time effort, staff, and dollars. Patients who are enrolled in clinical trials often receive products and services as part of the research study. Patients or third-party payers must be billed in accordance with applicable laws and regulations, including government requirements (federal, state, and local) and new coding requirements. Correct billing also requires a careful eye on reviewing standard operating procedures within your institution.

Compliance has become increasingly more intense for many reasons. *Qui tam* lawsuits, brought under the False Claims Act by a private plaintiff on behalf of the federal or state government (rather than by the government itself), are occurring on a more frequent basis. These include "whistleblower" lawsuits where an inadvertent or non-meditated research billing transaction, with a potential for a false claim, has occurred. Intentional fraudulent billing is considered a false claim and carries penalties. Settlements and suspension of research programs cost not only millions of dollars, but lost funding, penalties, and fines, and they negatively impact public relations and the institution's reputation with governmental agencies and industry sponsors.

Identifying high-risk billing areas in your institution can be difficult, including:

- Whether services are billable to Medicare or not, and the potential of actually billing Medicare (or the patient) for items or services that are otherwise reimbursable or free to the hospital through federal or private grant funds (i.e., "double billing" or "double dipping");
- Billing Medicare for experimental procedures or devices, unless covered specifically by an FDA-approved investigational device exemption (IDE);
- Charging for an investigational drug in a clinical trial under an investigational new drug (IND) application without approval from the FDA;
- Waiving Medicare co-payments and deductible obligations for study participants;
- Receiving remuneration from sponsors that could be viewed as kickbacks by Medicare;
- Receiving something outside of fair market value on reimbursements;
- Coding and billing for non-covered items or services as a covered benefit by an insurer;
- Billing for items solely to satisfy data needs or trial eligibility;
- Inadequate medical record documentation for items or services billed; and
- Incorrect use of an Advance Beneficiary Notice.

There are many obvious benefits of a compliant billing operation, including reducing the resulting legal and financial consequences of any noncompliant practices. This enhances the sensible, straightforward identification of possible compliance problems in any program. A compliant billing operation improves public relations and demonstrates an enhanced internal control of your research environment. It provides a process to address compliance issues internally while protecting the assets of your institution or practice.

A compliant billing program can be one of the most important pieces of your research process, and yet, it is often overlooked because it seemingly does not involve the direct care or benefit of the subject. However, that assumption is incorrect. Research billing is directly addressed in the research informed consent document, which identifies for potential research subjects exactly what, if any, expenses they will incur as participants in the research. Specifically promising items, procedures, or medications at no cost in an informed consent obligates the institution to fulfill that promise, whether or not there is contractual or other financing to support that claim. It relieves Medicare from that burden, even in cases where Medicare would have normally covered routine care in other circumstances.

As a practical tool, institutions should establish appropriate patient care budgets for clinical research, noting those grants or sponsor-supported projects that don't provide itemized coverage or utilize itemized budgets provided by sponsors. Creating transparency for what is and is not covered in a clinical research project is the first step in the process for making sure that items being billed to Medicare or third-party insurance are not already being covered. A compliant process ensures funding provisions for each study agreement for billing of patient clinical research and clarifies financial remuneration for adverse events. It establishes a process to ensure accurate patient care billing for clinical research, so that audits can be done to ensure billing compliance with federal regulations and Medicare regulations. It also helps to develop standardized tools that support a patient billing compliance program and establishes internal and external research billing control points, before it's too late. Knowing that a patient encounter should not be billed to a federal third-party payer and allowing the charge to go through anyway can be classified as a false claim, which can be punishable by criminal and civil penalties. Financial personnel typically do not understand clinical research language or concepts, and research staff do not understand the billing/financial side of their institution. Without

a standardized process backed by policy, it becomes increasingly difficult to audit and make institutional corrections. Doing an operational systems process review continually identifies "holes" where information from research subjects might not imprint into the billing system properly and decreases the chances for inappropriate billing practices.

Setting up a patient tracking system to identify all of your research subjects is also an essential tool to the research billing process. This can be done electronically through your billing system or manually, absent an electronic solution. A research subject tracking system adds information to the billing process and provides a resource for the patient billing group to assure that bills are discharged to third-party payers, including Medicare when appropriate. A tracking system provides statistical information on the finances of studies for the investigative team. Importantly, a robust subject tracking system can directly improve collections with sponsor organizations and provide revenue while helping to meet budget projections. It can prevent mischarging of procedures to the subject's insurance or to the clinical trial, and assist with authorization of procedures for each subject, based on the study in which they are enrolled. It can also be an effective communication tool for providing a template of procedures for each patient enrolled and assist the staff with confirming the billing status to the research account, prior to generating the bill.

If setting up a system manually, you should begin to track each budget vs. every subject entered in the trial. All milestone payments should be tracked against the negotiated contract, if applicable. All accounts receivable should also be noted, and any bills paid out for each particular subject should be done as well. Verifying all payments will ensure that you are tracking all dollars on each clinical trial. Auditing each study as it closes out will also help with the tracking of dollars paid out to third-party payers, including Medicare. Any deviation can be tracked down and noted, so that all bills are handled appropriately. Although this process can be incredibly time sensitive, identification of appropriate routing of the research-related items and where your dollars flow, may help you in the long run. The overall success of your initial negotiation of the clinical trial agreement may depend on it.

Ultimately, there are no easy solutions to the operation of research billing. Every organization is different, with different research profiles, organizational structures, and research experience. Prioritizing compliance issues at an institution can significantly affect the leadership buy-in and support of a research billing procedure, especially in the absence of a reliable understanding of the institution's current research billing operation. First steps are important. Assessing the current environment and putting together an initial group of stakeholders to look at the issues from a high-level can go a long way towards implementing a system that meets compliance standards. Leveraging operational and regulatory information that exists in the public domain and reaching out to peer institutions to understand their processes and the challenges they faced in putting their operations together is a tried-and-true solution. Lastly, any process or operation, no matter how well thought out and implemented, needs to have the ability to evolve and react according to internal and external changes. Like all compliance programs, research billing compliance is not a finite goal, but a moving target – one that organizations need to continually strive to reach for if they are to be successful in clinical research. ■

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HIPAA Security Rule and the telecommuter: Navigating the rough seas of remote usage

By Robyn J. Bartlett, Esq.

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"Work at Home." "Flex-time Available." These have become standard catch phrases in employment advertisements seeking health care professionals. Why? Well, recruiting health care professionals is tough work. Every incentive helps. First, there is a nursing shortage which is expected to intensify as baby boomers age and the need for health care grows. Second, tech-savvy Generation Y employees seek (or – should we say – demand?) flexibility in their working environment, which often includes the option of working remotely or during off-hours. Allowing health care professionals to set up shop at their home a few days week seems not only reasonable, but a necessary recruitment tactic.

Are there security concerns with allowing individuals to remotely access electronic Protected Health Information (e-PHI) from their personal computers? Of course. Obvious risks include the potential for intruders to access company systems without having to be on-site and opening up the company network to hackers and viruses. Does it violate the Health Insurance Portability and Accountability Act (HIPAA) Security Rule?[1] Well, if you're not careful in the implementation of your telecommuting program, it very well could. Here are some things to consider.

The HIPAA Security Rule sets forth the requirements that must be followed by "covered entities"[2] that transmit any e-PHI. Generally, a covered entity may use any security measures that allow it to reasonably and appropriately implement the many standards and implementations specifications set forth in the Security Rule. You have flexibility in the technology you choose to become HIPAA-compliant. However, at the end of the day, you still need to demonstrate that you have appropriate administrative, physical, and technical safeguards in place to guard all of your e-PHI, whether it is on-site or on a telecommuter's personal computer.

As the first step to compliance, the Security Rule requires a covered entity to conduct a risk analysis which includes an inventory of all assets containing e-PHI. The covered entity must then conduct an assessment of the potential risks and vulnerabilities to the company and set up a risk management process to reduce those risks and vulnerabilities to a reasonable and appropriate level. An organization desirous of implementing a telecommuting program has added challenges. The risk analysis, and subsequent risk management policy, must include not only on-site data and hardware that is owned by the company, but any instances of off-site data or equipment owned by a remote user (e.g., off-site personal computers [PCs], personal digital assistants [PDAs], laptop computers).

The Department of Health and Human Services (HHS) has spoken out strongly on the issue of remote usage.[3] After a variety of incidents involving stolen laptops and PDAs, HHS issued guidance stating that "covered entities should be extremely cautious about allowing the offsite use or access to e-PHI." Not exactly a glowing endorsement for telecommuting. HHS explains that the covered entity must make a business case that such offsite use is necessary and—even then—a covered entity must take great rigor to ensure that policies, procedures, and workforce training have been effectively deployed and that access is provided consistent with the applicable requirements of the HIPAA Privacy Rule.[4] The examples of justifiable business cases cited by HHS include: a visiting nurse using a PDA, a physician accessing an e-prescribing application while off-site, and a health plan employee transporting data to an off-site storage facility. Notably, HHS makes no mention of the "everyday" telecommuter, (e.g., the nurse or case manager who accesses e-PHI from home as a result of a need for flex-time or a shortage of on-site work space). HHS does not go so far as to say such telecommuting programs are impermissible, but the compliance bar appears to be high.

HHS restates general HIPAA Security Rule principles that [a] covered entity must evaluate its own need for offsite use of, or access to e-PHI, and when deciding which security strategies to use, must consider those factors identified in § 164.306(b)(2):

(i) The size, complexity, and capabilities of the covered entity.

ii) The covered entity's technical infrastructure, hardware, and software capabilities.

(iii) The costs of security measures.

(iv) The probability and criticality of potential risks to [e-PHI].[5]

Continued on page 55

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Practically speaking, what should a compliance officer look for when Human Resources pushes a "work-at-home" option for employees? First, you should not roll it out without demonstrating a business case as to why remote usage is necessary. It should then only be available to employees who can demonstrate that they really need the access. As HHS explains, "[r]emote access to e-PHI should only be granted to authorized users based on their role in the organization and their need for access to e-PHI." A preliminary step is to draft a telecommuting policy which clearly delineates the criteria for which roles and positions are open to a telecommuting option.

The telecommuting environment must then encompass the administrative, physical, and technical safeguards required by HIPAA. On the policy front, telecommuting policies should speak to issues of security, and security policies should address particular remote usage concerns. HHS suggests that covered entities include the following remote usage topics in their security policies:

- Workforce awareness and training programs for remote usage,
- Password management procedures (for changing and safeguarding passwords),
- Remote device/media protection to reinforce policies that prohibit leaving devices/media in unattended cars or public thoroughfares, and
- Prohibitions on transmission of e-PHI over open networks (including e-mail) or downloading e-PHI to public or remote computers.

And, if you're going to have policies, you need to enforce them with sanctions. That goes for high-level executives as well as lower-level employees. (For example, if the surgical chief is e-mailing unencrypted e-PHI over the Internet in violation of the policy, action should be taken). As HHS suggests, it is a good idea to require employees (especially those who intend to telecommute) to sign a statement of adherence to security policies and procedures as a prerequisite to employment.

After appropriate policies are drafted and a workforce training program is implemented, there are many physical and technical issues to grapple with. Certainly, one of the biggest concerns is that remote usage will lead to unauthorized access to e-PHI. HHS acknowledges this risk by suggesting that covered entities consider implementing "two-factor authentication" for granting remote access to systems that contain e-PHI. That means the remote user must have something more than a unique password, even if that password is complex (containing multiple alpha-numeric characters). The user may need to answer a security question or enter a computer-generated PIN number. For companies that do not yet have this type of authentication, this can be a technical and financial challenge. However, for a telecommuting program to pass muster, it is clear that implementation of robust authentication measures is critical.

Another concern with permitting remote usage is intrusion by hackers, viruses, malicious software, or other unwanted visitors. Remember, the Security Rule does not prescribe specific technology, but requires that reasonable and appropriate security measures be adopted to mitigate risk. Virtual Private Networks (VPNs) are often considered a best practice for securing communications to the organization's internal network. In simple terms, a VPN is a private network that uses a public network (most likely the Internet) to connect remote sites together. Additionally, a company is well-advised to set up access control so that only company-authorized PCs are allowed to connect to your VPN. By providing the computer, the employer can control what is installed and what activities are allowed. Of course, this is a big expenditure for a company. If it is not financially feasible to provide PCs to all remote users, at the very least, by policy, telecommuters should only use computers with a good firewall, virus protection, and spyware scanning capabilities. The policy should state what software is needed for the employee to work remotely, as well as what types of software will not be allowed on the computer.

Consistent with the statement that remote usage should only be available to users with a business justification, the storage of e-PHI on remote devices should only be allowed when required by a business necessity. As we've seen on the nightly news, it's too easy to lose physical control of a remote device. Some of the risk management techniques suggested by HHS include:

- Inventorying all remote devices and recording their movements,
- Requiring lock-down for unattended laptops,
- Password protecting files and remote devices,
- Prohibiting or preventing download of e-PHI onto remote devices without operational justification,
- Installing virus-protection on remote devices, and
- Encrypting data and employing biometrics for access.

It makes good sense to keep the data on a secure network, rather than a hard drive. If the data must be stored on a hard drive, it should be encrypted. Encryption is a method of converting an original message of regular text into encoded text by means of an algorithm.

And then, there's e-mail. Certainly, e-mail facilitates the work of telecommuters, but what does HIPAA require? The Security Rule

Continued on page 64

The administrator engages the biggest law firm in town, Billem & Milkem, hires a compliance officer, Jill Papermaker, and starts to build a very thick Plan manual.

In the first year of the Plan, Jill conducts all of the claim reviews herself. She notes the billing mistakes and other issues, such as poor handwriting seen in charts. She sends out a round of rather threatening letters to all of the surgeons, explaining their mistakes and that they need to do a much better job before the next claim review. Along with Jill's review letters, she included a copy of the Plan policy manual that contained over 100 new policies for the Village. Each surgeon had to sign and return an acknowledgement form stating that they read and understood the manual. Paychecks would be held back by the Village until the signed notices were sent back.

With respect to Dr. Goodwitch's review letter, Jill explained that one of the five claims reviewed needed better documentation to support the use of an evaluation and management services (E/M) code known as "modifier -24." There was no further explanation, other than a reference to the new policy manual and a citation that read "Medicare Claims Processing Manual, Pub. 100-04, Chapter 12, §30.6.6."[30] Upon receipt, Dr. Goodwitch skimmed the review letter, stared at the policy manual on its edge to assess the thickness of it, and tossed both in her to-be-filed-away pile (one of about 20 such piles her in cramped office). Not wanting to delay her paycheck, she immediately signed the acknowledgement form and dropped it in Jill's office mailbox.

Dr. Goodwitch just assumed she had to make better chart notes to support modifier -24. She had been told by an attending, during her residency training, that you have to get into the practice of documenting and billing for your entire day because medicine, like it or not, was a business. In other words, when you see a patient, you find a way to bill for the service. She thought this was just a matter of fairness and sticking to a routine coding process day after day, year after year, to maximize her reimbursement for her work. She had heard about issues such as billing for services not performed, upcoding (intentionally billing for a more expensive service or higher E/M code than the one actually rendered[31]) and clustering (coding/charging one or two mid-levels of codes exclusively, under the philosophy that the undercharges and overcharges will average out over an extended period[32]), but those practices were bad billing in her book. (Had she taken the time to read the citation in the 2007 Medicare Claims Processing Manual that Jill referenced, Dr. Goodwitch would have seen that E/M services provided by the same physician to surgical patients during the relevant postoperative period, if covered under a global surgical package, are not separately billable unless they are unrelated to the surgery.[30])

In the second year of the Plan, a newly hired coding expert, Jack Stickler, did the next round of claim reviews. Like Jill, he also noticed on one of Dr. Goodwitch's claims that modifier -24 may not have been used correctly to bill for an E/M visit in the hospital a few days after a patient's surgery. Jack decided to investigate the matter and called Dr. Goodwitch.

"Eight months ago, you billed for an E/M visit with Mrs. Lancelot, one of your Medicare patients. Why did you do that?" asked Jack.

"I do not really remember," Dr. Goodwitch responded truthfully. She added: "I am guessing that I billed it that way because my routine practice, I learned a while back, was to use the -24 code so I could bill for the E/M visit when patients came back complaining of pain after surgery."

Jack panicked in response to what Dr. Goodwitch relayed to him. He told Dr. Goodwitch: "You cannot bill for E/M visits after surgery. That is fraud!"

Dr. Goodwitch just thought Jack was too green at his job and did not think much of his comment. She responded: "What are you talking about?"

Jack was flustered. He said: "I will have to get back to you."

Jack took his claim review information to the Village administrator and said they should call their law firm right away. The Village administrator agreed. After a telephone conference, the corporate lawyer said he would think about the situation and get back to them. A few hours later a lengthy legal memo was faxed to the administrator with instructions to do a much larger audit on Dr. Goodwitch's claims. Jack jumped right on the new project because he knew exactly what days Dr. Goodwitch generally saw patients after surgeries and was able to amass a fair number of claims that used modifier -24.

Jack's findings soon made their way around the Village. After multiple closed door meetings in the administrator's office with the corporate lawyer as well as the employment lawyer, the judgment was that Dr. Goodwitch was fraudulently billing for her services. Use of the "f word" (fraud) immediately spread around the Village and chaos erupted.

The other Village surgeons started calling the administrator and were angry about Dr. Goodwitch and wanted her fired immediately. The administrator said they could not do that right away and had to be careful because they did not want a lawsuit for wrongful termination. She added that they needed to build an airtight case against Dr. Goodwitch.

To build such a case, the Village called a board meeting and asked Dr. Goodwitch to attend and explain herself. At the meeting, Dr. Goodwitch admitted she may not fully understand modifier -24. She added that if she made mistakes, she was sorry, and she would help correct problem claims. The administrator asked Dr. Goodwitch to leave the meeting so the rest of the Village could discuss the matter in private. Somewhat bewildered, Dr. Goodwitch got up and left.

As soon as the conference room door closed behind her, one surgeon angrily spouted: "See, we got her. She admitted she misused modifier -24. I would never use that modifier incorrectly."

Jack added: "Yeah, I bet it goes back a long way."

There was an uncomfortable silence. The corporate lawyer impulsively chimed in: "Well, we need to contain the problem, and we will do that. I have some ideas which I will let you know about shortly."

The next day another very long legal memo slid out of the Village fax machine. Rather than take any chances, the lawyerly decision was made to do another really big audit and look for any claims over the past six years where Dr. Goodwitch used modifier -24. To figure out how much money was at stake, an assumption was made that all of the claims should be labeled "bad" claims rather than do any analysis to see whether properly billed claims existed. Another lawyerly decision was made to report Dr. Goodwitch under the OIG's Protocol without telling her, because the lawyer stated it would be the only way to protect the Village and prevent Dr. Goodwitch or others from becoming whistleblowers under the False Claims Act.

The Village members were mentally rowdy and jubilant when they finally reported the matter to OIG, because they felt they had found a way to protect and distance themselves from Dr. Goodwitch and her alleged evil ways. Or, at least they thought they did.

While this all sounds like a campy 1970s movie, the unfortunate and likely outcome of the above tale is that the OIG would extract monetary settlements from and impose integrity agreements upon both the Village and Dr. Goodwitch. Why? Well, that is another "just because" matter.

Even though The Village and Dr. Goodwitch may not have committed fraud, the goal for the OIG under the Protocol, at least to the outside observer, is to settle cases and get noncompliant providers locked into federal agreements that make it easier for the OIG to keep an eye on the compliance and noncompliance of the provider. This outcome may be true, even if an independent analysis of Dr. Goodwitch's post-surgical services revealed that the bulk of the services were properly billed. Again, if the goal is settlement and a provider like the Village voluntarily comes forward with money in hand, there may be little incentive to undertake a detailed and balanced review of a matter.

Disclosures of potential overpayments under the Protocol are pretty much "found" money, so there is no need for the OIG to spend a large amount of resources picking apart the logic and numbers behind a disclosure. Further, under a settlement, no party admits any wrongdoing. And, in today's world, where defense costs could be well into the six figures to fully adjudicate a matter, sometimes a guaranteed settlement is the low cost and saner option, especially if the amount in controversy under the federal programs is not even six figures itself.

A Discussion

So, is there anything that can be done to avoid this type of tale?

For the Village. If you are in a position similar to the Village, find counsel who understands the nature of the Protocol and how to properly analyze the Village's, not necessarily Dr. Goodwitch's, legal obligations.

One key mistake, seen above, is to assume the billing problems of Dr. Goodwitch stand on their own and that having the Village file under the Protocol means only Dr. Goodwitch will be investigated and penalized. This assumption is not true if the Village is the actual billing entity that causes the third-party billing company to file claims. Like it or not, the billing problems belong to both Dr. Goodwitch and the Village. And, if the Village files under the Protocol, it would be admitting that it (the Village) may have violated federal law, not Dr. Goodwitch.

In a large group like the Village, a solid analysis of the problem from the group's perspective is essential. This is difficult when the staff and surgeons of the Village get fearful and angry about Dr. Goodwitch. An independent and objective analysis is highly recommended because a review by insiders, including longtime corporate counsel, may be tainted by individuals seeking to cover their own mistakes, misunderstandings, or even negligence.

For example, if Dr. Goodwitch is the only group member with billing problems compared to the other 24 surgeons and each surgeon bills about the same number of claims, that means, at most, 4% of the claims being billed by the group have potential problems. And, if a focused retrospective review of the problem is done correctly with as much credit given to the surgeon as possible, that error rate

Continued on page 59

may be far less than 4% for the group. From a health care fraud and abuse perspective, an error rate of less than 4% hardly seems like a fraud issue for the group and likely is not a false claims issue either, especially if the group caught the problem and Dr. Goodwitch agreed to cooperate with a corrective action plan.

Notably, the group might have been negligent in allowing the problem to have gone on for so long, but even the OIG has acknowledged that mere negligence is not a false claim and certainly is not fraud.[33] Use of the Protocol, therefore, must be carefully considered, because the Village should not be admitting to something it does not have to admit, simply out of fear and anger.

From a practical perspective, keeping the matter on the administrative and Carrier side of the Medicare world likely will save the group tens of thousands, if not hundreds of thousands, of dollars in defense costs associated with the Protocol. In the above example, the Village might have inquired about their Medicare Part B Carrier's voluntary refund process (usually found outlined on the Carrier's Web site). Typically, if the Village can demonstrate that it correctly identified and rationally responded to the problem, a voluntary refund might be part of a reasonable alternative to the Protocol. Should the Village make such a decision without the benefit of seasoned counsel or at least a consulting phone call to such counsel? Probably not.

The other more serious aspect to Protocol filings is the likely result that OIG will impose on the Village, and potentially the Villager, either a Corporate Integrity Agreement (CIA) or a lighter version of a CIA known as a Certification of Compliance Agreement (CCA). Neither a CIA nor CCA, however, are gold stars by any means, because they are documents (actually contracts with the federal government) that tell you how to run your business, give the government reports on your business, and open the door to periodic government site visits.

Traditionally, site visits were planned events and touted as meetings to assist with compliance, rather than formal investigations. But, the low-key nature of site visits may have changed. In 2007, OIG indicated that it will conduct unannounced site visits for some CIA and CCA parties.[34] This not-well-published news was an unfortunate change in OIG's practice, because surprise site visits likely mean that OIG will be using the visit as an ongoing investigative tool, rather than an educational tool.

Regardless of a planned or unannounced site visit, government personnel are just people too. Does the Village really want an OIG attorney randomly selecting a Village staff member to grill them about compliance? While the average attorney or physician might be used to intense face-to-face questioning, the average staff person likely is not, and could be emotionally affected by the event.

Notably, on April 15, 2008, OIG posted another in a series of open letters to health care providers about the Protocol.[35] In the letter, OIG indicated that if a provider has adopted effective compliance measures, it generally would not require a disclosing provider to enter into a CIA or CCA as part of a settlement with OIG. Because there is so little public information available about the Protocol, it is difficult to know if the latest open letter signals a major change in how OIG will resolve voluntarily disclosed matters. Until more public information is available about the outcome of settlements under the Protocol, providers still should carefully consider whether the Protocol is the proper response to take as part of their corrective action plan to correct identified compliance issues.

In short, the Village needs to obtain calming, level-headed counsel who understands the trappings of the Protocol as well as cost-effective, compliant, and perhaps more reasonable alternatives to the Protocol.

For the Villager. If you are being labeled a witch like Dr. Goodwitch, find counsel who not only understands the Protocol, but knows how to go about contacting the right individual within the government to get a proper dialogue going as early as possible. By the time the Village has filed under the Protocol, however, it may be too late. Most documents filed with OIG would be shielded from disclosure. Even attempts to obtain copies of documents under the Freedom of Information Act[36] may take too much time and money to pursue and might set the wrong tone with OIG.

As the Villager, again, the cost of defense easily could get into the hundreds of thousands of dollars. Some professional liability policies may have endorsements that cover the cost of defense in a governmental investigation regarding billing matters. But, those endorsements tend to limit the cost of defense to an unrealistic figure such as $15,000 or $25,000. Check to see if the Village has some type of errors-and-omissions policy that provided coverage for the Village as well as the Villager.

Unlike the Village, even if Dr. Goodwitch merely was negligent in her billing, she could face the real threat of not only losing her billing rights with Medicare, if excluded, but her license to practice medicine with the state medical board. In short, she could lose her livelihood. This is another reason why use of the Protocol is potentially abusive and devastating when used as a sword against an individual and as a shield for a larger corporate entity.

Continued on page 60

The potential problem with state medical boards is that billing issues tend to be reviewed and judged by other physicians who are not necessarily billing experts. Furthermore, Dr. Goodwitch's hands may be tied by state public record laws that prevent her from getting enough information prior to formally contesting any alleged statutory violations.[37] Without such information, she will be unable to engage in a meaningful dialogue with the board.

Another potential issue Dr. Goodwitch may face regarding state medical practice acts would be instances where regulatory definitions are broader than statutory terms. For example, state medical practices acts generally call for disciplining physicians who engage in "unprofessional conduct" versus outright "fraud." Logically, one would assume that the burden of proving fraud, normally considered a crime, is higher than the burden of proof for unprofessional conduct, which generally is treated like negligence or repeated negligence. Nevertheless, some medical boards have amended their administrative regulations that further define the statutory term "unprofessional conduct" to include the term "fraud." In other words, if a physician enters into a settlement agreement with a medical board and admits to general unprofessional conduct to resolve a case that is about negligent billing, he or she inadvertently could be admitting to fraud if the underlying regulation is broader than the statute. (Whether such a practice by a medical board is legitimate or even constitutional is beyond the scope of this article.)

By the time Dr. Goodwitch gets invited to any investigative meeting of the board, the board members already may be visualizing a fraudulent witch. Depending upon how badly the Village may have dressed up Dr. Goodwitch, she may find herself working her way up from a very dark hole. The challenge for Dr. Goodwitch when she goes before a state medical board is to be as cooperative as possible without rolling over.

During the course of her employment, if Dr. Goodwitch started hearing words like "fraud" and "Protocol" and "OIG" when members of the Village addressed her, she should start documenting her work day and the steps she took personally toward compliance. She should seek legal counsel familiar with the issues, and understand that if the Village does act out of fear and anger, more than one attorney or law firm may be necessary. The potential legal fronts that a target like Dr. Goodwitch may face likely are alien and mind-boggling to the layperson. Dr. Goodwitch may need an attorney who is familiar with health care laws, an employment lawyer, insurance defense counsel, and litigation counsel.

In addition to legal counsel, the most important asset on Dr. Goodwitch's team will be a billing consultant who understands the unique aspects of the specialty area billed by Dr. Goodwitch. These folks are hard to find, because competence in the billing trade requires knowledge of the particular codes for that particular medical specialty. Many billing issues are not well understood by administrators, attorneys, and government officials, because the issues are so detailed and complex. A competent billing consultant will be valuable in explaining the facts regarding potential problems.

In short, Dr. Goodwitch needs an advocate and possibly an entire legal team, depending upon how much fear and anger exist in the Village.

Conclusion

In sum, both the Village and the Villager need to think carefully about responding to allegations regarding Medicare fraud and potential use of the Protocol. The Village needs to be careful to avoid turning an overpayment case into a false claims case when it does not have to do so. The Villager needs to get an advocate in her corner to try and help her remove the witch nose, hat, and clothes put on her by other Villagers. Remember, the Protocol was designed to deal with real witches, not dressed up ones. ■

1 Statement on Initiatives to Combat Medicare and Medicaid Fraud Pub. 1 Pub. Papers 632 (May 3, 1995).
2 Health Insurance Portability and Accountability Act, Pub. L. 104-191, §§201-250 (1996).
3 See Publication of the OIG's Provider Self-Disclosure Protocol, 63 F.R. 58399 (Oct. 30, 1998) (hereinafter "Protocol").
4 Protocol, 63 F.R. 58400.
5 Protocol, 63 F.R. 58401.
6 Id.
7 See 31 U.S.C. 3729 (setting forth the potential penalties under the False Claims Act which call for double rather than triple damages where a person cooperates with a government investigation); and 42 U.S.C. 1320a-7a (describing the potential penalties under the CMPL which call for up to triple damages); see also 42 C.F.R. 1003.106 (discussing mitigation of damages under the CMPL and setting a floor of double damages for certain false claims violations).
8 42 U.S.C. 1320a-7.
9 See OIG Compliance Guidance for Individual and Small Group Physician Practices, 65 F.R. 59434, 59436 (Oct. 5, 2000).
10 See, e.g., 18 U.S.C. §287 (false, fictitious or fraudulent claims); 18 U.S.C. §669 (theft or embezzlement in connection with health care); 18 U.S.C. §1035 (false statements related to health care matters); 18 U.S.C. §1341 (frauds and swindles); 18 U.S.C. §1343 (fraud by wire, radio, or television); 18 U.S.C. §1347 (health care fraud); 18 U.S.C. §1518 (obstruction of criminal investigations of health care offenses); and 42 U.S.C. §1320a-7b (criminal penalties for acts involving federal health care programs).
11 42 U.S.C. §1320a-7b(b).
12 42 U.S.C. §1320a-7b(b).
13 See 42 C.F.R. §1001.952.
14 See 42 U.S.C. § 1320a-7d(b) (setting forth the statutory authority granted under HIPAA to the Secretary of the Department of Health and Human Services for issuing written advisory opinions).
15 31 U.S.C. § 3729.
16 31 U.S.C. §3729(a).
17 United States v. Sulzbach, No. 07-61329 (S.D. Fla. filed Sep. 18, 2007).
18 Complaint at 2, United States v. Sulzbach, No. 07-61329 (S.D. Fla. filed Sep. 18, 2007).
19 31 U.S.C. § 3730(b).
20 31 U.S.C. § 3730(d).
21 31 U.S.C. § 3729(b).
22 See, e.g., Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1053 (8th Cir. 2002) (stating that the standard for liability under the False Claims Act is knowing—not negligent—presentation of a claim); and U.S. v. Prabhu, 442 F. Supp. 2d 1008, 1028-29 (D. Nev. 2006) (stating that the False Claims Act knowledge standard does not extend to honest mistakes but only to lies); see also David E. Matyas & Carrie Valiant, Legal Issues in Healthcare Fraud and Abuse: Navigating the Uncertainties § 4-2(a)(2) (American Health Lawyers Ass'n 3d ed. 2006).
23 See, e.g., United States v. Lorenzo, 768 F. Supp. 1127, 1132 (E.D. Pa. 1991) (finding that dentist deliberately knew that information on claim forms was misleading); see also Matyas & Valiant, supra note _, at § 4-2(a)(2)(i).
24 See, e.g., United States v. Mackby, 261 F.3d 821, 828 (9th Cir. 2001) (finding that managing director of clinic acted in reckless disregard of Medicare requirements by failing to ensure proper billing numbers were used by the clinic); see also Matyas & Valiant, supra note _, at § 4-2(a)(2)(ii).
25 See 31 U.S.C. § 3729(a)(1) and (2).
26 Compare United States v. Krizek, 111 F.3d 934, 942 (D.C. Cir. 1997) (stating that where a physician had delegated to his wife the authority to submit claims on his behalf, he was no less liable than his wife for false submissions), with United States ex rel Kinney v. Hennepin County Medical Center, 2001 WL 964011 (D. Minn. 2001) (stating that admitting physicians who medically certified the necessity of ambulance runs did not cause false claims to be presented by the hospital because the physicians did not delegate to the hospital the authority to submit claims, they did not have control over the content of the claims submitted, and they did not have a right to review the claim forms being submitted).
27 OIG Compliance Program for Individual and Small Group Physician Practices, 65 F.R. 59434 (Oct. 5, 2000) (hereinafter "Guidance").
28 Guidance, 65 F.R. 59436.
29 Guidance, 65 F.R. 59437.
30 See generally Medicare Claims Processing Manual, Pub. 100-04, Chapter 12, §30.6.6, §40.1.A, §40.2.A.7.
31 OIG Guidance, 65 F.R. 59439.
32 In reality, this overcharges some patients while undercharging others. OIG Guidance, 65 F.R. 59439.
33 Guidance, 65 F.R. 59436.
34 OIG Will Engage in Unannounced Site Visits to Ensure Compliance with CIAs, Health Provider Alert, Crowell & Moring (April 27, 2007).
35 Daniel R. Levinson, An Open Letter to Health Care Providers, Dept of Health and Human Services, Office of Inspector General (April 15, 2008).
36 5 U.S.C. §552.
37 See, e.g., ORS 677.190(1) (unprofessional conduct); and O.R.S. §677.190(21) (making a fraudulent claim). See, e.g., O.A.R. §847-010-0073(1)(b)(D).

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:

I understand that auditing should be done by someone outside the area being audited. Can you provide more information on monitoring? How is it different from auditing? Should the department monitor or should the compliance office monitor? How do you validate accuracy of monitoring?

The answer below was provided by Mark P. Ruppert, CPA, CIA, CISA, CHFP, Director, Internal Audit at Cedars-Sinai Health System

Although typically used in tandem throughout the current health care industry, "auditing" and "monitoring" are separate concepts and activities. The primary defining characteristics that distinguish auditing and monitoring are independence, objectivity, and frequency. Auditing represents evaluation activities completed on a periodic basis by individuals independent of the process. Monitoring represents evaluation activities completed on a routine or continuous basis by individuals who may not be independent of the process. Auditing should thereby provide for a more objective assessment, at least in appearance. Auditing efforts also report outside the management structure, usually to the Audit Committee of the organization board.

Monitoring activities are directed by and reported back to management as an ongoing feedback mechanism to provide comfort that key controls in a process are working effectively. Typical characteristics of monitoring efforts include:

- Although audit techniques may be employed, monitoring is often less structured than auditing
- Usually completed by operations or compliance personnel
- Involves on-going checking and measuring
- Can be periodic spot checks, daily/weekly/monthly tests
- May identify the need for an audit
- Accountability for monitoring is typically to operations leadership
- Completed by department staff and communicated to department management
- If completed in relation to a compliance work plan, formal communication to the chief compliance officer and compliance committee

Both the department in question and the Compliance office can be part of the monitoring process. The decision on which to use will likely relate to available expertise and resources. However, I suggest that effective monitoring is built into existing processes wherever practical. For example, if you want to ensure that HIPAA privacy notices are provided to your patients, one of your staff might complete a spot check of "randomly" selected records on a monthly basis and report the results to you. Where non-compliance is identified, you would research the reason, implement necessary changes, and provide staff education to improve your processes. The accuracy of your monitoring efforts can be validated by internal audit to ensure the monitoring control is being effectively applied. Your Compliance office could also complete the validation, which would provide independence from management oversight, although not necessarily to the level of Audit Committee reporting.

For more details on the difference between auditing and monitoring and the roles of corporate compliance and internal audit, refer to the related articles in the February 2006 and June 2006 issues of *Compliance Today*. ■

Be Sure to Get Your CHC CEUs

Inserted in this issue of **Compliance Today** is a quiz related to the article: "Medicare compliance: We found a witch!" by Mark A. Bonanno beginning on page 6.

To obtain your CEUs, take the quiz and print your name at the top of the form. Fax it to Liz Hergert at 952/988-0146, or mail it to Liz's attention at HCCA, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Questions? Please call Liz Hergert at 888/580-8373.

Compliance Today readers taking the CEU quiz have ONE YEAR from the published date of the CEU article to submit their completed quiz.

COMPLIANCE 101

A beginner's guide to risk assessment and work plan development

By Steve Kelly, JD, CHC

Editor's note: Steve Kelly is 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.

If you are new to compliance, you are just beginning to learn about risk assessments. To the newly initiated, the prospect of performing such a large and important task, which serves as the predicate from which all of your other compliance activities will flow, can be overwhelming and a little intimidating. In preparation for conducting your first risk assessment, you probably have read an article or two about them. Maybe you've even attended a conference where an expert in the field has, in elaborate detail, dissected the proper way to perform a risk assessment. The presentation leaves you dazzled, but also feeling a little hopeless, because what the expert described seems completely out-of-line with either your abilities, the resources at your disposal, or both. In short, you remain mystified, and, dare I say it . . . scared.

Take comfort in the fact that you are not alone. In our industry, health care compliance officers tend to come from a diverse array of backgrounds; frequently, they are administrators, attorneys, nurses, consultants, and sometimes physicians, just to name a few of the occupations from which compliance officers are harvested. All of these pedigrees have many unique advantages and disadvantages to performing successfully in the role of compliance officer, but it should not be surprising that many newly-minted compliance officers are not entirely comfortable with performing a risk assessment. Thus, this article is intended to remove some of the fear-factor behind risk assessments by providing first-timers (or over-worked, under-staffed veterans) with an easy to follow, realistic, step-by-step approach that will allow them to proactively uncover the most significant compliance risks to their organization. A well-designed risk assessment leaves enough time to put out the fires that can never be entirely avoided and will always be part of the landscape of a compliance officer's workday.

The easiest part of conducting a health care compliance risk assessment is defining what one is. Simply put, it is the process of taking an inventory of the material compliance risks affecting the provider and then for each risk identified, assessing how vulnerable your organization is to each risk. The obvious goal is to identify the most serious risks, in terms of potential criminal or civil liability, financial loss, or loss of reputation to your organization in the community. When the risks are known, the organization can determine whether it has in place internal controls (e.g., policies and procedures, education, audits) that are designed to mitigate those risks. As a practical matter, a well-designed risk assessment will also establish to the government that your organization is making a good faith effort to operate an effective compliance program and to proactively uncover any legal or ethical violations that may exist.

At the same time, risk assessments have several frequently overlooked benefits that should not be discounted. So, even if your risk assessment is not perfectly designed to uncover all of the organization's risks, take heart in the fact that it has many other intangible benefits that are aimed at improving the culture of compliance in your organization. First, risk assessments can be an excellent vehicle for compliance education, because they present many teaching opportunities. Despite all the educational efforts surrounding compliance, there is still a lot of mystery about what compliance actually does. Every interaction you have as part of a risk assessment is a chance to explain the core function of your office and to discuss what the compliance risks to the organization are. Second, risk assessments are an opportunity to interact with many different people at different levels in your organization. Through this interaction, you have the opportunity to involve multiple stakeholders in compliance and to convey the key message that compliance is everyone's responsibility. Additionally, you also have the opportunity to establish ties with your colleagues and to develop their trust. By encouraging a dialogue across different levels of the organization, risk assessments have a central role in promoting a culture of compliance.

Once completed, the risk assessment should then be used by the organization to allocate resources towards the areas with the most significant potential exposure. After all, even with all the advances that have been made in promoting the provider community's self-enforcement efforts, the reality is that there are only so many resources to go around. Also, a disconnect often remains between the level of resources the government feels should be devoted to compliance versus the level of resources many organizations feel they can afford. As a result, your compliance staff and budget may not be sufficient to cover every significant risk identified in a given year.

Before you begin, it is important to engage your compliance committee and your board in the process. Although the level of detail

that you provide to each will be different, generally advise them of steps you intend to take, seek any guidance or feedback they may wish to offer, and ask for their endorsement of your process. Particularly with respect to the board, this is a perfect opportunity to gain buy-in and begin to educate them regarding compliance and their role in overseeing it. You are now ready to dive in.

Take an inventory

The first step in conducting a compliance risk assessment is to take an inventory of the potential risks that could impact your organization. You should keep an eye towards the risks that affect your class of provider, (e.g., hospital, skilled nursing facility) as well as the risks that are unique to your organization. Look to the Office of the Inspector General's (OIG) Compliance Program Guidance documents for a list of risks that the government is always concerned about in your setting. Once you have established a lay of the land, so to speak, review the last few OIG Work Plans, starting with the most recent. You want to identify any "hot risk areas" the OIG has established recently so that you can best predict any areas of your business that may fall under its scrutiny. (Time permitting, you may also want to review OIG advisory opinions and fraud alerts that have been issued in the last year or two, for similar reasons.) In addition to governmental sources, scan a year's worth of any trade journals that you receive. Trade journals are a great way to augment your risk assessment, because from issue to issue, common themes emerge that focus on areas currently receiving the greatest governmental scrutiny.

Develop a questionnaire and seek feedback

After you have an inventory of industry-wide risks, develop a simple questionnaire to give to your executives and key managers and directors. As part of the questionnaire, ask them to review your inventory and to comment on whether any of these industry-wide risk areas should be a concern to you. Also, ask them to comment on any risks that they have identified that are not on your list.

Conduct follow-up interviews

Undoubtedly, not everyone will respond, and, if they do, their responses will frequently be vague or incomplete. Therefore, in order to gain adequate input, it is advisable to conduct in-person follow-up interviews with your executives, including your General Counsel, the revenue cycle team, and several patient care representatives. At the beginning of the interview, explain that you are developing your annual work plan and need assistance from them in directing your resources efficiently. Suggest to them that the interview is an opportunity for them to advocate for gaining the assistance of your office in handling their department's compliance risks during the coming year. Otherwise, suggest that without their input, you may direct your resources elsewhere and may not be able to proactively address any of their compliance concerns. The body of the interview should simply be a non-threatening conversation about what risks are of concern to them and to identify whether or not there are any existing internal controls to mitigate the risks. As the risk assessment is a flexible process, close the interview by inviting your colleague to share any additional concerns with you as they come to mind in the future.

Conduct focus groups

It is also a good idea to conduct focus groups in several key areas, such as billing and coding. So far in the process, you have managed to speak only to senior management, but oftentimes staff members or low-level supervisors are privy to concerns that their higher ranking brethren are not. After all, working in the trenches is often the best place to discover the organization's operational deficiencies which, for various reasons, may not always percolate up the chain of command. Therefore, the idea behind the focus groups is to get a view from the front-lines as to what the hidden risks to the organization are. Keep in mind, focus groups are just another opportunity to have a brainstorming session with a group of people who see the organization from a different viewpoint. Don't let it intimidate you.

Also, it is very important, every few years, to arrange for a coding and billing consultant to conduct a more formal review, particularly if coding and billing are not your forte or if you do not have a strong relationship with the leaders in those departments. Similarly, you should also periodically engage an outside law firm to perform a legal review of your organization's relationships with physicians and other referral sources. Unfortunately, in many organizations, budgetary constraints do not always permit engaging a consultant on a regular basis. So, at the end of the day, you should just do your best and don't be afraid to ask questions.

Revise your inventory

Hopefully, at this point in the process, you have developed an intuitive, if not an empirical, sense for which risks are the most significant to your organization and whether they overlap with the concerns highlighted by the government or not. It is now time to pare from your list all of the risks that, in your judgment, are not material. This process may make you feel uncomfortable, but it is necessary to do some pre-screening to make the list manageable for efficient review and input from your corporate compliance committee (CCC).

Prioritize and assign risk levels

Once your revisions are complete, present the list of material risks to your CCC. It is the job of the committee to assist you in developing your work priorities and to help you vet

Continued on page 64

A beginner's guide to risk assessment and work plan development

...continued from page 63

your list. With the assistance of the committee members, discuss each risk on your list and assign a risk level of high, medium, or low to each of them. The seriousness of each risk depends on both the likelihood that the risk will actually occur (taking into account any controls that are already in place to prevent it) and the amount of harm that could potentially come to the organization if it does. At the conclusion of this process, you should have good documentation to demonstrate your due diligence in assessing your compliance environment and a workable list of 10 to 15 priorities for your work plan. Although this may seem like too many, it is important to remember that you will likely not make it through all of them in a given work plan cycle. On the bright side, when you conduct your next risk assessment, you may be pleasantly surprised to find that some of the risks you previously identified are no longer troublesome.

Board of trustees approval

Finally, once you have your work plan developed, you are ready to present your results to the board. Briefly remind them of your process, educate them on your findings, and allow them an opportunity to ask questions and provide additional input. Then, conclude by seeking their endorsement. In this way, you will have educated the board of the compliance risks that are a potential threat to the organization, assured them that they have an effective compliance program in place to mitigate those risks, and allowed them to exercise high-level oversight of the process, thereby indirectly contributing to a positive culture of compliance in your organization.

If you are new to compliance and are just about to conduct a risk assessment for the first time, you may be hesitant, out of concern for doing it the wrong way or because you don't want to appear like you aren't up to the task. Remember, a risk assessment doesn't have to be hard. It just takes a little bit of time and patience. As you do more of them, you will be pleased to find that your techniques have become more sophisticated. Even so, a perfectly designed and executed risk assessment may still not uncover all of the risks that could negatively impact an organization, so just relax and do the best you can, knowing that you are doing your best to protect your organization. ■

HIPAA Security Rule and the Telecommuter:

...continued from page 55

makes the use of encryption during data transmission an addressable implementation specification for both storage and transmission purposes. However, keep in mind that "addressable" does not mean "optional" under HIPAA. An addressable implementation must be implemented if, after an assessment, the entity has determined that the specification is a reasonable and appropriate safeguard in its environment. A few years ago, an argument could have been made that encryption was too expensive and cumbersome (slowing down processing time to an unacceptable degree). As encryption technology has improved, that argument may not be viable. In fact, HHS recommends that covered entities prohibit (unsecured) transmission of e-PHI via open networks, such as the Internet, and instead, implement and mandate appropriate strong encryption solutions for the transmission of e-PHI. The bottom line seems to be that telecommuters should not be sending unencrypted e-PHI over the Internet. Of course, this prohibition needs to be made crystal clear in your policies and, subsequently, monitored and enforced.

Telecommuting can be an important incentive for employees and an appropriate business tactic. But, to say the least, covered entities have to tread very carefully in this area. To ensure compliance with the Security Rule, the Human Resources department and HIPAA compliance officials should be steadfast partners in reviewing the program, developing appropriate and enforceable policies, and mitigating the very real security risks posed by remote usage. ■

1 Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule (the Security Rule), 45 CFR §§ 160, 162 and 164.
2 A covered entity is (1) a health plan; (2) a health care clearinghouse; and/or (3) a health care provider who transmits health information in electronic form for transactions covered by Section 1173 (a)(1) of the Social Security Act. 45 CFR § 160.103.
3 HIPAA Security Guidance for Remote Use of and Access to Electronic Protected Health Information, December 28, 2006, www.cms.hhs.gov.
4 The HIPAA Privacy Rule: Standards for Privacy of Individually Identifiable Health Information, December 28, 2000, 65 FR 82462, as amended August 14, 2002, 67 FR 53182.
5 45 CFR §164.306(b)(2).

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in the first 20% of the effort. The remaining 80% of time is spent perfecting the project, changing their changes, and it results in marginal improvement. That time could have been put to better use. Our people don't add things on just because they can think of more to do. They understand the ultimate mission and get the task done. They then move on to another unaccomplished task.

We are clear of purpose. We often have a single task in mind when we start a project. In most organizations, when people get together to work on a specific project, they see all kinds of other knobs on the dashboard that could be turned, twisted, or tweaked. Our leaders keep our volunteers on track and focused. For example, our conference planning committee focuses on program content and leaves the conference management to the conference managers. They don't change the timing of sessions just because they can think of another way to do it. They don't worry about how to register people. Our leaders focus their activities within their area of expertise. As a result, the content of our meetings is second to none.

Sometimes people get involved in projects and inevitably see something related to the task at hand but outside their project scope. They think there is a better way to do it. Many organizations will go along to get along, even though what they are suggesting to change was just changed. Oftentimes there are many ways to do something. The variation of benefit between the choices can often be minimal. A change may result in a better outcome, but the effort to reengineer something may not outweigh the time required to change it. There are lost opportunity costs too. That time could have been spent getting something done that had never been done before. Our volunteers don't change things because someone can think of another way to do it. Our volunteers don't cave in to reinventing the wheel to keep the peace. We get so much more accomplished because we don't change our changes, but rather, we use that time to accomplish new things.

We have meetings with up to 200 speakers. Our main planning committee is never more than three people who select track chairs who are delegated responsibility, authority, and accountability for selecting speakers within their track. We also have specific groups working on specific tasks, such as certification or the magazine. These groups perform a function. They don't get together to think of things others could do for them. Things happen between meetings because they stay focused, develop task lists, and follow up.

Each working group has someone in charge that can make sure that things are accomplished. We don't delegate all the decision making to the group, but rather to the leader of the group. Unlike other organizations, we don't always have to wait until the next meeting to make a decision or get approval. The leader gets feedback from the group and makes decisions. In other organizations, committees can't do anything without everyone on board. These groups act slowly and often water down what ever they are working on to get agreement. They wait until everyone signs off on it; therefore, things can take forever. People working in our system have a greater chance of feeling a sense of accomplishment.

Generally speaking, we delegate to those who can make a decision and who can get work done in a reasonable amount of time. We delegate to those who are collaborative and can keep it simple. We delegate to those who can take direction and keep their word. We are not successful because of an individual or two. We are successful because of the incredibly large number of experienced and knowledgeable people in our organization, how we assign tasks, and the system we ask people to work within.

It is harder to do it the easier way. People sometimes get mad because they can't decide things they want to decide, or can't get involved in things they want to get involved in. People get mad because they can't change something they want to change. It's frustrating not to be involved in everything and know everything that is going on.

However, we disappoint fewer people in the long run, because we get more done and the things get done better. Most importantly, this system results in growth and that means there are more opportunities for more people to get involved. It's not always true; however, it's true a materially significant amount of time. At the end of the year, we see the significant accomplishments because of our systems and people. The results at the end of the year more than make up for the compromises that are made along the way. It is significantly more rewarding than the alternative. As a result, we have an organization we can all be proud of. ■

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