HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

COMPLIANCE TODAY

Volume Thirteen
Number Seven
July 2011
Published Monthly

Meet

Dave McRae, CEO and Nancy Aycock, General Counsel of University Health Systems of Eastern Carolina

PAGE 14

Earn CEU Credit

WWW.HCCA-INFO.ORG/QUIZ—SEE PAGE 19

Feature Focus:

Compliance and health care reform: What your board should know

PAGE 44

Corporate Integrity Agreements offer a second chance

PAGE 50

Global Compliance: *Good for Business*℠

We've taken the guess work out of building and maintaining an effective risk reduction program by integrating our full suite of proven and field-tested services. Over 800 health care organizations are currently utilizing our expert solutions and insight to protect their organizations.

- Hotline Solutions
- Training & Education
- Expert Advice
- Performance & Benchmarking

Learn more about our complete ethics and compliance solutions. Contact us today at **800-876-5998** or **contactus@globalcompliance.com.**

GLOBAL COMPLIANCE™
Good for Business.

www.globalcompliance.com

INSIDE

6 **Documentation improvement trends and health care reform: Could these be related?**
By Kelly C. Loya
Small details in patients' health records may add up to big differences in reimbursement.

11 **Graphic fraud**
By Shawn DeGroot
A simple cut-and-paste to falsify a lapsed certification can have enormous consequences.

14 **Meet Dave McRae, CEO and Nancy Aycock, General Counsel at University Health Systems of Eastern Carolina**
An interview by John Falcetano

20 **Letter from the CEO** **By Roy Snell**
Speaking for our profession

21 **Social Networking** **By John Falcetano**
Policy management tips

23 **Exhale**
By Shawn DeGroot
Hobbies break the cycle of worry

24 **Achieving "meaningful use" in the Medicaid incentive program, Part 3: Nuts and bolts**
By Janice A. Anderson and Rebecca L. Frigy
An outline of the general criteria states will use to determine incentive payments for eligible professionals and hospitals.

32 **CEU: Return on investment in health care compliance**
By Ofer Amit and Draco Forte
Key steps that compliance professionals can take to identify returns gained in the potential avoidance of long-term risks.

40 **Compliance 101: Whistleblower lawsuits help provide Stark and Anti-kickback Statute guidance**
By Shauna B. Itri
Case law shows ample incentives for whistleblowers to report fraud.

44 **Feature Focus: Compliance and health care reform: What your board should know**
By Anjana D. Patel and Alexandra Khorover
As enforcement actions increase, the board's role in compliance oversight also expands.

47 **Why, how, and when to conduct an information security risk analysis**
By Feisal Nanji
An overview of a systematic, nine-step process to protect e-PHI.

50 **CEU: Corporate Integrity Agreements offer a second chance**
By Joseph R. Batte and Prashanth Shetty
Four tips for negotiating an acceptable agreement to avoid debarment from federal health care programs.

55 **An interview with Diana Adams—HCCA's own Regional Conference groupie**

57 **CEU: Employed physician compensation: Expense or investment?**
By Darcy Devine
Whether a physician employment agreement is commercially reasonable depends on how its value is determined.

60 **Newly Certified CHC®, CHRC®, and CHPC®**

61 **Pharmaceutical and device manufacturers: Sales and marketing laws**
By Stephanie L. Trunk
Federal and state transparency laws and gift laws are aimed at keeping patient care decisions impartial.

67 **Data mining result raises coding concerns**
By Gloryanne Bryant and Donna Wilson
Unexplained increases in billing codes for malnutrition and urosepsis are cause for concern.

71 **Court rejects False Claims Act quality-of-care theory** **By Lisa Estrada**
ESRD Conditions for Coverage may not be the same as conditions for payment.

74 **New HCCA Members**

ARE YOU PREPARED FOR THE RAC AUDITOR?

Take control with a strong defense

The RAC Auditors will soon be calling on your hospital. The RAC appeals process is very complex and missed deadlines can result in the automatic recoupment of your legitimate revenues. To minimize your risk of financial losses, you need to be prepared with practical, reliable processes and controls to ensure that critical appeals deadlines are met, with complete, substantiated information.

Compliance 360 is the leader in compliance and risk management solutions for healthcare. More than 300 hospitals nationwide rely on us every day to ensure compliance with legal and industry regulations. Using our unique software solutions, they are always "audit ready" with both proactive defenses and the audit management tools needed to ensure successful audit response and appeals. We are proud to help these healthcare organizations prevent and contain compliance sanctions and we stand ready to help you as well.

To learn more about the Compliance 360 Claims Auditor™ for managing RAC audits, visit www.compliance360.com/RAC or call us at 678-992-0262

Compliance 360
www.compliance360.com

CT Advisory Board

Publisher: Health Care Compliance Association
888-580-8373

Executive Editor: Roy Snell, CEO, *roy.snell@hcca-info.org*

Contributing Editor: Gabriel Imperato, Esq., CHC

Editor: Margaret R. Dragon
781-593-4924, *margaret.dragon@hcca-info.org*

Copy Editor: Patricia Mees, CHC, CCEP
888-580-8373, *patricia.mees@hcca-info.org*

Layout and Production Manager: Gary DeVaan
888-580-8373, *gary.devaan@hcca-info.org*

Compliance Today (CT) (ISSN 1523-8466) is published by the Health Care Compliance Association (HCCA), 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Periodicals postage-paid at Minneapolis, MN 55435. Postmaster: Send address changes to **Compliance Today**, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435.

Documentation improvement trends and health care reform: Could these be related?

By: Kelly C. Loya, CPC-I, CHC, CPhT

Editor's note: Kelly C. Loya is a Senior Consultant with Sinaiko Healthcare Consulting in Los Angeles. The firm has particular expertise with providing counsel to health care providers on their coding and compliance requirements. For more information, please go to www.sinaiko.com. Kelly may be contacted by e-mail at kelly.loya@sinaiko.com.

On March 23, 2010 President Obama signed a comprehensive health reform bill into law. The Patient Protection and Affordable Care Act (PPACA) included many changes that will occur in the next decade. Although the Act is intended to improve health care coverage, control costs, and improve the overall quality of care provided in the United States in the coming years, the industry is experiencing increased scrutiny of the quality of documentation. An argument can be made that some of the following items have always been required or remain important, but let's explore some of the recent clarifications. In addition, there is a significant number of new requirements and attempts at more stringent rules regarding basic documentation.

A renewed focus on signature requirements

For an element that should be standard in any patient's record, why all the crazy attention on signatures? First, a little history. With the government's increased focus on overpayment recovery, in order to fund portions of health care reform, there have been several messages sent to the Centers for Medicare and Medicaid Services (CMS) that ring loud and clear. As you may know, CMS has several initiatives to investigate and review claims for overpayments; however, their Comprehensive Error Rate Testing (CERT) program was specifically designed to produce an annual Medicare fee-for-service error rate. In FY 2009, the CMS CERT contractor noted in its review that the most significant payment errors concern six different provider groups. Inpatient hospitals, skilled nursing facility (SNF), home health, durable medical equipment (DME), outpatient hospital, and physician offices showed significant evidence of poor adherence to medical policy related to standard documentation practice requirements. In fact, in one provider group (DME), this accounted for over 92% of the errors found! Combined with the Office of Inspector General's (OIG) growing concern for fraud and abuse, the results of the annual review drew a great deal of attention from CMS.

As part of its 2009 annual report,[1] the OIG recommended that CMS use the results to identify documentation errors as programmatic weaknesses in order to strengthen the CERT program. CMS has published several provider documentation-related clarifications, has strengthened old ones, and introduced some new ones, which should have sent a clear message to Medicare providers that adherence to Medicare policy is not negotiable if reimbursement is to be expected for the services provided.

A profoundly impactful statement regarding the importance of documentation was made by the medical director of Cigna Government Services as early as 2001 and again more recently, and is also stated

by several other carriers. Cigna's medical director was specifically addressing observations made during paid claim reviews related to the use of scribes. However, the basic message can be applied to all types of documentation. Cigna's medical director stated, "Medicare pays for medically necessary and reasonable services, and expects the person receiving payment to be the one delivering the services and creating the record."[2] This would include the information contained in the documentation and the official acknowledgement that the information is a true and accurate account of the events that occurred, including signature, similar to any other legal document.

The devil is in the details

The 2009 OIG report also highlighted errors surrounding physician orders. Specifically, many physician orders were missing critical evidence of the treating physician's intent for diagnostic tests paid for by government programs. In other scenarios, the order did not sufficiently substantiate the billed service. Historically, CMS had considered unsigned diagnostic test requisitions sufficient to substantiate the physician's intent as long as reasoning for the tests could be easily inferred. However, when the requisition or formal order does not contain the necessary information for the purposes of medical review, the ordering physician's intent, including medical necessity for the performance of any diagnostic studies, must be clearly supported by the ordering provider's medical record documentation for the patient.[3]

It seems in their effort to find errors, CERT contractors have displayed an unusual focus on the smallest of things. A complete blood count (CBC) is a relatively inexpensive hematology laboratory test ordered by a physician to determine how to treat a wide variety of health disorders. This test can be ordered with or without differential of the white blood cells. The CBC lab test is one of the most frequently ordered laboratory tests, making it ripe for scrutiny. The reimbursement difference between a CBC and a "CBC with DIFF" is approximately $2. Although this isn't much of a difference, the reimbursement volume is quickly multiplied by the number of CBCs performed.

Several Medicare CERT contractors are reporting a growing number of these overpayment errors. The deficiency is noted as a lack of documentation in the ordering process to justify the clinical need for the differential. Because this test is quite common, practitioners have become habitual in ordering it. Perhaps a differential was provided in past reports as a result of an undocumented reflexive testing practice, and later practitioners may have come to expect to see the differential result, even when it was not specifically ordered by them. Errors such as this can snowball, and no one may realize it is happening until the error is identified during an internal audit or worse, during external CERT audits, where the potential financial payback can be unexpected and rather significant.

Not documented, not done (or at least not billable)

Another issue that has recently surfaced is proper documentation for specimen collection. When venous blood is collected for laboratory testing, the phlebotomist or office bills for a venipuncture with CPT code 36415. However, there is more than one method to obtain venous blood. In fact, there are at least four methods that can be represented by four separate CPT codes. One of the four methods (finger stick collection - CPT 36416) is not billable to Medicare. The other two methods involving a "port-draw" can only be billed under certain circumstances. You must ask yourself, "How is the service of blood collection supported if it is not documented"? For years this may have been overlooked, because the majority of collections are performed by venipuncture (36415) and are quite routine. As of today, at least one Medicare

Continued on page 9

Documentation improvement trends and health care reform: Could these be related?

...continued from page 7

Carrier/MAC has directly addressed this as an issue. On February 15, 2011, Palmetto GBA (the Medicare Part B Carrier for Ohio, West Virginia and South Carolina) responded publically (and specifically to these states) from a question posed to them regarding what documentation would be required when specimen collection is the subject of medical review. Their response was as follows, "The documentation must clearly reflect the venipuncture had been performed. Laboratory results alone are not sufficient to document that venipuncture was performed."[4] Although venipuncture results in only a $3 reimbursement per occurrence, it again is one of the highest volumes of charges nationally, having no boundaries to medical provider type, location, or specialty.

ICD-10-CM, MS-DRG, and HCC

"Lions and tigers and bears, oh my!" How can we forget ICD-10 codes? This new code set for reporting diagnoses will be required to report health care services for reimbursement, starting in 2013. It may be the single most daunting transition that has hit our industry since Y2K. Not only will systems need to be updated, staff trained, and just about every form in the current ICD-9 revenue cycle revised, but documentation as it exists today may not provide a sufficient amount of information and detail to properly utilize the new code set. As a result, if documentation isn't improved to sufficiently support ICD-10 coding now, it could mean a significant negative financial impact later.

For example, diagnosis-related groups (DRG) are the basis for reimbursement of inpatient hospital services. A few years ago, CMS restructured this payment system with Medicare Severity-DRG (MS-DRG), which requires more coding detail to properly code the hospital stay and extract the same reimbursement rate. As a result, hospitals may have seen a decline in reimbursement when compared with codes prior to MS-DRG implementation. One possible cause is that the clinical documentation is lacking enough disease-specific detail to properly assign all diagnosis codes to reflect the true severity of the patient's condition. In addition, the physician's time would be impacted by an increase in additional queries about unclear documentation in the medical record in order to clarify the patient's condition.

Similarly, Medicare Advantage plans are reimbursed on a risk adjusted model. This system also relies on the accuracy of the medical record related to the documented diagnosis in order to accurately report the severity of the patient's disease. Additionally, not only must the detail be present to accurately code and report the most specific condition, but CMS Risk Adjustment Validation (RADV) auditors have made it very clear that ICD-9 codes may only be used from documentation that meets very strict requirements.

The requirements include but are not limited to signatures, dates, and credentials on each progress note. When an opportunity is missed to code even one condition in order to request the payment for the upcoming year, it could result in a loss of $1,000 to $2,000 per patient (or even more) per year. This fact, multiplied by hundreds or even thousands of patients, poses a potential loss of incredible significance. Physicians may feel much of the facility and managed care reimbursement doesn't affect them directly, but in many ways it does. Right now, it is costing physicians' time—a lot of time—to deal with the extensive queries, reworking of the record, and documentation addendums (if justified), in order to more accurately reflect the patient's condition.

Evidence has shown that ICD-10 may play a larger role in the physician's reimbursement, beyond medical and payment polices, where it is expected to possibly affect reimbursement on professional claims.

Continued on page 10

Documentation improvement trends and health care reform: Could these be related?

...continued from page 9

First and foremost, clinicians and administrative staff at all levels must realize that the medical record is a legal document that serves as a chronological account of their patient's health care continuum. The accuracy and completeness of the medical record is vital to the patient's health and future care coordination for a myriad of reasons, both legal and ethical. Without clear, concise, and accurate documentation of past, present, and future, it is difficult—if not truly impossible—for health care providers to coordinate proper care and act in the patient's best interest. The old adage "I don't have time" or "That's obviously what I meant" can never be an excuse in foregoing a complete and absolutely accurate health care record. ■

1 Department of Health and Human Services: Analysis of Errors Identified in the FY2009 CERT Testing Program, July 2010. Available at http://oig.hhs.gov/oas/reports/region1/11001000.pdf.
2 Cigna Government Services: Non-Physicians Acting as Scribes for Physicians. Part B Medicare Bulletin, January 2007. Available at http://thdl.info/Medicare_Scribe_guidelines.pdf
3 CMS: Medicare Program Integrity Manual, Pub 100-08, Chapter 3, Section 3.6.1.1
4 Palmetto GBA: Frequently Asked Questions, 02/15/2011. Available at http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Ohio%20Part%20B%20Carrier~Browse%20by%20Topic~Frequently%20Asked%20Questions~EM~86FN2N0137?open&navmenu=%7C%7C.

HCCA's Compliance Today Needs Authors Like You!

Each month **Compliance Today** offers information to health care compliance professionals on:

- Enforcement actions
- New and changing regulations
- Compliance program management

To do this we need your help!

Compliance Today articles may address general health care regulatory and compliance concerns or may focus on a particular health care industry segment.

IMPORTANT: For those who are Certified In Healthcare Compliance® (CHC®), please note that CCB awards 2 CEUs to authors of articles published in **Compliance Today**.

Graphic fraud

By Shawn DeGroot, CHC-F, CCEP, CHRC

Editor's note: Shawn DeGroot is Vice President of Corporate Responsibility at Regional Health in Rapid City, South Dakota. She also serves as HCCA First Vice President. Shawn may be contacted by e-mail at sdegroot1@regionalhealth.com.

As with many technological inventions, computers and software serve many valuable purposes in expediting communication throughout the world. The "space" in which we live has become more condensed, and feedback can be immediate, exactly what we as consumers expect and enjoy. Conversely, there are negative aspects to creativity in technology, such as hacking, breaches of confidential information, and graphic fraud—all of which can negatively impact patients, health care professionals, and organizations. A strong emphasis is underway regarding the cut-and-paste feature in electronic health records (EHR), and physicians and mid-level providers must be cognizant of a similar issue with employees in reference to their licenses and certifications.

In health care, licenses, certifications, and other credentials are impressive and imperative for many roles. For many health care services rendered to government beneficiaries, the Centers for Medicare and Medicaid Services (CMS) requires that health care providers be licensed and/or certified in a specialty, prior to providing care to patients. Accrediting agencies, such as The Joint Commission, require evidence of original source verification, but we cannot rely on those standards completely as our only sense of security.

Certifications exist for pharmacists, respiratory therapists, nuclear medicine technologists, laboratory technologists, mammography technologists, financial auditors, social workers, compliance officers, and many more. Some of the professions may bill services to Medicare, some cannot. Organizations that sponsor the certifications maintain different eligibility criteria as well as a variable criteria for re-certification, which usually requires a fee and demonstration that additional education has been obtained over a specified time period. One approach to affirm the participant's additional education for re-certification is to view the original certification or validation with the names posted on the associate website; however, not all associations require that the certified professional participate in placing their name on the public database. Furthermore, states also have alternative requirements under their scope of service and, in some cases, require certification prior to licensure.

Potential consequences

With the above in mind, let's think about the "truth or consequences" with a potential lapse of a certification. For example, in medical imaging, technologists have several certifications available for ultrasound, echocardiography, mammography, etc. CMS requires that mammography technologists be certified before providing patient services if Medicare is to be billed. If that certification has lapsed, Medicare cannot be billed, and the organization may have an overpayment issue for services provided by that individual. An obligation may exist to voluntarily disclose the issue to your state Department of Health and/or a federal government agency. Add to that, the unwanted negative public scrutiny and the issue of potential fines imposed on the individual and/or organization, dependent on the circumstances. The consequences are more severe if an individual falsified a certification, willfully and intentionally, via a cut-and-paste method on a computer, (i.e., graphic fraud).

The underlying question in that instance is: Will the institution or individual be held accountable for submitting a service by a non-certified individual? Under Health Care Reform (HR 3590), the law requires that the organization surrender the overpayment within 60 days and, if the 60 day

Continued on page 13

Physician Practice/Clinic Compliance Conference

OCTOBER 16–18, 2011

PHILADELPHIA, PA

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

WHY YOU SHOULD ATTEND

Physicians, compliance officers, coders, and managers will learn to manage an effective compliance program. Designed with networking in mind, the conference provides many opportunities for choosing breakout sessions covering topics of interest for all. Participants will learn about compliance program development and management as it relates to physician practices; current government initiatives in the field of health care compliance specific to physicians and their group practices; correct documentation, billing and coding practices for physicians; and best practices utilized in physician practices.

www.hcca-physician-conference.org

requirement is not met, the False Claims Act (FCA) may be applicable.

What is not clearly understood by students, nor communicated to them, is the impact on the individual and his or her employer, which can be quite devastating. The issue of a falsified certification or a lapsed certification is commonly reportable to the state Department of Health with the potential consequences of a disciplinary action, probation, potential loss of certification and/or licensure, as well as other civil penalties. A career-altering consequence may be exclusion from participating in the Medicare program, if there was intent to defraud and the problem continued for many years.

Historically, Human Resources has validated licenses, specifically for nursing, predominantly based on original source verification; however, not as much attention has been given to certifications. Cases in several states have evolved wherein health care professionals continued to work with expired certifications, and their employers were unaware of this until the time of their personal evaluations. Dependent on their certification specialty and CMS rules, the services they provided for the past year may not have been billable to Medicare.

Accountability

Some measures can be implemented to prevent graphic fraud and protect patients and employers as a fundamental expectation of an effective compliance program:

- Perform original source verification for licenses and certifications for new employee hires.
- Validate renewed certifications without reliance on an optional electronic database.
- Write a licensing/certification policy in conjunction with Human Resources, and conduct risk assessments on the policy and process.
- Perform periodic monitoring or audits that original source verification was conducted.
- Report the results of the above to the board of directors as a component of the compliance program.
- Voluntarily disclose to the government any individual or organizational act of impropriety.
- Incorporate a message in new employee orientation about the truth and consequences of graphic fraud, as well as the need for original source verification.

Budget reductions that impact continuing education sometimes lead to unethical motivation and poor personal choices. Individual accountability examples are an effective method of educating others as to the seriousness of providing a service to a patient without the appropriate/validated credentials required. Assist your employees in understanding the impact of cut-and-paste to prevent, detect, and deter an issue for your organization. The field of compliance is growing exponentially, but so are those who choose the path of least resistance. ■

feature article

Meet Dave McRae, CEO and Nancy Aycock, General Counsel of University Health Systems of Eastern Carolina

Editor's note: John Falcetano, CHC-F, CCEP-F, CHRC, CHPC, CIA, HCCA Second Vice President and Chief Audit & Compliance Officer for University Health Systems of Eastern Carolina conducted this interview in May 2011 with Dave McRae, Chief Executive Officer, and Nancy Aycock, General Counsel for University Health Systems of Eastern Carolina. John may be contacted by e-mail at jfalceta@uhseast.com or by telephone in Greenville, NC at 252/847-0125. Dave may be contacted by e-mail at DMcRae@uhseast.com and Nancy may be contacted at NAycock@uhseast.com.

JF: Can each of you tell us a little about yourself and University Health Systems of Eastern Carolina?

NA: I am Nancy Barnhill Aycock. UHS of Eastern Carolina is a regional health care system. Our mission is to serve the health care needs of the people of eastern North Carolina, which we have done well, and to enhance the quality of life for the people and community we serve. We have eight hospitals that are either leased, owned, or managed. I have been General Counsel for a number of years, starting with the system in 1992. My professional legal background is as a Chief Assistant District Attorney in a multicounty district.

DM: You said it well. I am Dave McRae, the CEO of UHS of Eastern Carolina. I have been here for 35 years, since we were a single hospital called Pitt County Memorial Hospital. In the late 1970s, PCMH became the primary teaching site for a new state-supported medical school at East Carolina University, and now the medical school is called the Brody School of Medicine. As Nancy said, we became University Health Systems of Eastern Carolina in 1998 as we began to acquire other hospitals. In recent years, we have been reaching out to local physician practices to help us support our mission of "keeping health care local." This allows us to provide greater support in community disease prevention and health and wellness efforts throughout the region that we serve, which is a quarter of the state of North Carolina, about 1.4 million people.

JF: Some organizations have had difficulty in determining where to put their compliance officer in their organizational structure. Dave, can

you tell me how you came up with where to put your chief compliance officer? Where does he fit in the organization?

DM: From the earliest of days of having very little compliance commitment and progressing to where we are today, we have been through a transformation, a revolution if you like. I am pleased that we have a board of directors and an executive staff that understood and were committed from the earliest days to moving toward a much, much stronger audit and compliance program in this organization. I remember my own first early feelings about Audit and Compliance, and feeling that we were growing very rapidly and didn't have the checks and balances to assure that the systems that we thought were being put in place were in fact in place and being handled properly. I am especially pleased that we, collectively, had the foresight. Nancy helped tremendously. In addition John, you came on board and our board leaders became more involved. In fact, a long-time board member, Larkin Little, helped me in the actual interview process for the position. We made decisions in those earliest days to give Audit and Compliance the degree of independence for oversight functioning that would allow us to assure ourselves and our constituents, and the public at large that we were doing things the right things the right way.

NA: At the time UHS began to explore establishing our Compliance department, I was very relieved. The Compliance function, even if we didn't call it that, had been pretty much shouldered by Risk Management and Legal. I felt like I had plenty of support from the CEO, but I really looked forward to having a peer who was a compliance officer. We discussed at the time whether the compliance officer would report to general counsel as well as the CEO and the board, and decided that the autonomy of a Compliance department coupled with Audit function would be the right decision. There are some peculiarities of North Carolina law that made that a good thing as well. I have been extremely pleased with the structure. It was the right decision.

DM: Right. Just to be clear, our Audit and Compliance function reports directly to the CEO and to the Audit and Compliance Committee of the board at the system level. Therefore, the chairman of that committee and I regularly meet with John. To give that added degree of independence, John meets with the chairman of the committee even independent of the CEO from time to time, so that we can make very sure that we are able to answer all the questions and that there are no constraints on the Audit and Compliance function.

JF: Nancy, what is Legal's role in the compliance program?

NA: The Office of General Counsel provides legal advice for the Compliance staff. Since the general counsel and the chief compliance officer are peers, with both reporting to the CEO, the general counsel sits on the system's Compliance Steering Committee. We provide oversight to the system as a whole, as well as to the compliance program.

JF: We sometimes hear of communication difficulties between legal counsel and the compliance officers. Please say a little about the type of working relationship you (as the General Counsel) have developed with the Chief Compliance Officer (me).

NA: We work very well together. We meet regularly and keep each other informed of current issues within the system. While we have different roles, we work hand in hand. You, as the compliance officer, seek legal advice from me, my office, and the folks who work with me, but I seek practical advice from you. I think that this is one of the strong points in the relationship. I seek your advice and value your input. I run things by you and the relationship is not just one way, where the compliance officer seeks legal advice. Both of us want to serve the system, and you help me to be a problem solver in addition to providing the Compliance department with legal advice. We coordinate educational sessions on various new topics and try to make presentations together from time to time. We try to get ahead of sensitive topics, both at the national level and within the system. We

Continued on page 16

 ...continued from page 15

communicate on at least a weekly basis (sometimes on a daily basis) to prevent opinion shopping by our colleagues and to ensure that we share the same opinion on an issue, or identify when we do not and work out solutions.

JF: Dave, based on your observations, how well has the rest of senior management interacted with the Compliance staff?

DM: I'll start first by saying the two departments, Audit and Compliance and the General Counsel's office or Legal work very well together as Nancy has pointed out, and that is critical. But, I must say that starts with the two senior leaders. The fact that the chiefs of those sections collaborate and work together sets the tone for the two departments to work well together. Then you go to the system at large, the executives and presidents of each hospital and beyond, and they see the Audit and Compliance function as an appropriate and necessary function in their own world. The best example of that I can give is that the Compliance department gets many, many requests for independent audits from leadership and management within hospitals and service lines throughout our system. I don't have the exact numbers (John, I'm sure you have those), but it is a source of pride to me, and I think to you, that not only does your function provide the necessary regulatory inspection oversight, but people see your services as a consultant and an educator. The best example of that is the high number of requests for independent audits made by the people out there in the real world in operations.

JF: Several of our health system staff recently attended the annual HCCA Compliance Institute. What advice would you give to other CEOs when it comes to compliance training?

DM: Nancy can speak to this as well, having been there. Education is fundamental to knowing what is going on in the rest of the country, understanding the Office of Inspector General, and what's coming down the pike, as they say. All of those things are critical functions and we are blessed that you, John, have gone the extra mile to be out there and to learn and contribute. Regulators communicate to the people in the real world, and you've got to be at the table in order to be able to contribute. You then are able to carry out the regulatory aspects in your own institutions. You can only do that by being in meetings and learning and growing. Nancy, you have just recently participated and you maybe can help us with that as well.

NA: I did attend, for the first time ever, an HCCA program along with one of our board members in Orlando, Florida recently. It was a great program, very well organized. The presentations were at a very high level and provided a good combination of both basic and advanced topics. I normally attend AHLA sessions for legal education. I am thinking seriously of attending HCCA programs in addition in the future, because I think they are particularly good for in-house counsel.

JF: In your opinion, what value does the compliance program bring to University Health System of Eastern Carolina?

DM: Well, I touched on it briefly earlier, mentioning our early days of growth and arriving where we are today. I would be a very, very worried CEO if we didn't have the strong compliance program that we have today. There are simply too many opportunities for mistakes—even by people with good intentions—and not following through, not making sure that systems are appropriate, not reading the regulations and carrying them out. Our compliance program provides the oversight and the responsibility in all of those areas. From the earliest days of worrying about the cash in the cash box to today, running on IT systems and having the risks, much like banks do, of non-compliance on all sorts of regulatory measures. We would not be the health system we are today without a strong and independent compliance program.

NA: I think the compliance program at UHS brings a systematic operational approach to regulatory compliance, which was not necessarily present in the past, before this Compliance office

was set up. The combination of Audit and Compliance provides a reliable resource at the operational level, as well as oversight for system purposes.

JF: With all of the tentacles of health care reform, what are you doing to prepare for the compliance risks?
DM: There are so many things to do. As hospitals move from being just an internal operation that is central to a facility in a building, to having physician practices, to having prevention and wellness programs, to participating in or developing ACOs [Accountable Care Organizations]. You could go on and on about all the changes that are about to take place. It is more critical than ever to have Compliance functions that are far reaching, strong, and have the resources to provide oversight in all of those areas. It starts fundamentally with education. We've talked about the importance of attending meetings, about reading materials, about making sure there's the level of staffing for the Audit and Compliance function to be able to carry out their various important roles. All of that is part of it.
NA: Preparation for health care reform is a priority in the Office of General Counsel. I think it is an opportunity to work with the compliance staff to provide education across the system about the new requirements of PPACA. Both John and I have provided education at the board level and the executive level, and we need to plan to roll this out across other levels of the organization.

JF: Transparency has become a key focus by the government and society. What measures have you taken to promote transparency? What role does compliance play in transparency?
DM: Another critically important question. Our mission at UHS is to "improve the health of the people and communities we touch, serve, and support." In keeping with that mission, it is so important that patients receive the best and safest care possible. How do we do that? We support transparency in health care because we believe if patients have access to health care outcome information, it helps patients and families make good health care decisions and feel confident about their health system. Transparency is the key to our future. We will have a public that is more educated than ever. Our physicians will have patients coming to them who know much more even than the clinicians do about a disease and a problem, because of access to the Internet, because of so many ways to get information. Without transparency, we cannot move to the next level as a society and as a health system. Hospitals, physicians, and health systems have to lead the way in that effort.
NA: Our health system strives to apply the highest ethical standards to everything we do. Our expectation is that all UHS personnel interact with patients, customers, and business partners in the best interest of our patients, the health system, and in compliance with the laws and regulations that govern our industry. Our vision is that UHS has the "power to do good." We must set the example and do the right thing through regulatory compliance and following good governance practices.

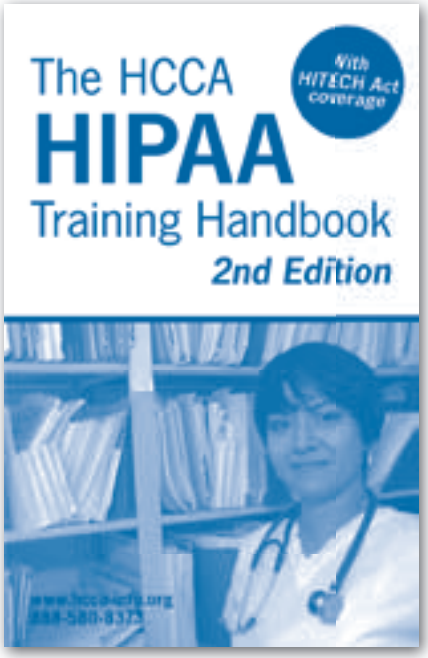
JF: Conflicts of interest often occur when a person's self interest and the organization's best interest are not the same. What processes do you have in place to monitor conflicts of interest?
NA: We have both a Board Conflicts of Interest policy as well as a Conflicts of Interest policy that applies to all personnel within UHS. We have annual questionnaires for those at the board and management level and those who are designated by management as appropriate to answer questionnaires that are reviewed by general counsel. When conflicts of interest are identified at the staff level, we address those. When they are identified at the board level, they are disclosed to the full board, addressed through investigation, and if appropriate, waiver by the board. Also, we do a lot of board education about the new IRS 990 governance terms and have a special conflict of interest questionnaire that is completed on an annual basis.

JF: With multiple entities throughout our organization, what approach do you use to oversee

Continued on page 19

NOW AVAILABLE:

The HCCA HIPAA Training Handbook



The Health Insurance Portability and Accountability Act (HIPAA) has had lasting impact on U.S. health care providers since its passage in 1996. Now HIPAA, along with HITECH, affect health care professionals on a daily basis. This newly revised handbook is intended for anyone who needs a basic understanding of the privacy and security regulations governed by HIPAA and HITECH. Suitable for staff training courses, it covers:

- Who must comply with HIPAA and HITECH
- When and by whom is the use or disclosure of protected health information (PHI) permitted?
- What rights does an individual have regarding his or her PHI?
- What are the basic safeguards required to protect the security of e-PHI?
- What happens when a breach occurs?
- And much more

This handbook can prepare all health care professionals to help protect the privacy and security of their patients' health information.

Order Now

HCCA MEMBER DISCOUNTS

# of handbooks	cost per book
1–9	$25
10–24	$23
25–49	$20
50–74	$18
75–99	$16
100+	$15

THE HCCA HIPAA TRAINING HANDBOOK

Qty — Cost

_____ HCCA Members ($25 or see chart at left) $ _____

_____ Non-Members ($30 per handbook) $ _____

_____ Join HCCA! $ _____

Non-members, add $200 to join HCCA, and pay member prices for your order (regular dues $295/year)

Total: $ _____

Bulk discounts available for HCCA members only. See chart at left to figure cost. All purchases receive free FedEx Ground shipping within continental U.S.

PLEASE TYPE OR PRINT

HCCA Member ID

First Name M.I. Last Name

Title

Organization

Street Address

City State Zip

Telephone

Fax

E-mail

Make check payable to HCCA and mail to:

HCCA, 6500 Barrie Road, Suite 250
Minneapolis, MN 55435

Or fax order to: 952-988-0146

☐ *My organization is tax exempt*

☐ Check enclosed

☐ Invoice me | Purchase Order # _____

☐ I authorize HCCA to charge my credit card (choose below):

○ AmericanExpress ○ Diners Club ○ MasterCard ○ Visa

Credit Card Account Number

Credit Card Expiration Date

Cardholder's Name

Cardholder's Signature

Federal Tax ID: 23-2882664

Prices subject to change without notice. HCCA is required to charge sales tax on purchases from Minnesota and Pennsylvania. Please calculate this in the cost of your order. The required sales tax in Pennsylvania is 7% and Minnesota is 6.5%.

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

6500 Barrie Road, Suite 250
Minneapolis, MN 55435
Phone 888-580-8373 | Fax 952-988-0146
www.hcca-info.org | helpteam@hcca-info.org

the government's activity involving Recovery Audit Contractors (RACs)?

DM: You can imagine the kinds of questions and concerns we've had as we moved from being a single hospital, even though it was a large teaching hospital, to a health system. Our approach has been to centralize all requests from RAC so that they are delivered to the Compliance office. They control them, they manage them, and they contact the people they need to. We've got a centralized coordinated effort so that we don't have different people doing things in different ways and not paying attention. We keep data on the numbers and the types and where they are in the process and all of that is done out of the Compliance office. It gives me a confidence level that I could not have otherwise as the CEO.

JF: Where do you see Compliance headed in the future?

DM: The future is going to be different; it's going to change. But, fundamentally it is going to still be about patient care, about patients with illness and disease and anxiety and worry and lack of confidence in what will happen to them. We have to use the very best up-to-date processes and approaches to delivering care and giving people the insight they need to understand the care that they are receiving. Compliance is an integral part of those initiatives. In the future, I see more responsibility for Compliance functions that will provide return on investments to our health system and to others. We need to be prepared with the talent, the people, the resources, the IT integration, the control, and the level of autonomy and independence that's necessary for our Compliance responsibilities to be fulfilled by the departments and people we have.

NA: I agree with Dave, the increased complexity of the regulatory environment will require appropriate internal controls as we meet the compliance challenges of the future. We need to maintain a strong compliance program to help ensure we implement the appropriate controls.

JF: One final question. Is there anything else that either of you would like to add that you would like to say to the Compliance community, either those who are just starting up or those who have processes in place?

DM: I'll just add a side note on behalf of the board and others. We are very proud of our compliance program and committed to it. John, we thank you for bringing us to where we are today, and for taking the time and initiative to guide us and study and understand and to get the certifications that go with your field and to be a leader in this area.

NA: I would like to encourage other general counsel to attend at least some of the many HCCA programs that are provided across the country on an annual basis and bring board members with them from time to time. I found it extremely helpful.

JF: I'd like to thank you very much for your time. ■

Be Sure to Get Your CHC® CEUs

Articles related to the quiz in this issue of **Compliance Today**:

- **Return on investment in health care compliance**—By Ofer Amit and Draco Forte, page 32
- **Corporate Integrity Agreements offer a second chance**—By Joseph R. Batte and Prashanth Shetty, page 50
- **Employed physician compensation: Expense or investment?**—By Darcy Devine, page 57

To obtain one CEU per quiz, go to **www.hcca-info.org/quiz** and select a quiz. Fill in your contact information and take the quiz online. Or, print and fax the completed form to CCB at 952/988-0146, or mail it to CCB at HCCA, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Questions? Please call CCB 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. Only the first attempt to pass each quiz is accepted.

Letter from the CEO

If you have any questions that you would like Roy to answer in future columns, please e-mail them to: roy.snell@hcca-info.org.

Speaking for our profession

It's stunning how many people feel qualified to speak for compliance professionals. People who have spent their career in ethics, audit, risk, legal, etc., all seem to think they should define our profession. When is the last time someone with no legal experience spoke for the legal profession? Why are these people telling the world how a compliance program should be defined? I'll admit, some of it's good for us. Any press is good press. The fact that everyone wants in on the act is a positive indication that what we are doing is at least interesting. Despite all that, damage is being done. People who have never been compliance professionals are likely to give bad information to others about what the job involves. And some of them are intentionally trying to manipulate the definition of our profession and compliance programs to their advantage.

There are people giving presentations about our job who have never held our job. We have people communicating with the enforcement community who have never spent a day managing a compliance program. We have people with very little experience writing several hundred page descriptions of compliance programs and whose motivation is to make money. We have people coordinating "compliance conferences" who could not identify a qualified compliance professional if their lives depended on it. And then there are the articles. We have 35-year veterans of other professions writing articles suggesting that compliance officers should report to the general counsel. This is against almost every piece of advice the enforcement community has served up. Some of these people have resumes (from their profession) that would cause many people to actually believe what they say. This is irresponsible. This is the equivalent of a risk manager giving legal advice, or an ethicist telling an auditor how to do business. It just doesn't happen. We should not allow this to happen to us.

And then there is academia. Theoretical solutions to this serious problem are not helping. These people are telling their students—our future leaders—that all you have to do is talk about doing the right thing and all your problems will be solved. There is no emphasis on finding, fixing, and disciplining. An overwhelming number of business schools teach no compliance course whatsoever. Sure, talking helps many people, but it doesn't help all the people and to imply that talking is all you need to do is a crime.

Some mean well. Some don't know what they don't know. The compliance profession is new and exciting; everyone wants to get in on the act. I understand. Compliance looks simple. I guess that has given them some confidence. Maybe they assume we need help. That can happen when you have no experience and a lot of confidence. There is a disconnect.

They feel strongly about it. Risk guys want compliance to be all about risk; ethics guys want it to be all about ethics; lawyers think it's all about the law, etc. If that were true, society's loss of confidence in business and business leaders would have been solved long ago. They want to push their specialty. If it was all about, "fill in the blank," we would not need compliance programs and compliance professionals. These other subspecialties have been around for 50 years. Pushing the methodologies of the past is

Continued on page 22

Social Networking

Editor's note: John Falcetano, CHC-F, CCEP-F, CHRC, CHPC, CIA is Chief Audit/Compliance Officer for University Health Systems of Eastern Carolina and Second Vice President of the HCCA Board of Directors. John may be contacted by e-mail at jfalcetano@uhseast.com.

One of the benefits of social networking is being able to find out how your peers are addressing an issue that is similar to one you are facing. For example, did you ever look for a document and could not find it? You know you had it. You remember reading it, but you just can't remember what you did with it. On our social network, Ray Lau blogged, "Policy management is like eating your vegetables. It's necessary and we know we have to deal with it every day to stay healthy." Ray provides five steps concerning policy management and discusses each step. Here is an excerpt of what Ray says about one of those steps.

"Start brainstorming. How your policies currently exist is a big factor in what this step means for you. If you already have all the documentation you need in one of the aforementioned formats (hard copy, PDF files, etc.), all you need to do is upload them and make sure you stick to a consistent naming convention."

To see the rest of what Ray blogged or for contributions by other compliance professionals, go to HCCA's Social Network site. Remember, there is something for everyone on the Social Network site. As a compliance professional, participating in social networking can help you in completing your everyday job. Join our network and more specifically, join a community. You will be glad you did. To participate in the discussion, review the comments, or just talk with your peers, you can access the Social Network site by going to the following link: www.hcca-info.org/sn ■

Web 2.0 is about the new, faster, everyone connected Internet.

HCCA is embracing this approach and offers you a number of ways to build out your network, connect with compliance professionals, and leverage this new technology. Take advantage of these online resources; keep abreast of the latest in compliance news; and stay ahead of the curve.

HCCAnet

Dozens of discussion groups and more than 6,800 participants
http://community.hcca-info.org

JOIN OUR GROUP LinkedIn

Profiles of over 4,500 compliance and ethics professionals
http://www.hcca-info.org/LinkedIn

FOLLOW US ON twitter

Follow HCCA_News to keep up with the latest compliance news and events
http://twitter.com/HCCA_News

Find us on Facebook

Connect with compliance and ethics professionals on Facebook
http://www.hcca-info.org/Facebook

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

HCCA HEALTH CARE COMPLIANCE ASSOCIATION

dangerous. They didn't prevent wrongdoing then and they can't now. And society is fed up with business.

What compliance programs are all about is the use of many tools in concert to prevent and find problems and fix the problems we find. These people want control of compliance programs, or at least control the definition of compliance programs. And yet, when there is a problem to fix that may involve big disappointment and possibly discipline, these people can be found hiding under the table, where they have been for 50 years.

Some would rather we didn't look for problems at all; instead they want to wait, see if we get caught, and then defend it. That is a paradox. Our profession was created because those who came before us failed to look for, find, and fix problems. Now they want to tell us how to do it. This is dripping with irony. All the while, the press, the public, and the politicians are fed up with corporate America because we can't seem to find and fix our own legal and ethical problems. It would be funny if it weren't such a travesty.

Compliance works because we use a balanced approach to all of the compliance tools. It's a very difficult job and business leaders need to be told how compliance works by people who actually have done the job. What people don't understand is how difficult the job is. The guys who have been hiding under the table when problems occurred in the past don't know how difficult it is to solve the problems you find. If they would have looked for, found, and actually fixed all the problems, they would know how tough this job is. They don't know how important having access to leadership and the support of leadership is. They don't know how important collaboration, negotiation, motivation, and other "people skills" are. They don't know how difficult it is to manage a whistleblower complaint about leadership. They don't know what it's like to wake up at two in the morning thinking "What if the government finds a problem that I should have found?" They don't know what it's like to make someone who is already busy add another step to their process. They don't know what it's like to have to force everyone to attend education. They didn't get it done and they don't know what it's like; and yet they insist on telling everyone how compliance programs and our profession should be defined. The arrogance of it all. It's maddening.

The only reason they keep doing it is because no one stands up to them. We don't stand up because we are a young profession. We don't talk about this because people are too nice. Most of all, you are all more humble about our profession than I am. My real problem is that I am impatient. I want everything done yesterday.

Here is my advice to compliance professionals: Stand up and do something about this. When you see some group trying to define your profession, who has never been in your profession, call someone involved and let them know what you think. Write about it. Speak about it. Mention it in your social media circles. The more we let the emperor know that he has no clothes, the more he is likely to stop. ■

Exhale

By Shawn DeGroot, CHC-F, CCEP, CHRC

Editor's note: Shawn DeGroot, CHC-F, CCEP, CHRC is Vice President of Corporate Responsibility at Regional Health located in Rapid City, South Dakota. Shawn also serves as Vice President of the HCCA Board of Directors. She may be contacted by e-mail at SDegroot1@regionalhealth.com.

As compliance professionals, we can anticipate communication from a variety of government agencies on a regular basis. As a health care provider in an integrated delivery system, monthly correspondence is common in the form of provider on reviews (PORs), additional documentation requests (ADRs), Comprehensive Error Rate Testing (CERT), and from various agencies, such as the Centers for Medicare and Medicaid Services (CMS), Office of the Inspector General (OIG), Office of Civil Rights (OCR), Office of Audit Services (OAS), and others under Medicare Part A and B. Conversely, Medicare Advantage plans, under Medicare Part C and D, undergo a similar level of scrutiny, but more in the form of required direct reporting to federal agencies.

Under Part C and D, quarterly and annual reports are submitted to CMS for appeals, grievance considerations, claims processing, sales oversight activities, and benefit utilization to name a few. Requests may also be initiated for ad-hoc reporting and/or certifications. As an example, one of the ad-hoc requests could be from CMS if an Advantage Plan is an outlier for one of its performance measures. In this instance, CMS would typically request a response within two weeks with a confirmation of the original data and an opportunity to submit corrected data. David Jernigan, Compliance Manager at Physicians Health Choice for the past two years, noticed that there is more direct reporting to the federal government under Medicare Part C and D than under Part A and B. The newest deadline imposed is under Health Care Reform regarding an overpayment requirement within 60 days (HR 3590 Sec. 6402).

What keeps David up at night?

His biggest concern is missing an important deadline. Missing a deadline can result in loss of appeal rights, financial sanctions, and/or increased regulator scrutiny. Worrying about what was missed or might have been missed causes sleepless or disrupted nights. David also believes that due to the nature of the Compliance field, another element of stress is self-criticism. The negative aspects of serving as the messenger and detecting noncompliance may outweigh the positive work performed and cause it to go unnoticed.

What is David's approach to managing the stress?

For his physical and mental health, David runs three times a week. Additionally, he started guitar lessons at the time his daughter did. Playing the guitar completely removes work from his mind. Learning how to play an instrument requires every ounce of attention and concentration. Because David lives in the Texas, a mecca of singers, songwriters, and bands, he is exposed to every musical genre, and he finds this inspirational. David's advice to other compliance officers is to discover a hobby and interest completely unrelated to your work. David also suggested that the simple diversion of a day trip to the country or a place you have never been can alleviate the chaotic thoughts of the multiple deadlines.

Finally, David arrives at work every day, determined to do the best job he can with the resources and time available. He added that our accomplishments outside the workplace, as well as our character, are the ultimate measures of who we are. ■

Achieving "meaningful use" in the Medicaid incentive program, Part 3: Nuts and bolts

By Janice A. Anderson, JD, BSN; and Rebecca L. Frigy, JD, MPH

Editor's note: Janice A. Anderson, Shareholder in the Chicago offices of Polsinelli Shughart PC, has over 25 years' experience focusing on health regulatory and compliance issues and over 30 years' experience working in the health care industry. She may be contacted by e-mail at janderson@polsinelli.com or by telephone at 312/873-3623.

Rebecca L. Frigy is an attorney in the St. Louis offices of Polsinelli Shughart PC and may be contacted by e-mail at rfrigy@polsinelli.com or by telephone at 314/889-7013.

The American Recovery and Reinvestment Act (ARRA) passed in February of 2009 through the Health Information Technology for Economic and Clinical Health Act (HITECH) established three incentive programs focused on promoting the adoption of electronic health record (EHR) technology: a Medicare Fee-For-Service (FFS) incentive program (addressed in our January 2011 issue), a Medicare Advantage (MA) incentive program (addressed in our June 2011 issue), and a Medicaid incentive program. This article on Medicaid is the third in this series in **Compliance Today**.

Under the HITECH Act, state Medicaid programs, at their option, may receive federal financial participation (FFP) for expenditures made as incentive payments to certain Medicaid providers for the adoption, implementation, upgrade, and meaningful use of certified EHR technology. The first round of final regulations related to the meaningful use incentive programs (the final rule) was released on July 13, 2010 by the Centers for Medicare and Medicaid Services (CMS). The final rule sets forth the exact criteria required to achieve meaningful use in the first stage of the incentive programs, the relevant time lines for each incentive program, and the amount of incentive payments that a provider may be eligible for in each program. Because the exact details of the Medicaid incentive programs will vary from state to state, the final rule only sets forth the general framework for the Medicaid incentive program. A description of this general framework is found below.

Details related to a specific state's program must be obtained from the applicable state. Registration for the state Medicaid incentive programs began on January 3, 2011 in Alaska, Iowa, Kentucky, Louisiana, Michigan, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, and Texas. Registration in the state of Alabama began on April 1, 2011; Missouri began on April 4, 2011; and registration in the states of Indiana and Ohio began on May 2, 2011. Other states that choose to participate in the Medicaid incentive program will likely launch their programs during the spring and summer of 2011. Additional information regarding specific state programs, registration, and launch times can be found at: https://www.cms.gov/apps/files/statecontacts.pdf.

Unlike in the Medicare incentive programs, a Medicaid provider is not required to meet the meaningful use criteria under the Medicaid incentive program to receive an incentive payment in the first payment year; rather,

Medicaid providers may receive an incentive payment simply for having adopted, implemented, or upgraded to certified EHR technology.

Qualifying Medicaid eligible professionals (EPs)

Medicaid participating providers who wish to receive a Medicaid incentive payment must meet the definition of "Medicaid eligible professional (EP)." This includes physicians, dentists, certified nurse midwives, nurse practitioners, optometrists (if the state's plan has specifically adopted the option of including optometrists in the Medicaid program under Section 1905(e) of the Social Security Act), and physician assistants (PA) practicing in a federally qualified health center (FQHC) or rural health clinic (RHC) that is led by a PA. A physician assistant is considered to be leading an FQHC or RHC if:

- the PA is the primary provider in the clinic,
- the PA is a clinical or medical director at the clinical site, or
- the PA is an owner of the RHC.

Medicaid EPs cannot be "hospital based," except for Medicaid EPs practicing predominantly in an FQHC or RHC, which means that more than 50% of the EP's patient encounters over a period of 6 months are provided at an FQHC or RHC. For Medicaid purposes, state Medicaid agencies will make the determination about whether or not an EP is hospital-based by analyzing an EP's Medicaid claims data; or in the case of EPs who deliver care via Medicaid managed care programs, by analyzing either patient encounter data or other equivalent data sources, at the state's option. For purposes of making this determination, states would be permitted to use data either from the prior fiscal year or calendar year.

Whether an individual qualifies as providing dental, nurse practitioner, physician assistant, or certified nurse midwife services will be determined under state scope of practice rules. Also, states and EPs should refer to CMS regulations related to provider scope of practice. States also generally have a Medicaid State Plan (and often state statutes or regulations) that designates how each provider is eligible to participate in the state's Medicaid program by practice type. The potential EPs must meet all of these other Medicare and state eligibility requirements in order to participate in the Medicaid incentive program.

For an EP to qualify to receive an incentive payment under the Medicaid incentive program, at least 30% of the EP's patient volume must be attributable to Medicaid patients, except:

- A pediatrician must have at least a 20% Medicaid patient volume.
- EPs practicing predominantly in an FQHC or RHC must have a minimum of 30% patient volume attributable to "needy individuals." A "needy individual" is defined as meeting any of the following three criteria:
  - Receives medical assistance from Medicaid or the Children's Health Insurance Program (CHIP);
  - Receives uncompensated care by the provider; or
  - Receives services at either no cost or a reduced cost based on a sliding scale determined by the individual's ability to pay.

Medicaid eligible hospitals (EHs)

Acute care and children's hospitals are the two types of institutional providers eligible for Medicaid hospital incentive payments. For purposes of the Medicaid incentive payment program, "acute care hospital" means a health care facility where the average length of patient stay is 25 days or less and the facility has a CMS certification number (CCN) with the last four digits in the series 0001 through 0879, or 1300 through 1399 (i.e., short-term general hospitals, critical access hospitals, and cancer hospitals). This definition does not include long-term care hospitals where the average inpatient length of stay is more than 25 days. For purposes of the Medicaid incentive payment program, a facility is a

Continued on page 26

...continued from page 25

"children's hospital" if it is a separately certified children's hospital in the 3300 through 3399 CCN series and predominately treats individuals under the age of 21.

For an acute care hospital to qualify to receive an incentive payment under the Medicaid incentive program, the acute care hospital must meet a 10% Medicaid patient volume threshold. Children's hospitals do not have patient volume requirements for Medicaid incentive program participation.

Patient volume determinations

As established above, for an EP and an acute care hospital to qualify to receive payments under the Medicaid incentive program, the EP must have at least 30% patient volume attributable to Medicaid patients (with several exceptions) and the acute care hospital must meet a 10% Medicaid patient volume threshold (See table 1).

The final rule sets forth the method for determining patient volume for purposes of Medicaid incentive payment eligibility. States may also seek approval from CMS for new methods for determining patient volume for purposes of the Medicaid incentive program. If CMS approves a method proposed by one state, the approved method may be considered an option for all states.

Providers are expected to estimate their patient volumes using verifiable data sources. In establishing the patient volume thresholds, individuals enrolled in Medicaid managed care plans should be included. This means that individuals enrolled in managed care organizations, prepaid inpatient health plans, or prepaid ambulatory health plans should be included in the calculation.

EP patient volume determinations

To determine patient volume for a Medicaid EP, the EP's applicable percentage of patient encounters must be attributable to Medicaid patients over any continuous 90-day period within the most recent calendar year prior to reporting. For purposes of determining whether the patient threshold is met, the EP may also consider Medicaid enrollees on the panel assigned to the EP within the representative 90-day period. (However, it is not intended for the EP to count a panel-assigned patient who also had an encounter more than once.) For purposes of determining patient volume for a Medicaid EP, a "patient encounter" means services rendered on any one day to an individual where Medicaid or a Medicaid demonstration project:

- paid for part or all of the service; or
- paid all or part of the premiums, copayments, and/or cost-sharing.

For purposes of calculating needy individuals' patient volume for a Medicaid EP practicing predominantly in an FQHC or RHC, a

Table 1: Requirements for Medicaid incentive program participation

Entity	Minimum Medicaid patient volume threshold	Or the Medicaid EP practices predominantly in an FQHC or RHC with a 30% needy individual patient volume threshold
Physicians	30%	
-Pediatricians	20%	
Dentists	30%	
Certified Nurse Midwives	30%	
Nurse Practitioners	30%	
Physician Assistants when practicing at an FQHC/RHC that is led by a PA	30%	
Acute Care Hospitals	10%	Not an option for hospitals
Children's Hospitals	No requirement	

"needy patient encounter" means services rendered on any one day to an individual:

- where Medicaid or CHIP or a Medicaid or CHIP demonstration project paid for part or all of the service;
- where Medicaid or CHIP or a Medicaid or CHIP demonstration project paid all or part of their premiums, co-payments, and/or cost-sharing; or
- billed on a sliding scale or that were uncompensated.

It is acceptable to include the same patient encounter for multiple providers when it is within the scope of each provider's practice, and clinics and group practices may use the practice or clinic Medicaid patient volume (or needy individual patient volume, as applicable) and apply it to all EPs in their practice, under three conditions:

- The clinic or group practice's patient volume is appropriate as a patient volume methodology calculation for the EP (i.e., if an EP sees only Medicare, commercial, or self-pay patients, this is not an appropriate calculation);
- There is auditable data to support the clinic's patient volume determination; and
- All providers at the clinic or group practice use the same methodology in each year (i.e., clinics could not have some EPs at the clinic use their individual patient volume for patients, while others use the clinic-level data).

If an EP works both in a clinic and outside the clinic, then the clinic/practice level determination may include only those encounters associated with the clinic/practice.

Medicaid EH patient volume determinations

To determine Medicaid patient volume thresholds for EH acute care hospitals, a minimum of 10% of patient encounters must be attributable to Medicaid patients over any continuous 90-day period within the most recent calendar year prior to reporting. For purposes of calculating EH patient volume, a "patient encounter" means services rendered to an individual:

- per inpatient discharge where Medicaid or a Medicaid demonstration project paid for all or part of the service;
- per inpatient discharge where Medicaid or a Medicaid demonstration project paid all or part of the premium, co-payment, and/or cost-sharing;
- in an Emergency Department, which is part of the EH under a qualifying CCN, on any one day where Medicaid or a Medicaid demonstration project either paid for all or part of the service; or
- in an Emergency Department, which is part of the EH under a qualifying CCN, on any one day where Medicaid or a Medicaid demonstration project paid all or part of their premiums, co-payments, and/or cost-sharing.

Criteria and time line for incentive payments

Unlike the Medicare incentive programs, the Medicaid incentive program allows EPs and EHs to receive an incentive payment in the first year simply for adopting, implementing, or upgrading certified EHR technology without fulfilling the meaningful use criteria. To prove this, Medicaid EPs and EHs will have to attest to having adopted or commenced utilization of certified EHR technology; or expanded the available functionality of certified EHR technology and commenced utilization at their practice site.

To establish "adoption," a provider must be able to demonstrate the actual installation of EHR prior to the incentive, rather than "efforts" to install EHR technology. Adoption does not include activities that may not necessarily result in actual installation, such as researching EHRs. To establish the "implementation" of EHR technology, a provider must have installed certified EHR technology and started using the EHR technology in clinical practice. Implementation

Continued on page 28

...continued from page 27

includes staff training, data entry of patient demographics and administrative data, and establishing data exchange agreements and relationships between the provider's certified EHR technology and other providers, such as laboratories, pharmacies, or health information exchanges. Efforts to redesign provider workflow would also be considered implementation of EHR technology. To establish the "upgrade" of EHR technology, a provider must show the expansion of the functionality of certified EHR technology, such as the addition of clinical support, e-prescribing functionality, computerized physician order entry (CPOE) systems, or other enhancements that facilitate the meaningful use of certified EHR technology.

For years beyond a year in which a provider receives Medicaid incentive payments for adopting, implementing, or upgrading certified EHR technology, states must implement the same meaningful use requirements and criteria (including clinical quality reporting measures and the use of certified EHR technology) used in the Medicare EHR incentive programs. States, however, are able to seek a modification to such criteria or to propose alternative criteria; the state must submit the proposed methods to CMS for prior approval.

Because there is concern that many states do not currently have the electronic infrastructure to receive and store clinical quality measures and because Medicaid providers may receive Medicaid incentive payments for adopting, implementing, or upgrading certified EHR technology in their first payment year (prior to demonstrating meaningful use of EHR technology), the final rule gives states the ability to identify in their state Medicaid Health Information Technology (HIT) Plans how the state intends to accept clinical quality data from Medicaid providers who seek to demonstrate meaningful use, either via attestations or via electronic reporting. States must include in their state Medicaid HIT Plans an environmental scan of existing HIT and quality measure reporting activities related to Medicaid. States are expected to include details about how these other on-going efforts can be leveraged and supported under HITECH, and how HITECH will not result in duplicative and/or burdensome reporting requirements on the same providers or organizations. Therefore, unless otherwise approved by CMS, Medicaid EPs and EHs must meet the same meaningful use requirements and submit the same required information for clinical quality measures as for the Medicare incentive program for years after the year in which they have received an incentive for adopting, implementing, or upgrading EHR technology.

Computation of incentive payments

Medicaid EPs

EPs may participate in the Medicaid incentive program for up to 6 years (an incentive for adopting, implementing, and upgrading EHR technology plus additional incentive payments for up to 5 years for demonstrating meaningful use). A Medicaid EP who has already adopted, implemented, or upgraded certified EHR technology and can meaningfully use EHR technology in the first incentive payment year will be permitted to receive the same maximum payments as a Medicaid EP who merely adopted, implemented, or upgraded certified EHR technology in the first year. Therefore, the maximum incentive payments for Medicaid EPs who demonstrate that they are meaningful users in the first payment year will be identical to the maximum payments available to those who demonstrate adoption, implementation, or upgrading certified EHR technology in the first year. Medicaid providers in their second participation year (or their first payment year, if they are qualifying based on meaningful use) will need to demonstrate meaningful use over a 90-day reporting period and

over 12-months for their third and subsequent years.

Medicaid EPs are not required to participate in the incentive program on a consecutive annual basis, however, the last year an EP may begin receiving payments is 2016, and the last year the EP may receive incentive payments is 2021. Medicare EPs do not have this same flexibility. This means that an EP may receive a Medicaid incentive payment in 2012 for adopting, implementing and upgrading EHR technology, not meet the meaningful use criteria in 2013, and then begin receiving Medicaid incentive program payments again in 2014 when it is able to meet the meaningful use criteria. This also means that if an EP does not receive an incentive payment for a given year, then that year would not constitute a payment year. For example, if a Medicaid EP receives incentive payments in 2011 and 2012, but fails to qualify for an incentive payment in 2013, the EP would still be potentially eligible to receive incentives for an additional four payment years.

Payment for EPs under the Medicaid incentive program equals 85% of the "net average allowable costs" of EHR technology (See table 2). "Net average allowable costs" are the average allowable costs of EHR technology minus payments from other sources (other than states or local governments). The net average allowable costs are capped at $25,000 in the first year, and $10,000 for each of the five subsequent years (pediatricians who have a minimum 20% patient volume may qualify for up to a maximum of $14,167 in the first incentive payment year and up to a maximum of $5,667 in the five subsequent incentive payment years). Therefore, the maximum incentive payment an EP could receive under the Medicaid incentive program equals 85% of $75,000, or $63,750, over a period of 6 years (or for pediatricians, no more than $42,500 over the maximum 6 year period). EPs must begin receiving incentive payments no later than calendar year 2016 (which means the final incentive payment, assuming meaningful use is maintained, will be made in 2021).

States must have a process and a methodology for verifying that payment incentives are not paid at amounts higher than 85% of the net average allowable cost and that Medicaid EPs pay 15% of the net average allowable cost of the certified EHR technology. As such, states may choose to establish a process whereby individuals attest to having completed their forms correctly. In states that choose this attestation method, Medicaid EPs run the risk of audit in the event that the state has reason to believe a form was not appropriately completed. States may also allow EPs to count their initial costs

Continued on page 30

Table 2: Net average allowable costs

Cap on net average allowable costs	85% allowed for EPs	Maximum cumulative incentive over a 6-year period
$25,000 in Year 1 for most EPs	$21,250	$63,750
$10,000 in Years 2-6 for most EPs	$8,500	
$16,667 in Year 1 for pediatricians with a minimum 20% patient volume, but less than 30% patient volume, Medicaid patients	$14,167	$42,500
$6,667 in Years 2-6 for pediatricians with a minimum 20% patient volume, but less than 30% patient volume, Medicaid patients.	$5,667	

...continued from page 29

in purchasing EHR technology for purposes of meeting the 15% threshold, because there is no prescribed time frame for when the EP's initial expenditure must have occurred.

Under the Medicaid incentive program, states will disburse Medicaid incentive payments to EPs in alignment with the calendar year. The reason for this is to align Medicaid incentive payment disbursements with that of the Medicare incentive programs, in order to support consistency between the programs, as well as among the states.

Medicaid EHs

The payments to an EH under the Medicaid incentive program are similar to those under the Medicare incentive programs. A Medicaid EH may receive an incentive payment equal to its overall EHR expense amount times its Medicaid Share. The EH's Medicaid Share is based on its Medicaid inpatient bed days, total inpatient bed days, and charges for charity care. The Medicaid share includes both Medicaid inpatient-bed-days and Medicaid managed care inpatient-bed-days.

States may pay an EH up to 100% of an aggregate EHR hospital incentive amount provided over a minimum of a 3-year period and a maximum of a 6-year period. No payments can be made to an EH after 2016 unless the EH received a payment in the previous year, and payment years after 2016 must be consecutive. As under the Medicare incentive programs, an EH will receive Medicaid incentive payments in alignment with the federal fiscal year (beginning October 1 and ending September 30 of the subsequent calendar year). An EH may receive incentive payments from both the Medicare and Medicaid incentive programs, contingent on successful demonstration of meaningful use and other requirements under both programs. Additionally, in any given payment year, no annual Medicaid incentive payment to an EH may exceed 50% of the EH's aggregate EHR incentive payments.

States are responsible for using auditable data sources to calculate Medicaid EH incentive amounts. Auditable data sources include providers' Medicare cost reports, state-specific Medicaid cost reports, payment and utilization information from the state's Medicaid Management Information Systems, and EH financial statements and accounting records.

Process for making and receiving Medicaid incentive payments

EPs must make a selection between receiving incentive payments through either the Medicare or Medicaid incentive programs. EPs are prohibited from receiving incentive payments under the Medicaid incentive program unless the EP has waived any rights to incentive payments under the Medicare FFS or MA incentive programs.

Furthermore, the HHS Secretary is required to assure no duplication of funding with respect to a physician and the Medicaid and Medicare programs. To aid in such efforts, the HITECH Act requires the Secretary to post online the names of Medicare EPs, EHs, and CAHs that are meaningful EHR users for the relevant payment year. EPs receiving a Medicaid incentive payment would remain eligible for incentives under the Medicare Improvements for Patients and Providers Act (MIPPA) E-Prescribing Incentive Program. EPs can change their election once during the life of the incentive programs after making the initial election for payment years 2014 and before.

If an EP switches programs, the EP will be placed in the payment year the EP would have been in had the EP begun in and remained in the program to which he or she has switched. An EP may make one incentive program election change prior to the 2015 payment year, and no switching is permitted after the 2014 payment year. In any event, no incentive payments will be made to any EP

that would allow the EP to exceed the Medicaid threshold.

Medicaid EPs and EHs must select one state from which to receive incentive payments. Medicaid EPs and EHs can annually change the state they select when they re-attest to program requirements. EPs in multiple group practices must select one tax identification number (TIN) for Medicaid incentive payments. EPs are not permitted to require a state to divide payments among different practices based upon group TINs; however, once a payment is disbursed from the state, nothing precludes the EP from further disbursing the incentive payment, subject to applicable fraud, waste, and abuse laws, regulations, and rules.

Generally, incentive payments must be made directly to the EP; however, there is an exception which allows incentive payments to be made to "entities promoting the adoption of certified EHR technology" if participation in the payment arrangement is voluntary for the EP involved. Additionally, the entity must not retain more than 5% of the incentive payment for costs unrelated to certified EHR technology and support services, including maintenance and training.

An entity is "promoting" the adoption of certified EHR technology if it enables and provides oversight of the business, operational, and legal issues involved in the adoption and implementation of EHR and/or exchange and use of electronic health information between participating providers, in a secure manner, including maintaining the physical and organizational relationship integral to the adoption of certified EHR technology by EPs. Using this definition as a guideline, states will have the discretion to identify entities that promote the adoption of certified EHR technology and must assure that such entities receive no more than 5% for costs not related to certified EHR technology.

The waiver and non-duplication requirement applies only to EPs who meet both the Medicare FFS/MA and Medicaid EHR incentive program eligibility criteria, and does not apply to EHs (which, if eligible could receive incentive payments from both Medicare and Medicaid simultaneously).

Provider compliance and audit

Under the Medicaid incentive program, CMS explicitly contemplates that states will fight fraud and abuse related to the Medicaid incentive program, including ensuring that no duplication of payments occurs between the Medicare and Medicaid programs. States are required to set forth compliance mechanisms related to the Medicaid incentive payments in their state Medicaid HIT Plans. Because providers are required to attest to their ability to meet the patient volume eligibility requirements, in most state Medicaid HIT Plans there will no doubt be an audit and verification procedure to ensure the accuracy of all information attested to by a provider. Additionally, CMS has required that states also include in the state Medicaid HIT Plans, a process for recoupment of monies, if overpayments or erroneous payments are found to have been paid. ■

Return on investment in health care compliance

By Ofer Amit and Draco Forte

Editor's Note: Ofer Amit is a Research Compliance Administrator at Baptist Health South Florida in Miami. He may be contacted by telephone at 786/594-6709 or by e-mail at OferA@baptisthealth.net.

Draco Forte is a Clinical Research Consultant in the Health & Life Sciences Practice at SNR Denton, US LLP. He may be contacted in Chicago by telephone at 312/876-2623 or by e-mail at draco.forte@snrdenton.com.

Hospitals, academic medical centers (AMCs), and private practitioners did not escape the effects of the downturn in the economy. In 2008, hospitals saw significant decline in elective procedures and an increase in the need for subsidized services, the number of uninsured patients, and the number of patients covered by programs for low-income populations – trends that led to a nearly 25% decline in operating margins when compared to 2007.[1]

The shakeup in the capital markets eroded hospitals' non-operating income, reduced their reserves, and put constraints on hospitals' ability to access capital to meet their obligations and to fund improvement projects.[2] Expectedly, in 2008 and 2009, Compliance departments and programs in all provider settings also felt the brunt of the shrinking operating budgets. Nevertheless, in late 2010 and with the overall sense of economic improvement, compliance professionals anticipated compliance budgets and staffing to increase in 2011.[3]

Compliance needs are not necessarily in tune with the changing economic landscape, and this pattern of fluctuating compliance resources presents an enormous challenge to compliance officers. As hospitals struggle to balance economic needs with regulatory requirements, compliance officers are expected to more clearly justify their budgets. This article will explore the return on investment (ROI) in health care compliance. It will suggest a definition for ROI in compliance, explain the investment in health care compliance, review the cost of noncompliance, and make suggestions on practical steps to maximize the ROI in compliance in health care organizations.

Defining ROI in health care compliance

In an era of economic challenges, high-cost low-return endeavors often come under scrutiny. In recent years, compliance has been perceived in many health care institutions as a "pure cost" activity. Before we proceed to discuss this perception, we make the following two assumptions: (1) Care can be provided to patients only in a manner that fully complies with pertinent laws, rules, and regulations; and thus (2) Compliance, as a function, is an enabler without which the institution will be unable to deliver care. To this end, the provision of care is not limited to the actual act of delivery of care to the patient at the point-of-care. It includes also the full scope of clinical and business operations that take place throughout the provider's enterprise that lead to and culminate in a patient receiving care. The availability of an effective, capable, and responsive function that assures compliance with relevant laws, rules, and regulations is therefore a critical asset for the health care entity or provider, and one that requires attention and investment.

ROI is viewed, most commonly, as the ratio between the change in the value of an investment and the investment's value or cost. In this relationship, the return can be directly connected to the value or cost. In health care compliance,

however, making the connection between the two is challenging. Although the investment is largely of a known size, a complete account of often immaterial values extracted from compliance due to this investment is frequently difficult to assemble. More specifically, the investment in compliance is actual and almost readily quantifiable. It includes primarily budgets of Compliance departments and the overall amounts dedicated to sustaining compliance activities. Consider however, that in the modern health care environment, many compliance activities are woven into the fabric of business in a manner that blurs the distinction between operations and compliance. Such activities can include, for example, administration of consent or notice of privacy practices, calculation of fair market value for contract negotiations, or a quality assurance review in a coding process. Accounting for the full investment in compliance is thus challenging and, in addition, the value rooted in this investment is often not credited to compliance either. Further, the cost of noncompliance can be difficult to reliably measure. It includes such before-the-fact estimates as fines, legal costs, bad press and brand erosion, lost business, resource reallocation, and a probability-of-occurrence factor that are all difficult to calculate.

Investment in health care compliance

The regulatory burden on providers has increased relentlessly. Hospitals and AMCs are bracing for more than 25 new sets of federal rules, only a few of which have been promulgated to date, in connection with the Patient Protection and Affordable Care Act (PPACA).[4] In addition, and with increased budgetary pressures, federal and state governments have intensified enforcement and tightened regulatory loopholes. The effect of the increasing regulatory burden on hospitals and AMCs is short-term (or transitional) and long-term with more permanent implications. The coping strategies adopted by providers and subsequent investments in compliance are similar in nature. To help manage the transition, providers are enlisting the services of law firms, consultants, and subject-matter experts who assist with evaluating the impact of new regulations on the organization, assessment of risks, development of new operational strategies, enactment of new policies, and revision of existing policies.

Although providers with enough resources hire such organizations to help with facing new challenges, Compliance departments cannot avoid the need to increase in-house expertise and capacity to handle and internally manage the transition to a new health care regulatory landscape. Among the most common approaches taken by hospitals and AMCs is to identify temporary space, allocate necessary resources, leverage existing or slightly modified systems, and hire professionals who, in addition to subject-matter expertise, can demonstrate project management experience and a track record in change management in highly stressful environments.

The above approach is common to organizations that have the resources and seek to respond quickly to new challenges or to promptly address identified deficiencies. Upfront investment in professional services and dedicated in-house transition staff can accelerate the response to new and changing regulations. It can create a spike in monitoring and audit activity, and accelerate development and revision of training and education programs. It can improve the efficiency of developing and implementing new policies and processes and thus materially reduce the required investment of transition. However, an initial one-time and relatively short-term investment in the transition may not suffice to prevent an increase in the long-term compliance burden. Providers need to commit capital resources in order to make longer-term investments in Compliance and Operations that will sustain the long-term effort by adding personnel, space, information systems, etc.

Continued on page 36


If you want to increase compliance, start with a training progam that engages your staff.

Healthcare facilities that are serious about reducing risk choose HCCS.

Compliance is serious business and it takes a serious training program to increase awareness and change staff behavior. Compliance training must have emotional impact and must change attitudes to be effective.

Engaging, professionally designed multimedia content is more effective than page-turning text.

An effective training program requires more than asking your staff to flip through some electronic text pages. HCCS online compliance and competency training courseware uses professional multimedia elements to create an engaging, interactive learning environment. Real-life video scenarios with professional actors in healthcare settings, audio narration and interactivity are combined to increase the retention of the information presented.

Adult learning is what works.

HCCS courseware is designed using accepted principles of how adults learn and retain information.

Research shows that retention is greatest when the learner sees, hears and interacts with training content.

HCCS courses combine expert up-to-date content with expert learning methods to create a truly unique learning experience.

The top University hospitals in the country choose HCCS.

More than 50 Academic Medical Centers, 25 medical schools and hundreds of other healthcare facilities have chosen HCCS training courseware for their online education. With over one million registered learners, HCCS is the leading provider of online multimedia compliance and competency training courseware.

When employees pay attention, you reduce your risk.

Looking for a more effective training solution? Want to increase compliance?

Don't take our word for it, take one of our free educational webinars or test drive our courseware yourself at www.hccs.com.

hccs

Experts in Healthcare Learning

Call 877-933-4227 for more information and a schedule of **FREE training webinars** or go to www.hccs.com

Medicare • Medicaid • HIPAA • Quality Improvement • Research • Nursing

 ...continued from page 33

The enactment of the Transparency Reports and Reporting of Physician Ownership Interests[5] (TR&RPOI) provision included in the PPACA illustrates this point. In its current form, TR&RPOI requires pharmaceutical companies, biotech firms, and medical device manufacturers to publicly report payments or other transfers of value made to physicians and teaching hospitals by manufacturers and group purchasing organizations. Under TR&RPOI, hospitals do not have responsibility for reporting, but it is in their best interest to obtain the data and leverage them to better manage physician and institutional financial conflicts. To achieve this goal, not only will strategies, policies, and processes need to be outsourced for creation, but in addition, hospitals will need to enhance their ability to acquire and manage the data by adding, for example, data acquisition and analysis mechanisms, data repository systems, and support personnel.

Long-term investment in Compliance infrastructure and operating capacity may increase the capacity of compliance personnel to stay current with new and changing regulations, to perform more assessments of new regulations and their impact on the organization, and to conduct more risk assessment and risk mitigation activity. It may mean that specialized compliance risk areas or topics can be identified, specialized personnel can be hired, and dedicated training programs can be designed to address these areas. It may also mean that more time may then be available for compliance personnel and other organizational leaders to ensure better coordination among Compliance, Legal, Audit, Risk Management, and Government Relations functions so that an integrated, collaborative plan is established.

Cost of health care noncompliance

Investing in a comprehensive Compliance infrastructure may appear to be expensive in terms of operating and capital costs (e.g., salaries, benefits, space, information systems, etc.), but the cost of noncompliance can be much higher. These costs can be organized into three categories:

- Fines and settlements
- Corrective actions
- Public trust and brand-damage costs

When compared with the actual events or concerns that can trigger incidents of noncompliance, these costs have the potential to disproportionately drain resources from the institution over long periods of time. An inappropriate or untimely response to an event of potential noncompliance can severely increase these costs further.

Many of the laws and regulations that govern health care are complex; and an institution's inability to comply may be interpreted as fraudulent activity, negligence, or criminal behavior. To protect the government's financial resources and the welfare and wellbeing of the population, states attorneys general, the US Department of Justice (DOJ), and Health and Human Services Office of Inspector General (OIG) have increased their fraud and abuse investigation and enforcement activities. In March 2007, Medicare established Fraud Strike Forces that are now active in seven major cities.[6] During fiscal year 2010, the federal government won or negotiated approximately $2.5 billion in health care fraud judgments and settlements.[7] In the 6-month period ending March 31, 2010, the OIG reported exclusion of 1,935 individuals and entities from participation in federal health care programs and 293 criminal actions against individuals or entities.[8]

Noncompliance can result in heavy financial penalties. However, it is not only the penalties that render noncompliance expensive to institutions; litigation, regardless of its outcome, can also be costly to institutions. The costs do not end with the payment of the penalty or legal settlement. Settlements may include provisions or requirements for ongoing oversight to ensure

future compliance that may lead to significant long-term investment in compliance.

Corrective actions—which often include significant expectations of future new monitoring and internal mechanisms to detect and manage compliance risks—are commonly incorporated into a settlement of a noncompliance matter. They can range from complete redesigns of a provider's Compliance infrastructure to increased reporting requirements. They are typically a part of a Settlement with Integrity Provisions (SIP), Corporate Integrity Agreement (CIA) or Certification of Compliance Agreement (CCA). For example, when institutions consent to CIAs with the OIG, they may be required, in addition to the payment of fines and penalties, to appoint a compliance officer, implement a training program, develop new policies and procedures, and much more. These activities require additional time and effort from existing staff, or the hiring of new staff or consultants, and other costs associated with establishing new processes.

Implementation of corrective actions often means diversion of resources from normal operations and a potentially adverse effect on the institution's ability to carry out its mission in an efficient and cost-effective manner.

The greatest cost of noncompliance is the damage that can be done to the reputation of the institution. Public perception—justifiable or not—that a health care institution is unable to operate in a compliant manner can erode the trust that both staff and patients have in the organization, raise questions about the institution's integrity and ethics, significantly impact its perceived moral standing, and adversely alter the institution's reputation in the community. Negative media attention, suspension or debarment of staff, or loss of provider participation in federal programs can lead to low morale internally and to a lack of community confidence externally. It may also lead to a decrease in patient accrual, increased difficulty in attracting world-class practitioners, reduced number and quality of funding opportunities, dwindled political support, and an overall significant decrease in the institution's ability to conduct business.

Practical steps

Institutions face a significant challenge when trying to balance the sometimes staggering investments necessary to establish a "right-sized" effective compliance function, with the far-reaching consequences and potentially high costs of noncompliance. The dynamics of this balancing of resources are unique to each institution. The choices that provider organizations make often hinge on an individual institution's tolerance for risk, its culture and history, its priorities, and its financial means. Institutions can leverage in-house resources, or they can hire outside professionals to help maximize the return on their compliance investment and to optimize the ratio between the required investment and the anticipated return to their specific circumstances. Many organizations are risk-averse enough to authorize both in-house and outsourced solutions.

An investment in enhancing the capabilities and scope of the compliance program should be associated with an anticipated and justifiable return with a plan for how to maximize ROI. Provided below are a number of key steps that compliance professionals and other organizational leaders can take in their institutions to help identify the level of investment that they may choose to make, given their unique circumstances, resources, priorities, and market position:

- Identify compliance focus areas and priorities for your institution.
- Assess the current state of these priority areas (i.e., current resources dedicated to carry out compliance program initiatives associated with organizational compliance priorities).

Continued on page 39

 ...continued from page 37

- Determine the institution's risk tolerance in each of the areas. Discuss with colleagues, including executive level management. Evaluate national and regional trends in enforcement in these areas.
- Consider your institution's history, track record of compliance prioritization, culture, infrastructure, and operations. Create a scale and quantify your conclusions. Quantify the potential impact of non-compliance in each of the areas on your organization.
- Visualize a desirable and attainable future state for each of the focus areas. Leverage your network of compliance peers to gain an understanding of what the desirable future state entails. Factor into your considerations your institution's risk tolerance level for each of the areas.
- Assess the gap between the current state and the desired future state. Quantify the investment in time and resources necessary to shift from the current state to the desired future state in each of the focus areas.
- Evaluate the necessary investment in relation with the potential impact of non-compliance in each of the focus areas. Prioritize the focus areas according to the ratio between the two.
- Revisit each of the focus areas and explore ways to reduce the necessary investment without increasing the potential impact of non-compliance.

Conclusion

Hospitals and AMCs were required historically to invest resources in compliance. These investments were critical to their operations, but typically did not directly generate revenues. Increased regulation and intensified government enforcement efforts may require an even larger future investment in this perceived cost-only activity. The need to continue to invest in compliance comes, naturally, under close scrutiny in an era of economic turbulence, and compliance officers are challenged to justify continued investment by demonstrating a return.

Making an ROI argument in favor of investment in compliance is, nonetheless, a daunting task. Primarily, it is due to the asymmetrical nature of the issue. On one hand, it can be relatively simple to quantify the amounts invested in the compliance enterprise. On the other hand, potential savings due to compliance activity in the form of avoided fines, bad press, and brand erosion are difficult to quantify. Unless an institution is willing to invest also in financial quantification of potential noncompliance, it would be extremely difficult for its compliance professionals to demonstrate the financial benefit of the compliance effort.

There is, however, broad consensus that hospitals and AMCs can provide care only if they are compliant throughout their operational structure and, subsequently, the compliance enterprise is to be considered an asset deserving attention and investment. Compliance officers are therefore challenged to identify the financial benefits of their activity, dedicate resources to measuring and documenting how their Compliance departments add value to the institution, and to continually educate the organizational leadership on the meaning and correct application of ROI in health care compliance. ■

1. American Hospital Association Hospital Statistics. TRENDS: Even as Health Reform Takes Center Stage, Economic Challenges Remain. (December 2009).
2. Ibid
3. The Society of Corporate Compliance and Ethics and the Health Care Compliance Association: Survey: The Evolving Role of the Chief Compliance and Ethics Officer. February 2011. Available at http://corporatecompliance.org/Content/NavigationMenu/Resources/Surveys/default.htm
4. P.L. 111-148
5. P.L. 111-148, Section 6002
6. HHS OIG Semiannual Report to Congress, Spring 2010.
7. The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2010 is available at http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2010.pdf
8. Ibid

Whistleblower lawsuits help provide Stark and Anti-kickback Statute guidance

By Shauna B. Itri, Esq.

Editor's note: Shauna Itri is an Associate in the Philadelphia offices of Berger & Montague, PC. She may be contacted by telephone at 267/973-4265 or by e-mail at sitri@bm.net.

The False Claims Act (FCA) is designed to protect the federal treasury and to deter fraud committed against the government. The FCA places power within the hands of private citizens, allowing them to become "private attorney generals," and, with the assistance of an attorney paid on a contingent fee basis, challenge government payments on behalf of the government. The citizens who bring a case on behalf of the government ("whistleblowers") can be employees, former employees, and/or competitors. They receive protection from retaliation under the FCA and obtain a share of the ultimate recovery for their work. Through their litigation, whistleblowers fight, prevent, and deter fraud; their lawsuits can also provide Stark and Anti-kickback Statute guidance.

FCA actions may be predicated on violations of the Stark and Anti-kickback Statute. In simple terms, the Anti-kickback Statute prohibits any person/entity from offering or accepting cash or in-kind payment in exchange for the purchase, ordering, or recommending of goods/services. The Stark Statute prohibits paying cash or in-kind in exchange for referrals. The Stark Statute and the Anti-kickback Statute contain "safe harbors" which are considered "legitimate common business arrangements" and exempt the entities from the statutes if they comply with the elements. Complying with the statutes has however, proven to be difficult and thus, it is important to stay current on settlements and enforcement actions for cases where Stark and Anti-kickback violations are alleged, in order to report fraud and/or adjust policies accordingly.

The cases listed below show the types of FCA cases that have been brought for underlying violations of the Stark and Anti-kickback Statutes. In most of the cases listed below, the whistleblower brought the fraud to the government's attention by filing a FCA case and received a portion of the settlement.

- *United States ex rel. Moilan v. McAllen Hospitals LP* (October 2009). The whistleblower, a former employee, alleged that the hospital had entered into financial relationships with doctors in exchange for referrals. Per the complaint, the hospital disguised the payments to doctors through "sham contracts" such as bogus medical directorships and lease arrangements. The hospital paid $27.5 million to the government to settle the case, the whistleblower received $5.5 million from the proceeds of the settlement.
- *United States ex. rel. Reimche v. Tulare Local Healthcare District* (2009): In this case, the whistleblower and former chief financial officer alleged that Tulare Healthcare paid kickbacks to physicians from 2001 through 2007 in the form of debt forgiveness and below-market rentals and purchase prices for office space in exchange for referrals of Medicare patients. The defendant settled the case for $2.4 million.
- *United States ex rel Fry v. Health Alliance of Greater Cincinnati* (2010): In this case, Christ Hospital of Cincinnati was accused of engaging in a "pay-to-play scheme." Whistleblower, Dr. Harry Fry, a cardiologist who used to work at Christ Hospital, alleged that the hospital referred patients to a cardiology practice whose doctors, in

turn, were allocated panel time at the hospital's outpatient testing unit, based on the amount of procedures they performed and revenue they generated. The two organizations will pay $108 million, including $23.5 million to whistleblower Dr. Harry Fry, to settle the allegations that the assignment of physicians to the cardiac testing station resulted in the inducement of local cardiologists to refer patients to the hospital.

- The Detroit Medical Center (December 2010)[1] agreed to pay the federal government $30 million to settle claims that it engaged in improper financial relationships with referring physicians. The settlement resolved allegations that the DMC violated several federal laws, including the Anti-kickback Statute and the Stark Statute, which restrict the financial relationships that hospitals may have with doctors who refer patients to them. Most of the relationships at issue in the DMC matter involved office lease agreements and independent contractor relationships that were either inconsistent with fair market value or not put in writing.
- Christiana Care Health System in Wilmington, Delaware (March 2010)[2] agreed to pay $3.3 million to settle claims made by a whistleblower that the health system allegedly paid kickbacks to neurologists for referring patients to its Wilmington hospital. According to the charges, Christiana Care overpaid physicians at Neurology Associates for in-hospital readings of EEGs allegedly as a "reward" for referring patients to the hospital. The court documents noted the payments were part of a contract dating to 1989, prior to the enactment of the current Stark Act. The whistleblowers in the lawsuit were a group of physicians from a competing neurology group and will receive $190,000 in the settlement.
- Tuomey Hospital was ordered in June 2010 to pay the federal government $44.9 million plus interest for a Stark Act violation.[3] A federal jury found Tuomey Hospital in Sumter, South Carolina, part of Tuomey Health System, guilty of violating the Stark Act for providing kickbacks to physicians in return for referrals at the hospital. This case involved the providing a number of part-time employment arrangements to physicians that exceeded fair market value and were nothing more than vehicles to reward referrals. A federal jury found the hospital guilty of violating the Stark Act for the contracts, which it began offering to physicians in 2004. Tuomey may face a new trial on an alleged False Claims violation.
- University of Medicine and Dentistry in Newark, New Jersey (2009)[4] settled with the government for $8.3 million. Here, the government alleged the hospital illegally paid kickbacks to cardiologists in exchange for referring patients to the hospital. The government alleged that the hospital experienced a drop in certain cardiac procedures that jeopardized the hospital's Level 1 Trauma Center status. As a result, the hospital allegedly provided local cardiologists contracts for part-time employment, which the government alleged only served as vehicles to provide illegal kickbacks.
- Covenant Medical Center in Waterloo, Iowa (2009)[5] settled a case for $4.5 million for alleged violations of the Stark Law and False Claims Act. The alleged violations stemmed from compensation that Covenant paid to five physicians employed by the hospital who referred patients to it. It was reported that the physicians were among the highest paid physicians in the entire U.S., making as much as $2.1 million. The CEO states that a competing independent physician group reported this fraud to the government. The government

Continued on page 43

The Health Care Compliance Professional's Manual

SUBSCRIPTION SERVICE INCLUDED WITH PERIODIC UPDATES

- Hard-copy subscribers receive quarterly updates
- Internet subscribers receive updates as soon as they are issued

The Health Care Compliance Professional's Manual gives you all the tools you need to plan and execute a customized compliance program that meets federal standards. Available via print or the Internet, the Manual walks you through the entire process, start to finish, showing you how to draft compliance policies, build a strong compliance infrastructure in your organization, document your efforts, apply self-assessment techniques, create an effective education program, pinpoint areas of risk, conduct internal probes and much more.

The Health Care Compliance Professional's Manual shows you how to:

- Confidently use OIG publications and Federal Sentencing Guidelines to help you plan and execute a customized compliance strategy that meets strict federal standards
- Perform risk assessments within your program to help you uncover possible areas of risk
- Draft your own compliance policies that will form the basis for your organization's program
- Develop and reinforce a solid infrastructure, including guidelines for hiring the right personnel
- Design an effective education program that instills the importance of compliance
- Conduct your own internal probes to surface and cure questionable activities, thus mitigating possible penalties
- Keep continually up-to-date with the latest regulatory changes, including practical coverage of federal and state laws

MEMBER PRICE: $359
NON-MEMBER PRICE: $399

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

Wolters Kluwer
CCH
Medi-Regs
Aspen Publishers

www.hcca-info.org | 888-580-8373

Whistleblower lawsuits help provide Stark and Anti-kickback Statute guidance

...continued from page 41

would not comment on how it determined fair market value, but the significant discrepancies between the compensation of the five Covenant physicians and other physicians in the region and around the country led the US Attorney's Office for the Northern District of Iowa to conclude that the hospital was paying the physicians for referrals, in violation of the Stark Law.

From 2001 through 2010, there were nearly 100 different physician self-referral and kickback settlements; 20 of the settlements have occurred in just two years, 2008 through 2010. At the same time, there has been an upswing of interest by hospitals and other health care entities to align more closely with physicians. Many of the more recent settlements and actions involve alleged improper attempts at aligning with physicians; and the type of whistleblowers in these actions ranged from former and current employees, competitive practice groups, doctors, and management.

A review of the recent settlements and enforcement actions provides the following non-exclusive categories of potential Stark Statute and Anti-kickback Statute violations for which a whistleblower can bring a claim under the FCA. The different types of Stark and/or Anti-kickback Statute violations involve the hospital or entity:

- providing free services or staff, including administrative assistants, physicians assistants, athletic trainers, or information technology to a practice group of physicians;
- paying for services not really needed, including paying for medical directorships or providing part-time employment (those relationships that are entered into that don't have a true purpose other than to reward physicians for referrals);
- providing discounts on items, such as insurance or leased space;
- paying physicians under contract different amounts than are contracted (e.g., a hospital may contract a physician at a fair market rate for a medical directorship, but then actually compensate the physician at a higher rate);
- physician compensation arrangements not meeting fair market value and commercial reasonableness thresholds; and
- compensating physicians for work they did not or do not perform (e.g., if the hospital/entity pays a portion of a physician's salary in exchange for the physician's performing teaching, research, and clinical duties, and the physician does not fulfill the contractual obligation to teach, research, or perform clinical duties, this could be a potential Stark Statute violation).

The importance of complying with Stark and Anti-kickback Statutes has never been more important. The settlements and enforcement actions based on the Stark and Anti-kickback Statutes, as described above, clearly reflect whistleblowers' and the government's readiness to seek remuneration related to violations. Such settlements and actions have brought millions of dollars to the federal and state governments. Between 1987 and 2009, the average reward paid to a whistleblower was $1.9 million. In order to avoid such liability and comply with the statutes, it is important to be aware of the current enforcement actions and adjust policies and compensation arrangements accordingly. ■

1. See http://www.justice.gov/opa/pr/2010/December/10-civ-1484.html
2. See http://www.justice.gov/usao/de/press/2010/Christiana%20Care%20PR.pdf
3. See http://www.theitem.com/news/article_06cb1712-3bac-11df-b09c-001cc4c002e0.html
4. See http://www.nj.com/news/index.ssf/2009/09/umdnj_to_pay_83_million_to_set.html
5. See http://www.justice.gov/opa/pr/2009/August/09-civ-849.html

feature focus

Compliance and health care reform: What your board should know

By Anjana D. Patel and Alexandra Khorover

Editor's note: Anjana D. Patel is Vice-Chair of the Health and Hospital Law Practice Group at Sills Cummis & Gross, PC in Newark, New Jersey. She may be contacted by e-mail at apatel@sillscummis.com.

Alexandra Khorover is an Associate in the Health and Hospital Law Practice Group at Sills Cummis & Gross, PC in Newark. She may be contacted by e-mail at akhorover@sillscummis.com.

Recently, the federal government has been increasingly successful at detecting fraud and abuse in the health care industry. The newly enacted Patient Protection and Affordable Care Act (PPACA) provides the government with additional tools to combat fraud and abuse, signaling intensified government scrutiny of the industry under the Obama Administration. In this environment, an organization's implementation and maintenance of an effective compliance program will provide a crucial defense against allegations of improper conduct, and its board will be tasked even further to ensure that the organization's compliance program is effective.

This article outlines the key legal guidance affecting the role of the board in overseeing its institution's compliance program and provides recommendations to keep in mind as government enforcement activities intensify.

Recent developments

PPACA implements sweeping changes to the delivery and reimbursement of health care. One of the core initiatives of PPACA is the expansion of value-based purchasing by Medicare. Value-based purchasing involves holding health care providers accountable for both the quality and cost of the services they provide. The shift to a value-based purchasing system will require the board to take an expanded role in not only overseeing the financial bottom line of the institution, but also in ensuring that the organization provides high-quality care.

Other provisions of PPACA demonstrate the government's efforts to increase transparency in the industry by requiring organizations to implement compliance programs. For example, Section 6102 of PPACA requires nursing homes to adopt a compliance and ethics program for their employees and agents. One of the mandatory elements of Section 6102 is that nursing homes appoint specific individuals with authority and resources to oversee compliance activities. Moreover, Section 6401 grants the Secretary of the Department of Health and Human Services (HHS) the authority to require other types of health care providers to adopt compliance programs as a condition of participation in federal health care programs.

In addition to PPACA, millions of dollars have been recovered by the government in recent years as a result of sweeping enforcement efforts. In fiscal year 2010 alone, HHS' Office of Inspector General (OIG) reported that its enforcement activities resulted in record savings and expected recoveries of $25.9 billion.

The recent uptick in enforcement has also resulted in the assessment of individual liability against health care executives. In 2009, the CEO of a California hospital, who also served as its chief compliance officer, entered into a $64,000 individual settlement with OIG in connection with allegations that he personally negotiated arrangements with physicians in violation of the Stark Law. More recently, in December 2010, three former executives of Purdue Pharma pled guilty to charges that the company had misled patients and physicians in connection with certain claims made regarding OxyContin. The executives were excluded from participation in federal health care programs for 12 years.

President Obama's 2011 budget includes $1.7 billion for the Health Care Fraud and Abuse Control Program, indicating that this current enforcement trend will continue in 2011. The developments described above underscore the vital role that board members play in connection with overseeing an organization's compliance efforts.

The board's duty of care

Board members owe a fiduciary duty of care to their organization. Generally, the duty of care requires the board to act in good faith, with the care of a reasonably prudent person in similar circumstances, and in a manner that he/she reasonably believes is in the best interest of the organization.

Board members exercise their duty of care by making decisions for their organization and by overseeing its operations. This requires asking questions, performing due diligence, and reviewing meaningful information prior to making decisions. As discussed in the landmark case *In re Caremark*,[1] a board member's fiduciary duties include ensuring that a corporate information and reporting system exists, and that the system is sufficient to assure that appropriate information regarding the organization's compliance will come to the board's attention in a timely manner.

In another case, In re Citigroup,[2] the court expanded on the Caremark concepts and held that board members can be held personally liable for failure to oversee corporate compliance activities where they: (1) utterly failed to implement any reporting or information system or controls; or (2) consciously failed to monitor or oversee the operations of the reporting/information system, thus disabling themselves from being informed of risks or problems requiring their attention.

Thus, the duty of care requires board members to oversee their organization by ensuring that appropriate systems are in place to enable the board to receive meaningful, timely information and to act in good faith upon receiving such information, including making further inquiry if need be. Failure to do so may not only put the organization at risk, but also potentially subject each board member to personal liability.

OIG compliance guidance

The health care industry is highly regulated, thus creating additional challenges for board members' compliance with their fiduciary duties. Recognizing this, OIG has published compliance program guidance for various types of providers. Although an organization's compliance program must be carefully tailored to the types of services it provides, as well as its size and resources, the OIG's guidance is a useful tool.

For example, OIG recommends that the following seven elements[3] be included in any effective compliance program:

1. The development of written policies and procedures
2. The designation of a compliance officer and compliance committee
3. The implementation of regular, effective training and education
4. The development and maintenance of a process to receive complaints

Continued on page 46

 ...continued from page 45

5. The development of a system to respond to improper activity and the enforcement of appropriate disciplinary action
6. The use of audits and other evaluation techniques to monitor compliance
7. The investigation and remediation of systematic problems

OIG has expressed that an effective compliance program is characterized by a formal commitment to compliance by the board as evidenced by a written statement or resolution and on-going board participation in compliance functions. Additionally, an organization's compliance officer should be a member of senior management with direct access to and the full support of the board.

State law

States are increasingly playing a role in regulating the compliance activities of providers. New York's Medicaid program, for example, recently adopted regulations requiring providers and their boards to adopt a compliance program and certify annually that the program meets the standards established by the New York State Office of the Medicaid Inspector General (OMIG). Failure to comply may result in sanctions, penalties, or the revocation of the provider's Medicaid participation. Additionally, if OMIG determines that an organization's compliance program is weak or ineffective, it will inquire into whether the board has exercised reasonable oversight of the compliance program. Serious deficiencies in oversight may result in sanctions against individual board members, including censure and exclusion from the Medicaid program.

Recommendations

Set forth below are recommendations for board members with respect to their organization's compliance activities:

- A commitment to compliance comes from the top. Board members should set the tone in a code of conduct that is widely disseminated within the organization.
- Board members should educate themselves about their organization's specific compliance program. They should ask questions and actively discharge their duty of care.
- Board members should be familiar with federal and state rules and guidance regarding the implementation of compliance programs and should gain an understanding of how their organization has implemented these recommendations and mandates.
- The board must ensure the existence of adequate and effective lines of communication and reporting. The compliance officer should have direct access and answer to the board.
- Recognizing the OIG's preference, the board should ensure that the compliance officer and the general counsel positions be staffed by different individuals.
- The board should require regular reports from the compliance officer. The reports should be clear and easy to understand. In light of PPACA, the board should request and review reports regarding quality of care data.
- Lastly, recognizing that compliance functions are not static, board members should periodically re-assess all of the above and incorporate changes as necessary. ■

The authors would like to thank Diana Giampiccolo, a law clerk with the firm, for her assistance with this article. The views and opinions expressed in this article are those of the authors and do not necessarily reflect those of Sills Cummis & Gross, PC.

1 *In re Caremark*, 698 A.2d 959 (1996).
2 *In Re Citigroup, Inc.*, 964 A.2d 106 (2009).
3 See for example, Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (1998).

Why, how, and when to conduct an information security risk analysis

By Feisal Nanji

Editor's note: Feisal Nanji is the Executive Director of Techumen, LLC in New York City, an advisory firm providing services to secure health information. He can be reached at feisal@techumen.com.

Under the Health Insurance Portability and Accountability Act (HIPAA), all electronic protected health information (e-PHI) created, received, maintained, or transmitted by a "covered entity" is subject to the Security Rule. If we assume that information technology powers modern health care, then it stores or disseminates most everything an entity might know about a patient. Thus, e-PHI security and privacy is fundamental and paramount.

The Security Rule requires entities to evaluate risks and vulnerabilities in their technology environments and to implement reasonable and appropriate security measures to protect e-PHI. The Office for Civil Rights (OCR), the security watchdog for the Department of Health and Human Services (DHHS), in particular, is responsible for issuing annual guidance on the provisions in the HIPAA Security Rule.[1] The OCR is also the body responsible for ensuring that covered entities are complying with the intent of the Security Rule. From a compliance perspective then, it may seem especially wise to take heed to what the OCR is saying.

In its first guidance released on July 14, 2010, the OCR states

> A risk analysis is foundational, and must be understood in detail before OCR can issue meaningful guidance that specifically addresses safeguards and technologies that will best protect electronic health information."[2]

In short, an information technology risk analysis is the fundamental security cornerstone the DHHS expects covered entities to meet. As the OCR ratchets up its compliance activities, as it has promised to do after the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, covered entities who have not conducted an adequate risk analysis must be prepared to face the OCR's wrath.

How to conduct a risk analysis

A risk analysis using a risk-based approach is the very foundation from which to build your information security compliance program. Without this baseline, your organization is swimming aimlessly.

The OCR goes on to stress in its Guidance on Risk Analysis:

> We note that some of the content contained in this guidance is based on recommendations of the National Institute of Standards and Technology (NIST). NIST, a federal agency, publishes freely available material in the public domain, including guidelines. Although only federal agencies are required to follow guidelines set by NIST, the guidelines represent the industry standard for good business practices with respect to standards for securing e-PHI. Therefore, non-federal organizations may find their content valuable when developing and performing compliance activities.

So in short, OCR "suggests" that a covered entity might use the NIST risk-based approach for doing a risk analysis. Our view is that when CMS "suggests" something, it very much is like God

Continued on page 48

 ...continued from page 47

telling you to do so. "Suggestion" is merely loosely worded as an imperative. Of course, other good risk frameworks exist, such as Control Objectives for Information Technology (COBIT) developed by the Information Systems for Auditing and Control Association (ISACA), or Octave developed by the CERT Institute at the Carnegie-Mellon University. These frameworks may be used, but why bother? The NIST guidance, as provided in its Special Publication 800-30, is excellent, thorough, and easily tailored for small, medium, and large covered entities.

NIST's risk assessment methodology encompasses nine primary steps. Considerable detail is available in NIST's Special Publication 800-30. For this article, however, it is appropriate to provide an overview of each of these nine steps.

1. System characterization. To fully understand your technology risk, you must understand key technology components in your infrastructure. These could be applications, hardware, operating systems, laptops, and mobile devices. In other words pretty much anything that receives, stores, or transmits information is in play.

2. Threat identification. Threats can be highly specific and discrete and will usually be based on threat motivation and capability. In general, however, threats can be divided into three types:

- **Human** threats created or instigated by human beings;
- **Environmental** threats caused by what insurance companies term "Acts of God"; and
- **Natural** threats that arise from the inherent nature of information systems.

3. Vulnerability identification. Your systems will be vulnerable to a wide range of these threats, but what exactly are your systems? They could be described as applications, databases, networks, and amalgams of these. So step 1 (i.e., a "system characterization" or inventory of how your information flows within your organization) is vital. If your systems have been identified well, vulnerability identification becomes much easier to do.

4. Controls analysis. Analyzing its controls allows an organization to assess the capabilities of its existing set of controls to meet the environment's needs. The analysis helps identify any existing policies and procedures or standards that may be in violation. Controls are typically described as one of three types:

- **Preventative:** These lower the likelihood of the threat exercising the vulnerability.
- **Mitigating:** These lower the impact if the threat exercises the vulnerability.
- **Detective:** These alert management that the threat has exercised the vulnerability.

Thus, controls will be technology or processes based, or involve interactions among people. Because many controls safeguard against multiple vulnerabilities, it is usually easier to keep track of multiple instances of a control than to attempt to define and consolidate an "underlying control."

5. Likelihood determination. The risk assessment team should use their best judgment to assign likelihoods, considering the threat motivation and ability, the nature of the vulnerability, and the current and planned controls. We suggest that a risk assessment methodology use three tiers to determine likelihood:

- **High:** The threat will successfully exercise the vulnerability more than once a year.
- **Medium:** The threat will successfully exercise the vulnerability less than once a year, but more than once every three years.
- **Low:** The threat will successfully exercise the vulnerability less than once every three years.

The output of this step of the risk assessment process is a likelihood determination for each threat-and-vulnerability pair facing the system or systems undergoing the risk assessment.

6. Impact analysis. In the absence of any historical data, the risk assessment team should use their best judgment to analyze that impact, considering for each system the effects of lost confidentiality, integrity, or availability, and the effect of any current or planned mitigating controls. For a recent client, we suggested a risk assessment methodology that uses three tiers to determine impact:

- **High:** The impact will cost more than 0.1% of covered entity revenue in financial outlays, require more than 400 man-hours to repair, endanger patient safety, or damage a covered entity's reputation for security.
- **Medium:** The threat will cost more than 0.01% of revenue in financial outlays or require more than 40 man-hours to repair.
- **Low:** The threat will cost less than 0.01% of revenue or require less than 40 man-hours to repair.

7. Risk determination. This is a combination of the impact rating and the likelihood determination. We suggest a three-tiered matrix to quickly make decisions (see table 1). Response speed is critical when an incident occurs, and having a ready way to gauge risk is therefore instrumental. The area marked with an asterisk (*) is potentially problematic; these are low likelihood, high impact events that are, by nature, difficult to predict. As part of the risk management process, the Compliance group, IT Security Committee, or the Audit Committee should review all risks assigned to this quadrant to determine if the risks have been appropriately ranked, and if additional controls are needed.

Table 1: Risk matrix

	Likelihood		
Impact	High	Medium	Low
High	High	High	Medium*
Medium	High	Medium	Low
Low	Medium	Low	Low

8. Control recommendations. Based on the determination of risk, your organization will need a road map for planning controls for future implementation. Through this process, your management team can make fundamental decisions to either accept each risk as it stands or alleviate some of the risk by imposing additional controls. This is an especially useful exercise, because it covers approvals, scheduling, and budgeting for additional control implementation.

9. Results documentation. Finally, all of this effort must be documented. As compliance officers who have gone through frequent audits, you know the value of excellent documentation. This, therefore, is a must and should be considered the capstone of your work. A readily available, well written, and thoughtful document that describes your entire risk analysis process will go a long way to assuage any auditor.

When to conduct a risk analysis

Risk occurs when change happens. As a compliance officer, you should require a risk assessment over a period of time when enough technology change has occurred.

The beauty about doing an annual risk assessment is that it becomes part of the compliance process; that is, the risk assessment can be merely updated as an addendum and not as an overbearing intrusion that is upsetting to staff and patients. A regular review of your risk posture is what is required to protect e-PHI. Too many new threat vectors and vulnerabilities are introduced into our information environments each day. We all need a reasoned, systematic, and regular approach to do good work. ■

1 45 C.F.R. §§ 164.302 – 318
2 Office of Civil Rights: Guidance on Risk Analysis Requirements under the HIPAA Security Rule. July 14, 2010. Available at http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf.

Corporate Integrity Agreements offer a second chance

By Joseph R. Batte, CFE and Prashanth Shetty

Editor's note: Joseph R. Batte is President of Kristall Associates, located in Marco Island, Florida. He was formerly a Supervisory Special Agent with the OIG. He may be contacted by e-mail at joebatte@marcoislandemail.com or by telephone at 239/394-3563.

Prashanth Shetty is Vice President, GRC Solutions with MetricStream. He may be contacted in Palo Alto, California by e-mail at prashanths @metricstream.com or by telephone at 650/620-2934.

Corporate Integrity Agreements (CIAs) are detailed and restrictive agreements that usually last four to five years. They are imposed on providers by the US Department of Human Services, Office of Inspector General (OIG) when serious misconduct (fraudulent or abusive-type action) is discovered through an audit, investigation, or self-disclosure. Compliance initiatives such as training, designating a compliance officer, or implementing a communications hotline are built into the CIAs and are designed to ensure that fraudulent behavior does not occur again. CIAs give providers a second chance by allowing them to continue to participate in federal health care programs.

Health care providers who find unintentional coding or documentation errors and report them to their Medicare contractors, intermediaries or private payers should not worry about CIAs. The CIA comes into play when intentional actions of fraud are committed. Self-disclosure by the health care provider is a positive mitigation step, even if there is a later conclusion by the payer that fraud did exist, because self-disclosure is a sign to payers that the practice wants to be compliant.

OIG oversees many CIAs, and there will be more as they strengthen their compliance enforcement at small- and medium-size group practices, as per the new health care law. Past OIG Work Plans specifically address CIAs: "We will increase the number of site visits to entities that are subject to the integrity agreements to verify compliance efforts and confirm information submitted."[1]

OIG Work Plans have also stated that OIG will:

> modify the requirements of CIAs, e.g. audit and training provisions, to reduce the costs (to providers) associated with implementing the agreements while continuing to promote the integrity of federal health care programs."[2]

Changes observed in the OIG indicate that they are trying to be more responsive to the medical community's efforts to stay compliant. Billions of dollars are lost annually to faulty claims, a good portion from coding errors, unsupported services, unnecessary services, and non-covered services.

OIG has found that providers are responding favorably to this new approach, via fraud alerts, legal advisory opinions, compliance guidance, and news releases. OIG also recognized there was an overall lack of education about compliance and a great deal of misinterpretation of the complicated and subjective guidelines.

Negotiating CIAs with the OIG

If OIG determines to settle a provider's wrongdoing by developing a CIA, an acceptable agreement should be negotiated. (You can review active CIAs at http://oig.hhs.gov/ciacurrent.htm to learn how they are set up and the steps taken.) This enables you to better control some of the negotiations with the OIG and possibly help to carry out specific requirements set

up in the negotiations. You should also consider hiring an expert who has experience in developing these agreements. Consider asking some of the providers who are in a CIA what information they can offer, and ask them which areas the OIG is most likely to negotiate.

Steps to follow when developing a CIA

If the OIG determines to settle a provider's wrongdoing by developing a CIA, an acceptable agreement should be negotiated. Here are some tips:

- **Be proactive.** If OIG is considering a CIA, there must be factors regarding your practice or facility that they consider positive and redeemable. Their goal is to make the agreement reasonable and workable. Show that you want to resolve the problem and prevent reoccurrences by outlining what corrections have already been made (i.e., corporate compliance officer assigned, compliance program implemented, quarterly independent audits set up) and what the results are.
- **Never agree to something you cannot achieve.** For example, on the Internet you may have found several CIA samples that showed that OIG required "written policy and procedures" implemented within 120 days. However, you know, based upon your current staffing and work schedules, that it would be impossible to achieve that goal. Alternatively, you can present a reasonable argument why you cannot achieve that 120-day goal and suggest an option. Perhaps you could agree to enact monthly training sessions for the next year and develop written policies and procedures during that time.
- **Establish a relationship.** Understand that the CIA will establish a relationship between the provider and the OIG. Learning about each other is a part of that relationship. Because the agreement will be for at least four years, work on establishing a good dialogue, show your sincerity, and demonstrate that you are trying to work towards an effective resolution.
- **Ask for changes.** One of the most prevalent complaints by agreement participants has been the high cost of the required annual independent review audits (usually in the thousands of dollars), a non-negotiable element in every CIA. This may lead to revising the review of current statistically detailed "multiple level samples" of claims to a much less arduous non-statistical and simpler "discovery samples" review. This will make an audit by an independent review organization (IRO) less expensive for providers.

  There is also a potential change in the form of permitting balancing out "underpayment and overpayment" of claims. In many cases, providers know they undercoded because they don't want the hassle of submitting additional supporting documentation. They feel they should be able to credit such undercoding towards any discovered overcoding. It will depend on the severity of the overpayment, but being proactive to get some of the overpayments credited to those underpayments is wise to consider.

Brief walkthrough of a "real" CIA

A written Notification of Violation to Provider letter from OIG is usually the first step involved in a typical CIA. Such a notification requests a meeting to discuss the situation in total. This is the time that you need to "gather the troops (experts) in your group.

In a real-life CIA, one of us (Joe) was retained by a small hospital to bring some expertise to the planning for the response to the violation letter. The hospital performed a thorough review of historical billing problems, and a risk analysis was done to get a handle on the level of exposure the hospital might have. An internal review of all the findings of this analysis and documentation of historical communication between the hospital and the Medicare Part A Intermediary were done. All positive mitigating

Continued on page 52

 ...continued from page 51

(defensive) factors were listed prior to the meeting requested by OIG.

The meeting request from OIG was responded to quickly, so as not to give the OIG the impression that the seriousness of the situation was being ignored by the hospital. Key hospital staff were prepared to be at this meeting with OIG, especially the compliance officer. If a compliance officer is not a part of the provider's staff, the presence of the chief financial officer and the chief executive officer is a must! First impressions are important, so the staff were briefed clearly regarding the importance of this meeting. OIG was allowed to set the meeting date, and every attempt was made to meet at the OIG's convenience.

Careful notes were taken during this meeting to ensure all problematic areas were documented and understood. During this meeting, immediate response in defense of any cited violations was done, to demonstrate total knowledge of compliance with program requirements. An offer to show the OIG members through the hospital was made to demonstrate confidence in the hospital operations. Once the "offer" was made by OIG to settle this matter via a CIA, a date was set for the construction of the specific elements to be included in the CIA.

The CIA team was then set up at the hospital, headed by the compliance officer. All the proactive material needed to attempt to shape the CIA to the hospital's benefit was developed by the hospital, including what corrective actions had already been instituted, a list of problem areas and any questions about the ability to complete work in each area, and ways to develop a good system of communication with the OIG partners going forward.

OIG came back with a draft CIA and a meeting to obtain agreement was set up. Here the hospital used all of the prior planning done to respond to the OIG draft elements and attempted to shape them to the hospital's benefit, including modifications to the IRO process and its desire to keep costs low. The hospital was fortunate that many of the requests were agreed to by the OIG. The final CIA was awaited, and the hospital deployed a team to immediately begin working on corrections needed and compliance required in the various elements of the CIA. Continuous dialogue with OIG contacts was implemented during the following months regarding progress or questions and interpretations. We were on our way!

Role of technology

Technology has an important role to play in helping health care providers comply with CIAs. An existing compliance program supported with the right technology can help health care companies negotiate an effective agreement, even aligning the agreement to the current compliance program in place. Health care organizations that are proactive in nature are more successful in complying with a CIA than those that are reactive in nature. Proactive steps include:

- deploying a technology framework that can manage compliance,
- defining and deploying policies throughout the organization,
- assessing and evaluating risks,
- defining and assessing controls,
- managing issues, and
- deploying and tracking an action plan and report.

The difference between proactive and reactive can be attributed to the fact that the same technology framework is being extended to the scenario wherein the health care organization enters into a CIA. Health care organizations do not have to feel apprehensive about independent audit reviews if they already have an effective internal audit program in place, supported by the right technology. Real-time reports and dashboards that give a complete view of the progress of compliance activities to the chief compliance officer are another important aspect that can help health care organizations

comply with CIAs. Access to data and documents on a need-to-know basis is critical for health care providers who are making attempts to comply with CIAs and other regulations, and this requires support by effective IT systems. Technology should also enable real-time integration with external regulatory measures to keep track of changes in regulations and obtain fraud alerts. It is important that the entire process of compliance management is supported by a work flow system.

Typically, a CIA lasts for a minimum duration of four years. What happens after that? It is important for health care organizations to extend their compliance programs to meet other regulatory requirements. Although complying with the CIA is important, health care organizations should increasingly move towards a proactive and integrated approach in managing their governance, risk, and compliance programs supported by the right technology framework. ■

1 OIG FY 2000 Work Plan-http/oig.hhs.gov/wrkpln/index.htm
2 OIG 2006 Work Plan-http/oig.hhs.gov/wrkpln/index.htm

People On the Move

Received a promotion? Have a new hire in your department?

Send your job change information to:

margaret.dragon@hcca-info.org

Beginning on June 1, 2011, the law offices of Deborah Randall, Esq. will be relocated to 1391 Penn. Ave. SE, #527 Washington, DC 20003. E-Mail: drandall.solutions@comcast.net; Tel: 202-257-7073

HCCA'S UPCOMING 2011 REGIONAL CONFERENCES

HCCA's regional one-day conferences provide high-quality, convenient, inexpensive education and networking opportunities. Don't miss the opportunity to attend one in your area!

NEW ENGLAND
September 9, 2011
Boston, MA

UPPER MIDWEST
September 16, 2011
Minneapolis, MN

MIDWEST
September 23, 2011
Overland Park, KS

NORTH CENTRAL
October 3, 2011
Indianapolis, IN

EAST CENTRAL
October 14, 2011
Pittsburgh, PA

HAWAII
October 21, 2011
Honolulu, HI

MOUNTAIN
October 28, 2011
Denver, CO

MID CENTRAL
November 4, 2011
Louisville, KY

DESERT SOUTHWEST
November 18, 2011
Scottsdale, AZ

SOUTH CENTRAL
December 2, 2011
Nashville, TN

LEARN MORE AND REGISTER AT
WWW.HCCA-INFO.ORG

Health Care Compliance Association
6500 Barrie Road, Suite 250
Minneapolis, MN 55435
888-580-8373 (p) | 952-988-0146 (f)
www.hcca-info.org

An interview with Diana Adams—HCCA's own Regional Conference groupie

Editor's note: We interviewed Diana Adams, a Consultant with RRA, Inc. located in Bedford, Texas (E-Mail: adamsrra@tx.rr.com) to learn why she attended five Regional Conferences in 2010. And here is what she told us.

Q: Diana, please tell us a little about yourself, your professional experience, as well as how and why you entered the compliance profession?

DA: I've been a Registered Health Information Administrator (RHIA) for the last 38 years, and for the last 18 years I have focused on physician and hospital coding and documentation compliance through auditing. In other words, not the typical person with my type of degree that often is found in hospitals. I opened the door of opportunity many years ago and went into compliance auditing before it was the "in" thing. HCCA was the best choice for me in the world of Compliance, because it keeps me in touch with the activities of the "real" world when it comes to compliance—the good and bad.

Q: It's come to our attention that you attended five HCCA Regional Conferences in 2010! That is terrific! Please tell us why you decided to go to multiple HCCA Regional Conferences.

DA: My decisions were based mostly on where I have clients. That is how I chose the following: Southeast Regional Conference in Georgia, South Atlantic Regional Conference in Florida, the Upper North Central Regional Conference in Ohio, and the Pacific Northwest Regional Conference in Washington. My decision to attend the Alaska Regional Conference was based on the fact that I have done work for the Indian Health organizations in the northwest and well, I thought it would be "cool" to go Alaska in the winter. And getting there is always an interesting challenge, but it has been well worth the travel.

It should be noted that I have always attended my local Regional Conference, the Southwest Regional in Texas. But in 2010, I decided that I needed to venture out to see what the other Regional Conferences were doing and reap the local atmosphere of health care compliance. Learning processes, gaining an insight into auditing, as well as expanding my horizons in the world of Compliance has always been a goal of mine.

Q: What made you select the five HCCA Regional Conferences that you attended—agenda, geography?

DA: Besides having clients, the program agenda is an added benefit to attending these Regional Conferences. Often, when one goes to the national conference [Compliance Institute], you don't get a chance to attend all the sessions that you would like because of time and sessions being scheduled at the same time. With Regional Conferences, one gets the opportunity to hear from a variety of speakers in the region and to network with those attending on that local basis. You gain perspective on what is actually going on with hospitals on a real time basis and thus, you also learn how the "locals" approach their issues and handle the situations.

Q: What benefits did you derive from attending five HCCA's Regional Conferences?

DA: I would have to say that for 2010, one of the best sessions was at the Southeast Regional in Georgia. It was a panel discussion that included RAC [Recovery Audit Contractor] issues, and one of the speakers was from CMS' Zone Program Integrity Contractors (ZPICs). He had all of us concerned as he addressed their biggest issue for auditing, which was identity theft in health care. We were shocked when he told us of a case that broke in the news earlier this year. It

Continued on page 56

 ...continued from page 55

truly made you aware of how fraud and abuse can come at you from all areas, even with patients who sell their Medicare numbers or those individuals who hack into computer systems from "old garages" in the south. In other words, it does not have to be a fancy system or fancy building, and if someone wants your information, they can mostly likely get it.

The Alaska conference has a speaker whose background is in computer security with the government and private agencies. He is just an amazing speaker. He always makes one think, "Am I safe with what I have?" "Is my computer system free from hackers?" Most likely not, as security is an issue that truly needs more research, and internally is often overlooked by all entities. We just think that we are safe, but actually checking our systems is a must.

I feel the program agendas for the Regional Conferences are often overlooked, and they should not be, especially if the national conference cannot be attended. Regional conferences are truly economical and have a lot to offer; plus, being able to network locally is always a benefit. The HCCA regional coordinators (and Beckie, the Conference Coordinator) put a lot of effort into these conference agendas, and I consider these meetings to be the diamond in the rough.

Q: Have you attended HCCA's Regional Conferences in the past, before 2010, and if so, why?

DA: I first began attending the Southwest Regional in Texas. The program is always good and includes many Department of Justice agents as speakers. Hearing the DOJ agents speak helps you learn for yourself how the inner working of the compliance due process is handled from their point of view.

Next, I expanded to the North Central conference in Indiana, because that year the agenda included the RAC for that area of the country. How they (the RAC) introduced themselves to the audience was interesting, because they went one-on-one to personally introduce who they were to the audience members prior to their presentation. Imagine meeting the owner, the coding compliance person, and the medical director up close and personal. It sticks with you when you hear the RAC owner say "We are a business and we will not go after anything that has the opportunity of being overturned; we will review and pick the areas of concern carefully."

Also, I enjoyed the one in Texas one year where the topic of "low hanging fruit" was discussed. I see a lot of that in my own auditing experience and actually have used that phrase every now and then, when I am doing my client educational sessions.

Q: Is there a specific value you gain in attending HCCA Regional Conferences?

DA: In addition to what I've previously mentioned is knowledge and growth in a field that is continuing to expand. Staying updated on what is happening keeps you on your toes and allows you to see the bigger picture in the world of compliance vs. fraud.

Q: Do you recommend HCCA's Regional Conferences to other compliance professionals, and if "yes" what do you tell them?

DA: I have often told others to attend HCCA's Regional Conferences because they can't miss out on the "local news" so to speak. Plus, the opportunity to network on a local level, not only with attendees but with the speakers, means growth in your work world. Take the initiative and check out the program agenda for your local area. You will not be disappointed.

Q: Are there other HCCA Conferences you attend regularly, and if "yes," why?

DA: The National conference when I can (I have for the past 3 years), and I also have attended the joint conference with the AHLA that is held every September or October in Baltimore and then the Regional Conferences I've mentioned. One has to stay aware of all the aspects of compliance. (Hmmm, I keep saying that don't I? But that is true.) If you don't know the answer

Continued on page 73

Employed physician compensation: Expense or investment?

By Darcy Devine, AVA, AIBA

Editor's note: Darcy Devine is a Principal with the consulting and accounting firm GatesMoore in Atlanta. She specializes in the valuation of health care assets and physician services, focusing on physician and hospital transactions and financial arrangements. She may be contacted by e-mail at ddevine@gatesmoore.com.

A common assignment for a health care valuation consultant is to review a proposed employment agreement between a hospital (employer) and a physician (employee) and determine whether the compensation described in the agreement is consistent with fair market value (FMV). In addition to reviewing the agreement from an FMV perspective, valuation consultants are often asked to assess whether the proposed arrangement is commercially reasonable.

These reviews are very important components of a hospital's compliance efforts. Hospitals are employing physicians on an ever-increasing basis. The Stark laws require that the compensation hospitals pay to employed physicians is FMV and is part of a commercially reasonable agreement. These are separate and distinct determinations for the valuation consultant to make, because employment compensation that meets the FMV standard may not necessarily be part of a commercially reasonable agreement, and vice versa.

Determining the FMV of a physician's services presents its own challenges, but there appears to be even more uncertainty and inconsistency in the health care valuation industry related to commercial reasonableness opinions. Part of the challenge is the limited guidance that has been provided by the Centers for Medicare and Medicaid Services (CMS) regarding the definition of "commercially reasonable" and what constitutes a commercially reasonable arrangement for physician services. Below is a summary of the guidance that appears in the Stark regulations:

- We are interpreting "commercially reasonable" to mean that an arrangement appears to be a sensible, prudent business agreement from the perspective of the particular parties involved, even in the absence of any potential referrals.[1]
- With respect to determining what is "commercially reasonable," any reasonable method of valuation is acceptable, and the determination should be based upon the specific business in which the parties are involved, not business in general.[2]
- In the absence of referrals, an arrangement will be considered "commercially reasonable" if the arrangement would make commercial sense when entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.[3]

In the absence of a safe harbor or universally accepted methodology, the valuation consultant—using generally accepted approaches to valuation—must find a logical approach to determine what is commercially reasonable and then support his/her findings (See box on page 58). A good starting point when reviewing a physician employment arrangement is to find out the purpose of the arrangement (i.e., Why is the physician being employed?) and evaluate the commercial reasonableness of the arrangement with that purpose in mind.

Continued on page 58

As a financial investment

For example, one way to determine commercial reasonableness is to look at a physician employment arrangement as a financial investment and decide whether or not, in the absence of referrals, it is a good one. This approach works if the primary purpose of the arrangement is to produce financial returns for the hospital employer. In this scenario, benefits from the arrangement must exceed costs for a "go" versus a "no go" investment decision. The analysis consists of projecting professional collections, operating expenses, and physician expenses and then determining whether the professional services of the physician generate positive cash flows for the hospital. It is easy to argue that a rate of return in excess of the hospital's minimum acceptable return on an investment (i.e., its hurdle rate) would make the employment arrangement commercially reasonable.

The problem with this approach is that market research data indicate that the "profitable" hospital-owned physician practice is a rarity. Survey reports published by the Medical Group Management Association (MGMA) show that the median net income/loss for a hospital-owned family practice is a loss of $124,807 per full time (FTE) physician. For hospital-owned internal medicine practices, the median loss is $219,959 per FTE physician; for hospital-owned multi-specialty practices, the median loss is $190,626 per FTE physician. Considering this data alone, hospitals should not expect meaningful financial returns when employing physicians. Understandably, it is difficult to prove that these arrangements are commercially reasonable when analyzing them from a purely financial investment perspective.[4,5]

Generally accepted approaches to valuation

Cost approach. A general way of determining a value indication of an individual asset by quantifying the amount of money required to replace the future service capability of that asset.

Income (income-based) approach. A general way of determining a value indication of a business, business ownership interest, security, or intangible asset using one or more methods that convert anticipated economic benefits into a present single amount.

Market (market-based) approach. A general way of determining a value indication of a business, business ownership interest, security, or intangible asset by using one or more methods that compare the subject to similar businesses, business ownership interests, securities, or intangible assets that have been sold.

Source:
BV Resources, International Glossary of Business Valuation Terms

As a necessary expense

A second way to determine commercial reasonableness is to look at a physician employment arrangement and determine whether or not it constitutes a good and necessary expense for the hospital. This approach is especially appropriate if the rationale for the employment arrangement is that it helps the hospital meet the IRS's community benefit standard for tax-exempt status or maintain compliance with other laws. An argument can be made that the employment arrangement, viewed as an expense, makes commercial sense and is a necessary cost of doing business, if the arrangement accomplishes one of these goals at a cost that is less than or consistent with other alternatives (e.g., entering into professional services arrangements with private practice physicians or recruiting new physicians to a start-up practice).

For example, the Patient Protection and Affordable Care Act (PPACA), enacted in 2010, requires that tax-exempt hospitals conduct a community health needs assessment (CHNA) every three years and adopt an

implementation strategy to meet the identified community health needs.[6] These assessments will likely need to identify any community shortages of primary care physicians and specialists who accept Medicare, Medicaid, and uninsured patients and find solutions for addressing those shortages. Accordingly, fair market value compensation paid to a physician under a hospital employment arrangement may also be commercially reasonable—even if the physician's medical practice generates a financial loss—if that arrangement helps secure or improve access to care for the Medicare, Medicaid, and uninsured populations. This may also be true for situations in which an existing non-employed physician (1) is a roadblock to recruitment in his/her specialty, (2) won't participate in succession planning for his/her practice, and/or (3) will not cooperate with hospital initiatives (such as quality reporting, etc.). In these situations, it may be commercially reasonable to employ the physician (assuming that he/she will comply as a result of employment), even though the medical practice won't generate a profit.

In any of these situations, providing a description of community benefits stemming from the physician employment arrangement and any uncompensated care the employed physician provides in its CHNA could be instrumental in the hospital's efforts to maintain a tax-exempt status and could show that the arrangement is a commercially reasonable expense. Supporting documentation for the commercial reasonableness review would include analyses of the external market factors (e.g., a national or regional physician shortage, physician compensation benchmarks, recruitment offers being made to comparable physicians) that help defend the amount of compensation paid to the employed physician and show that more cost efficient alternatives were not readily available.

Another example of a physician employment arrangement that may be commercially reasonable (from the expense perspective, not the financial investment perspective) is one that does not produce a profit (from a medical practice standpoint), but does help the hospital-employer comply with the Emergency Medical Treatment and Active Labor Act (EMTALA). It stands to reason that if an employed physician's professional services generate a loss for the medical practice, his employment arrangement could still be considered commercially reasonable, if his employment resulted in emergency coverage for a new specialty and/or reduced on-call payments to independent contractors by a substantial amount. Further evidence of commercial reasonableness would include data showing that the quality, consistency, and/or reliability of call coverage improved because of the employment arrangement.

Conclusion

The commercial reasonableness of a hospital/physician employment arrangement can be determined from at least two different points of view: one in which the arrangement is viewed as a financial investment or one in which it is viewed as an expense. If the arrangement is viewed as a financial investment, it would need to produce some minimum rate of return to be deemed commercially reasonable. If the arrangement is viewed as an expense or a cost of doing business, it would need to be proven necessary and would need to be comparably priced or less costly than acceptable alternatives to be considered commercially reasonable.

These are just two examples of ways in which health care valuation consultants can assess commercial reasonableness. Furthermore, as previously noted, CMS has indicated that any reasonable method of valuation is acceptable, thus implying that there are many other valid approaches, including those that seek to quantify the value of the community benefit (such as increased access to quality care) that can come from

Continued on page 60

CCB The Compliance Professional's Certification

The Compliance Certification Board (CCB) compliance certification examinations are available in all 50 states. Join your peers and demonstrate your compliance knowledge by becoming certified today.

Congratulations!! The following individuals have recently successfully completed the CHC® certification exam, earning their certification:

Nadine Alliance
Donna Viladesau Angiulo
Lisa Badie
Kimberly A. Bailot
Karen Baxter
Jenny M. Bernhard
Kimberly R. Boyett
Timothy M. Brown
Pamela Brunner
Teressa Campbell
Cheri L. Caraway
Katrina J. Church
Annette R. Ciavarella
Angela J. Cox
Carlos A. Cruz
James Alexander Donaldson
Vicki L. Dwyer
Karen M. Eastmond
Larry W. Field
Suzanne M. Forrest
Margaret E. Fortin
Richard Michael Garpiel
Paul H. Gleis
Larry J. Goldberg
Janet Green
Bonnie M. Groneberg
Keith J. Halleland
Teresa J. Hernandez
Susanne Hiland
Laura A. Jarrett
Rasma B. Kancs
Martha A. Knutson
Carrie E. Kusserow
Sherry L. Lawson
Rhonda L. Longo
Kelly S. Martinelli
Philip J. Masser
Minerva L. Mendoza
Michael J. Miller
Denise M. Mitchell
Vikram K. Mohan
Mark T. Morrell
Nancy A. Mundy
Nancy A. Odeh
Barbara A. O'Neill
Eva K. Osur
Nike Otuyelu
Ralph N. Parish
Deborah L. Payne
Ronald J. Peterson
Gary W. Portman
Mary G. Ptacek
Sheri L. Rees
Lisa A. Reese
Scott A. Reitz
Sybil M. Richard
Regina A. Richard
Cindy J. Richards
Pam G. Roberts
George M. Rousis
Michelle F. Rush
Nancy A. Schallert
Katie A. Shigemitsu
Peggy I. Siebert
Carol E. Smith
Kristy L. Spruell
Christine Maria Thomas
Whitney W. Tolbert
Christy D. Warner
Kathleen E. White
Jane L. Wingquist
Annette L. Zerbe

Congratulations!! The following individual has recently successfully completed the CHRC® certification exam, earning his certification:

Jason D. Mckinney

Congratulations!! The following individuals have recently successfully completed the CHPC® certification exam, earning their certification:

Sharon M. Anderson
Cathleen C. Armato
Theresa M Bervell
Karla B. Dreisbach
Catherine B. Dutreil
Kimberly D. Easley
Matt Frederickson
Robert J. Johnston
Juliet H. Lane
Craig Lewis
Marie Moseley
Lisa E. Oswald
Brian J. Rappe
Barbara A. Skane
Thomas Mark Spinelli
Cheryl A. Wasserman
Amanda L. Yoh

For more information about certification, please call 888/580-8373, email ccb@hcca-info.org, or visit our website at www.hcca-info.org.

Employed physician compensation: Expense or investment?

...continued from page 59

hospital/physician employment arrangements. Regardless of the approach used, a commercial reasonableness analysis requires an understanding of the purpose of the arrangement being reviewed; acknowledgement of the relevant facts and circumstances of the situation; and an appreciation of the unique requirements and needs of the hospital, the physician, and the community involved. ■

1 Federal Register / Vol. 63, No. 6 / Friday, January 9, 1998 / Proposed Rules
2 Federal Register / Vol. 66, No. 3 / Thursday, January 4, 2001 / Rules and Regulations
3 Federal Register / Vol. 69, No. 59 / Friday, March 26, 2004 / Rules and Regulations
4 Medical Group Management Association, Cost Survey for Single-Specialty Practices: 2010 Report Based on 2009 Data
5 Medical Group Management Association, Cost Survey for Multi-Specialty Practices: 2010 Report Based on 2009 Data
6 U.S. House of Representatives, 111th Congress, 2d Session PRINT 111–1, Compilation of Patient Protection and Affordable Care Act, U.S. House of Representatives, May 2010

HCCA has stepped up our environmental responsibility by printing **Compliance Today** on recycled paper. The interior pages are now printed on paper manufactured with 100% post-consumer waste. The cover stock is made up of 10% post-consumer waste and is locally produced in Minnesota near our printing facility. In addition, the energy used to produce the paper is 100% renewable energy. This is not to mention that the ink used in our magazine is 100% soy based water soluble inks. Certifications for the paper include The Forest Stewardship Council (FSC), Sustainable Forestry Initiative (SFI), and Green-e.org.

Pharmaceutical and device manufacturers: Sales and marketing laws

By Stephanie L. Trunk, Esq.

Editor's note: Stephanie Trunk is an attorney with Arent Fox LLP in Washington DC. She may be contacted by email at trunk.stephanie@arentfox.com.

As long as manufacturers have been producing drugs and devices, their sales representatives have been seeking innovative ways to market such products to physicians and other prescribers. Not all manufacturer sales and marketing techniques are untoward or problematic, but some practices have been viewed as detrimental to patient care, and to the medical profession in general, particularly when they involve personal financial benefits to physicians or prescribers. Such questionable practices include: (1) the provision of a fancy lunch to a physician by a manufacturer's sales representative; (2) a lucrative speaker relationship between a physician and a device manufacturer pursuant to which he/she is paid handsomely for speaking about the manufacturer's device; or (3) the furnishing of a research grant by a pharmaceutical manufacturer to a teaching hospital to study a potential new drug.

Whether such practices really do have an effect on patient care or cloud a physician's sound clinical judgment, it is clear that federal and state legislatures perceive such financial relationships between pharmaceutical and device manufacturers and physicians and other health care practitioners as problematic or as potential conflicts of interest. The legislatures have responded by passing federal and states laws that mandate reporting of such relationships (i.e., transparency laws) and placing limitations on the sales and marketing practices of pharmaceutical and device manufacturers (i.e., gift laws). This article provides an overview of federal and state transparency and gift laws applicable to pharmaceutical and device manufacturers and highlights some practical considerations for manufacturers in complying with these laws.

Transparency under the Affordable Care Act

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (PPACA)[1] into law. Subsequently, Congress passed the Health Care Education Affordability and Reconciliation Act that contains a negotiated set of proposed changes to PPACA, which was signed into law by President Obama on March 30, 2010 (the Reconciliation Act).[2] PPACA and the Reconciliation Act are collectively referred to as the Affordable Care Act (ACA). Pursuant to Section 6002 of the ACA, drug, device, biological, and medical supply manufacturers will be required to electronically report certain payments or transfers of value made to a physician and/or a teaching hospital, starting on March 31, 2013 and on the 90th day of each year thereafter.

Reports must include in-kind items or services; stock, options, or any other ownership or investment interests in a publicly traded security; or any other form of payment or transfer of value held by a physician or his/her immediate family. Transfers of value may include:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gifts, entertainment, or food

Continued on page 62

 ...continued from page 61

- Travel (including the specified destination)
- Education
- Research
- Charitable contributions
- Royalty or license fees
- Current or prospective ownership or investment interests
- Direct compensation for serving as faculty or as a speaker for a medical education program
- Grants
- Other types of payment or transfers of value defined by the Secretary of the federal Department of Health and Human Services

The following payments or transfers of value are excluded from the reporting requirements:

- Gifts under $10 (as long as aggregate compensation to a physician or hospital during the year is less than $100 in total)
- Product samples
- Educational materials
- A device provided for a trial period of less than 90 days
- A transfer of anything of value if the recipient is a patient
- Discounts
- In-kind items for charity care
- A dividend or other profit distribution

Manufacturers can be fined up to $150,000 in penalties for noncompliance with the reporting obligations set forth in Section 6002 of the ACA and up to $1 million for knowingly failing to report. Reports will be publicly available on a searchable website by September 30, 2013 and on June 30 of each subsequent calendar year, and will include any enforcement actions taken against manufacturers related to the reporting obligations.

Duplicative state transparency laws will be preempted by the federal transparency law set forth in Section 6002 of the ACA. However, federal preemption will not apply to state laws that reach beyond the scope of the reporting requirements set forth in Section 6002, including more robust state transparency laws and state gift laws that impose restrictions or limitations on the sales and marketing practices of pharmaceutical and device manufacturers.[3]

State transparency laws

Currently, five states (Maine, Massachusetts, Minnesota, Vermont and West Virginia) and the District of Columbia mandate reporting of payments or transfers of value from pharmaceutical manufacturers to physicians, hospitals and other health care practitioners. Of these six laws, two (Massachusetts and Vermont) also specifically apply to device manufacturers.

In the District of Columbia, manufacturers and labelers of prescription drugs who use marketing representatives must report advertising, marketing, and direct promotion costs annually to the District's Department of Health.[4] For each category of reportable costs, the value, nature, purpose, and recipient of the expenditure must be detailed. The statute requires the reporting of the following costs/expenses with respect to health care professionals licensed in the District and their staffs, as well as licensed health care facilities, pharmacies, and health plans: (1) costs of company-sponsored educational and informational sessions, (2) food, entertainment, travel, and gifts valued at $25 or more, (3) anything provided to a health care practitioner for less than fair market value, (4) health care practitioner travel costs, and (5) drug samples (unless provided exclusively for patient use). The implementing regulations add consulting fees to the list of expenditures that must be reported. The report need not include bona fide clinical trial activities and certain scholarship expenses.[5] The report must be filed with the Department of Health by July 1 of each year. The District of Columbia imposes an annual fee of $2,500 on each filer.

In addition to the foregoing, the District of Columbia requires pharmaceutical manufacturers to report public advertising expenses "as they pertain to the District," including the cost of advertisements on radio, on television, and

in newspapers and the aggregate cost of all "employees or contractors [who] . . . engage in advertising or promotional activities" in the District.

Under the Maine law, a pharmaceutical manufacturer or labeler that distributes prescription drugs for dispensation to residents of Maine and employs, directs or utilizes marketing representatives in Maine must file a report detailing marketing costs of the manufacturer or labeler.[6] Each report, due by July 1, must include the total expenses from the previous calendar year. A $1,000 annual fee is imposed on each filer. Reportable expenses include: (1) all expenses associated with advertising, marketing and the direct promotion of prescription drugs through radio, television, magazine, newspaper, direct mail, and telephone communications directed at Maine residents (national and regional campaigns are excluded); (2) expenses associated with educational and informational programs and trips and travel for medical professionals; (3) food, entertainment, and gifts valued at more than $25 for medical professionals; (4) cost of trips and travel provided to licensed health professionals or entities; (5) product samples (not including those samples to be provided to patients); (6) costs of free or in-kind services provided; and (7) the cost of employees and contractors engaged in advertising activities in the state or directed to state residents.

In addition to the sales and marketing reporting requirements set forth above, under Maine law a manufacturer or labeler must also publicly disclose information on its clinical trials of prescription drugs.[7] Under the statute, the disclosed information must include the name of the entity conducting the trial, the purpose of the trial, the dates of the trial, and the results of the trial.

Under the Massachusetts law, drug and device manufacturers are required to file annual reports with the Department of Public Health by July 1 of each year, covering activity in the prior calendar year.[8] Manufacturers are required to report all economic benefits of at least $50 in value which have been provided directly or indirectly to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner, or other person in the state who is authorized to prescribe, dispense, or purchase prescription drugs and devices. The State imposes a $2,000 filing fee on each filer, which must accompany the annual report.

In Vermont, pharmaceutical and device manufacturers are required to file an annual report with the Attorney General by October 1 of each year covering activity in the previous 12-month period from July 1-June 30.[9] The report must include the value, nature, purpose and recipient of all gifts and allowable expenditures made to health care providers in Vermont. The statute excludes the following from the disclosure requirements: (1) royalties and licensing fees, (2) rebates and discounts, (3) payment for clinical trial; and (4) samples of a prescription drug provided to a health care professional for free distribution to patients. In addition to the foregoing, the Vermont annual report must include the name and address of the person at the pharmaceutical or device manufacturer who is responsible for ensuring compliance with this law.

In 2004, West Virginia law created the West Virginia Pharmaceutical Cost Management Council (the Council) and required all pharmaceutical manufacturers and labelers of prescription drugs dispensed in West Virginia that employ, direct, or utilize marketing representatives to report their advertising costs to the Council annually.[10] Under regulations implementing the West Virginia transparency law, annual reports are due to the Council by April 1 of each year and must cover reportable expenses incurred during the preceding calendar year.[11] The following must be

Continued on page 64

 ...continued from page 63

included in each annual report: (1) the aggregate amount of gifts, grants and payments furnished to prescribers for the purpose of advertising prescription drugs; (2) a list of all drugs advertised using direct-to-consumer (DTC) advertising that reaches West Virginia, together with the total expenditure by the company on such DTC advertising that targets West Virginia; (3) a list of payments greater than $10,000 per year made for the purpose of advertising prescription drugs to disease-specific patient support or advocacy groups that operate in West Virginia; and (4) a list of all advertising programs with or involving pharmacies with expenditures greater than $10,000 per year.

State laws imposing gift limits

Currently, five states (California, Connecticut, Massachusetts, Minnesota, and Vermont) and the District of Columbia impose restrictions or limitations on the sales and marketing practices of pharmaceutical manufacturers. Of these six laws, four (California, Connecticut, Massachusetts and Vermont) also specifically apply to device manufacturers.

The California and Connecticut gift laws establish limitations on the provisions of gifts, meals, payments, and transfers of value from pharmaceutical and device manufacturers to physicians and other health care practitioners consistent with the PhRMA and/or AdvaMed Codes.[12] Notably, the California gift law also requires manufacturers to specify an annual aggregate limit on gifts, promotional materials, and other items that the manufacturer may otherwise provide to an individual physician or health care practitioner.

Pursuant to District of Columbia law, pharmaceutical companies are prohibited from offering gifts or remuneration of any kind to a member of a medication advisory committee that is responsible for making recommendations or decisions regarding a formulary to be used by a health program administered by the government of the District of Columbia.[13] There is a $1,000 fine per violation of this prohibition. The prohibition does not extend to the provision of drug samples provided to members of a medication advisory committee who are licensed physicians engaged in the practice of medicine.

The Massachusetts gift law and its implementing regulations prohibit pharmaceutical and device manufacturers from providing to physicians or other health care practitioners: (1) meals that are not provided as part of an information presentation given at the health practitioner's office or in a hospital setting; (2) entertainment or recreational items of any value; (3) financial support related to attendance at continuing medical education events or other professional meetings; (4) cash or cash equivalent payments not being made as compensation for bona fide services; and (5) any form of financial support (e.g., grants, scholarships, consulting work, etc.) in exchange for prescribing prescription drugs.[14] In addition, the regulations add that even when meals are provided in an otherwise compliant manner, those meals still must be "modest and occasional in nature." Every transaction that violates the Massachusetts gift law is punishable by a fine of up to $5,000.

Minnesota law generally prohibits a pharmaceutical manufacturer from providing gifts, including meals, of any value to a physician or other prescriber.[15] The following items are explicitly excluded from the statutory definition of "gifts" and, therefore, are allowable: (1) drug samples provided for distribution to patients; (2) payments to sponsors of medical conferences, professional meetings, and other education programs (provided the payment is not made directly to a health care practitioner); (3) "reasonable honoraria" for professional conference faculty members; (4) compensation for "substantial professional or consulting services;" (5) publications and educational materials; and (6) employee benefits and salaries. Furthermore, other items of value, including

modest meals, may be provided to a health care practitioner as long as the total retail value of the items provided does not exceed $50 in a calendar year.

The Vermont gift law generally prohibits pharmaceutical and device manufacturers from offering or giving any gift to a health care provider.[16] "Gift" is defined as "anything of value provided to a health care provider for free [or] any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider." The Vermont gift law allows gifts that fall into one of the following narrow "allowable expenditures" categories: (1) indirect payments to the sponsor of an educational, medical, scientific or policy-making conference, as long as the program content is free from industry control and does not promote specific products; (2) honoraria to faculty at a "significant" conference or seminar, as long as the faculty and manufacturer enter a specific type of contract and the content of the presentation is determined by the faculty; (3) bona fide clinical trial gross compensation, direct salary support, and expenses paid for review of the clinical trial; (4) expenses associated with specified research projects; (5) royalties and licensing fees paid in return for contractual rights to patented materials; and (6) "other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value." If a manufacturer violates the gift ban, the state may impose a civil penalty of up to $10,000 per violation. The attorney general also may seek injunctive relief, costs, and attorney's fees from the manufacturer.

Other state laws

In addition to state transparency and gift laws, there are also several states which mandate that drug and device manufacturers implement compliance programs that comply with the OIG Guidance for Pharmaceutical Manufacturers and the PhRMA and/or AdvaMed Codes.[17] Also of note, several states require sales representatives who engage in the practice of "detailing" physicians and health care practitioners to be licensed by or registered with the state.[18]

Practical considerations

In order to comply with state and federal transparency laws, pharmaceutical and device manufacturers must ensure that they have in place accounting systems capable of tracking relationships with individual physicians and other prescribers. The accounting systems must be able to track each individual physician/health care practitioner, each type of expenditure (i.e., gift, consulting fee, etc.), and must be able to pull data from different sources. For instance, most gifts and meals to physicians and other prescribers are likely to be identified in sales representative expense reports, but research grants are most likely recorded as general entries to accounts payable and supported by written contracts. In addition, manufacturer accounting systems must be flexible and capable of querying by type of expenditure/relationship in order to generate different reports to meet the varying requirements under state and federal transparency laws. Although some state transparency laws will be preempted by the federal transparency law under the Affordable Care Act, beginning in 2013, more robust state transparency laws are not preempted. In addition, manufacturers must be able to comply with all state transparency laws until 2013. Also, the Affordable Care Act will not preempt state laws imposing aggregate spending limits, such as the California law, and manufacturer's accounting systems must be able to track spending by physician/prescriber in comparison to the annual aggregate spending limit per physician/prescriber set by the manufacturer and/or applicable law. The system should alert users when the limit is reached.

Because federal and state transparency laws have different reporting time frames and requirements, manufacturers should charge a department or individual with

Continued on page 66

Pharmaceutical and device manufacturers: Sales and marketing laws

...continued from page 65

responsibility for timely and accurate reporting. Practically, a member of the manufacturer's Accounting department, with assistance from the Compliance and Legal departments as needed, is probably in the best position to produce the reports and ensure compliance with applicable legal requirements.

Because many state gift laws impose restrictions on the sales and marketing practices of pharmaceutical and device manufacturers and impose fines and penalties on manufacturers for non-compliance, robust oversight of sales representatives, particularly contract sales representatives, is imperative. First, manufacturers should properly train sales representatives on applicable state transparency and gift laws at regular intervals. For instance, any sales representatives who may call on a physician/prescriber in Vermont must be trained that the provision of gifts and meals to physicians/prescribers in Vermont is prohibited by state law, subject to limited exceptions. Because state laws that impose restrictions on sales and marketing practices are rapidly evolving, it is suggested the manufacturers train sales representatives more frequently than annually, perhaps through quarterly or monthly reminders and updates. Policies and procedures should be regularly reviewed and updated to reflect sales and marketing practice limitations set forth in state gift laws. The conduct of sales representatives, including contract sales representatives, should be regularly monitored through expense report audits, ride alongs, physician/prescriber surveys, and other various monitoring and auditing techniques. Sales representatives who violate sales and marketing limitations imposed by state gift laws should be properly, swiftly, and consistently disciplined. ■

1. The Patient Protection and Affordable Care Act, Pub. Law No. 111-148, 124 Stat. 119 (2010).
2. The Health Care Education Affordability Reconciliation Act, Pub. Law No. 111-152, 124 Stat. 1029 (2010).
3. PPACA § 6002.
4. District of Columbia Code §§ 48-833.01-48833.09.
5. 22 District of Columbia. Regs § 1800 et seq.
6. 22 Maine Rev .Stat. Ann. § 2698-A.
7. 22 Maine Rev. Stat. Ann. § 2700-A.
8. Massachusetts General Laws, ch. 1111N §§ 1-7; 105 Massachusetts Code Regs. §§ 970.000-970.101.
9. 18 Vermont Stat. Ann. § 4632.
10. West Virginia Code §§ 5A-3C-8 and 5A-3C-13.
11. Legislative Rule – Prescription Drug Advertising Expense Reporting, West Virginia Code Regs. § 206
12. California. Health & Safety Code § 119402; Connecticut Public Act No 10-117 § 94.
13. District of Columbia Code § 48-842.03.
14. Massachusetts General Laws, ch. 111N and 105 Massachusetts Code Regs. §§ 970.000-971.101.
15. Minnesota. Statute. § 151.461; FAQ on Gifts to Practitioners produced by the Board of Pharmacy, available at http://www.phcy-brd.state.mn.us/forms/giftsfaq.pdf.
16. 18 Vermont. Statute. Ann. § 4631a and 4632.
17. See Connecticut Public Act No 10-117 § 94; Massachusetts General Laws, ch. 111N; Nevada Revised Stat. § 639.100 et al.
18. District of Columbia Code § 3-1207.14. See also Louisiana Board of Ethics, Ethics Board Docket No. 2005-560a, January 17, 2006, which requires pharmaceutical sales representatives who meet with members of a Medicaid Pharmaceutical and Therapeutics Committee to register as lobbyists.

Data mining result raises coding concerns

By Gloryanne Bryant, RHIA, CCS, CCDS and Donna Wilson, RHIA, CCS, CCDS

Editor's note: Gloryanne Bryant is Managing Director HIM Revenue Cycle, NCAL Kaiser Permanente in Oakland, California. Gloryanne may be contacted by e-mail at Gloryanne.h.bryant@kp.org.

Donna Wilson is a Senior Director at Compliance Concepts, Inc. in Wexford, Pennsylvania. Donna can be contacted by e-mail at dwilson@ccius.com.

A new compliance issue comes to light with the *San Francisco Chronicle* and California Watch[1] on February 19, 2011 in an article titled "Hospital chain, already under scrutiny, reports high malnutrition rates."[2] This article discusses California state data of malnutrition represented with ICD-9-CM code 260 Kwashiorkor and hospitals with high frequencies of this code/condition within their inpatient population. With regard to the impact on the payment for Medicare Part A (Fee for Service) patients, the article stated that:

> [I]n 2009, Shasta Regional Medical Center in Redding reported that 16.1 percent of its Medicare patients 65 and older suffered from kwashiorkor, according to a California Watch analysis of state health data. That's 70 times the state average of 0.2 percent. At Desert Valley Hospital in Victorville, the kwashiorkor rate among Medicare patients also was high: 9.1 percent, or about 39 times the state average. Both hospitals are owned by Prime Healthcare Services, a Southern California chain. Concerns were raised by coding staff [employees] to their union representatives, which resulted in further scrutiny.

Malnutrition has always been a bit of a challenge from a coding perspective. Understanding the clinical aspects and indications of a diagnosis or condition are part of the basic coding competencies for accurate coding and reimbursement. Malnutrition is a condition that occurs when a person's body is not getting enough nutrients. The condition may result from an inadequate or unbalanced diet, digestive difficulties, absorption problems, or other medical conditions. Malnutrition may be mild enough to show no symptoms. In some cases, however, it may be so severe that the damage done is irreversible, even though the individual survives. Worldwide, malnutrition continues to be a significant problem, especially among children who cannot fend adequately for themselves. Often we see malnutrition in patients who have liver disease, alcoholism, hepatitis, or chronic and systemic diagnoses such as cachexia (i.e., weight loss, wasting of muscle, loss of appetite, and general debility that can occur during a chronic disease).

The ICD-9-CM separates malnutrition into several specific codes to capture the degree of malnutrition and specific types of malnutrition. The alpha index contains a list of specific subcategories for malnutrition; however, coding staff know they should not code from the alpha index alone, but rather from the tabular listing, and check the "includes and excludes" instructional notes. Also, from the alpha index you do not see the specific kwashiorkor malnutrition code description that has come into question recently.

On the following page are the classification categories for malnutrition within ICD-9-CM:

Continued on page 68

 ...continued from page 67

- 260 Kwashiorkor
- 261 Nutritional marasmus
- 262 Other severe protein-calorie malnutrition
- 263 Other and unspecified protein-calorie malnutrition

ICD-9-CM code 260 Kwashiorkor diagnosis represents nutritional edema with dyspigmentation of skin and hair. It is classified as a syndrome, particularly affecting children, characterized by excessive carbohydrate with inadequate protein intake, inhibited growth potential, anomalies in skin and hair pigmentation, edema, and liver disease. It is often seen in Third World countries. In some inpatient cases, a diagnosis of "protein malnutrition" may be documented by the physician, which would be assigned to code 260 Kwashiorkor; but is that really correct? Under Medicare-Severity DRGs Inpatient Prospective Payment System (IPPS), the ICD-9-CM code 260 is a major complication/comorbidity (MCC). Sometimes this is the only MCC in the patient's chart and it groups the case to a higher paying MS-DRG. There may be a problem with the terminology the physician is using to describe the malnutrition, and that needs further clarification. The term/diagnosis "protein malnutrition" indexes to code 260 Kwashiorkor, but "protein-caloric malnutrition" indexes to code 263.9, which is a complication/comorbidity (CC). Herein lies the compliance and payment concerns being raised of late.

Example: Hospital has a base rate of $6,000 for MS-DRG (669) Transurethral Procedure with CC (ICD-9-CM code 263.9) as the only CC. With the relative weight of 1.2597, the estimated reimbursement is $7,782.

Using "protein malnutrition" (ICD-9-CM code 260) as the only MCC results in MS-DRG (668) Transurethral Procedure with MCC. With the relative weight of 2.5175, the estimated reimbursement is $15,105.

According to the *San Francisco Chronicle* article:

> California Watch reported in October 2010 that authorities are investigating Prime hospitals to determine whether a reported cluster of septicemia infections in 2008 reflect a health care problem or a fraudulent billing practice known as upcoding."[2]

Upon deciphering the reasoning behind this "cluster of septicemia infections in 2008," one must first understand the dilemma that coders face today in the world of ICD-9-CM for coding the term urosepsis. There are two different codes for urosepsis:

- Urosepsis (localized infection), meaning urinary tract infection (599.0)
- Urosepsis (generalized infection), meaning septicemia-systemic infection (038.xx).

Urinary tract infections (UTI) can oftentimes be treated with antibiotics. Simple UTIs may include conditions such as pyelonephritis or cystitis. However, there are times when UTIs can lead to septicemia. Patients who are immunocompromised or elderly are more at risk for developing septicemia. A diagnosis of septicemia is associated with a systemic process of the infection, which means the infection has spread into the bloodstream.

Coders' confusion begins with the inconsistency in the documentation. Physician documentation may vary from day to day in the same patient's chart. For example, on Day 1, Dr. XYZ writes "urosepsis." On Day 2, Dr. ABC writes "sepsis." This inconsistency continues throughout the record without final clarification at the time of discharge. Clinical indications are used to try to better define the level of infection. The physicians may be unaware of the differences in the terms urosepsis and sepsis.

In 2000, The American Hospital Association (AHA) Coding Clinic™ published an issue on ICD-9-CM, outlining some of the clinical indications coders may reference when coding potential sepsis records. (Remember, this

is only a guide and the physician should be queried on any and all cases where the documentation is unclear or inconsistent!) The compliance and payment concerns around septicemia are as follows.

Example: Hospital has a base rate of $6,000. MS-DRG (690) Kidney & Urinary Tract Infections w/o MCC would be ICD-9-CM code 599.0. With the relative weight of 0.7864, the estimated reimbursement is $4,718.

Using "Sepsis" (ICD-9-CM code 038.xx) as the principal diagnosis results in MS-DRG (872) Septicemia or Severe Sepsis w/o Mechanical Ventilation 96+ Hours w/o MCC. With a relative weight of 1.1545, the estimated reimbursement is $6,927.

The saving grace for coders is coming in the form of ICD-10. With the new coding classification, effective October 1, 2013, the term urosepsis is nonexistent. Therefore, if your query forms are entitled "Sepsis/Urosepsis" consider eliminating the word "Urosepsis" and replacing it with "UTI" to get the physicians used to writing diagnoses that can be coded in the world of ICD-10.

Another area to be cautious of is electronic tools that physicians may utilize to help with diagnosis selection. Although electronic checklists or pick-lists can be useful and save time, there are several aspects that need closer consideration:

- The programming of these diagnosis lists should have the input and review of a coding professional who understands the classification system.
- Watch that the programming of these diagnosis lists is not missing all the choices of a particular condition (i.e., malnutrition). This may require the provider to make an additional "click" to obtain a drop-down choice, but it is worth it to obtain coding and data accuracy.
- The first listed diagnosis or condition on the electronic list is often the one most often selected by the providers/users, so training regarding specificity is vital.
- The mapping of the diagnostic terms on the selection list may not map to the correct and/or the specific ICD-9-CM code that was intended, so validation of mapping is essential.

Additional steps

Some steps to take to validate coding accuracy and identify any potential malnutrition risk include the following.

Action #1. It is recommend that you run a data report starting with October 2007 to find inpatient cases (in particular, Medicare) with the 260 code assigned as a secondary code. If you find cases with 260 code assigned, these should be reviewed for accuracy, not only for the documentation, but also for the clinical components of malnutrition.

Action #2. The review of records with the 260 code should include a validation that the documentation and clinical indicators support the code assignment. Determine whether further clarification is needed regarding the terminology being used by the physician/provider. If the documentation states only "protein malnutrition," then it is advised that a query be initiated.

Action #3. Generate a physician query explaining to the physician that documentation of the term "protein malnutrition" indexes within the classification system to kwashiorkor, which is a rare form of malnutrition seen in children. Ask for clarification regarding whether the diagnosis is actually kwashiorkor (260) as opposed to protein-calorie malnutrition (263.9); severe malnutrition NOS (261); severe protein-calorie malnutrition (262); or other malnutrition NOS (263.9) Ask physician to please specify type, if known. It is best not to use code 260 without clarification of actual kwashiorkor from the physician.

Action #4. Develop or use a physician query that offers an explanation and also some choices for the physician to help better understand the classification of malnutrition.

Continued on page 70

Data mining result raises coding concerns

...continued from page 69

Here is some sample wording you might use in a query:

> Dear Dr. _____:
> You have documented "protein malnutrition" which ICD-9-CM classification indexes to "kwashiorkor," a rare syndrome occurring mostly in starving children. Please clarify whether your patient had kwashiorkor, or whether he/she had "protein-calorie malnutrition," "malnutrition unspecified," or some other nutritional diagnosis (please specify) _____. Thank you."

Action #5. Share this information with your coding staff and your Clinical Documentation Improvement (CDI) staff who are querying or clarifying the nutritional diagnosis with the physician. The good news is that there is work being done at the national level to possibly revise the classification or indexing for malnutrition in the ICD-9-CM classification.

Conclusion

Coding professionals need to apply the basic coding competencies when seeing documentation of "protein malnutrition." Because kwashiorkor is a type of malnutrition not often seen in the United States population, review the clinical documentation carefully. In addition, similar action steps can be taken with regard to sepsis coding or other potential coding and documentation risk areas. Regulatory auditors, such as RACs, will be conducting their own data mining practices and looking for unusual or unexplained volume increases in high relative weight MS-DRGs and in particular, ICD-9-CM codes that appear as the only MCC or CC.

Compliance professionals and Health Information Management coding professionals need to be doing some data mining also, and should be diligent with instructing staff to follow coding conventions and guidelines. In addition, when in doubt, talk to your coding supervisor or query the physician for clarification. Accurate documentation, coding, and reimbursement will aide in maintaining compliance and diminishing potential risk. ■

1 *The San Francisco Chronicle* is a member of the California Watch Media Network. California Watch is part of the nonprofit Center for Investigative Reporting.
2 Lance Williams, Christina Jewett, Steven K. Doig: "Hospital chain already under scrutiny, reports high malnutrition rates." *San Francisco Chronicle*, February 19, 2011. Available at http://californiawatch.org/health-and-welfare/hospital-chain-already-under-scrutiny-reports-high-malnutrition-rates-8786

Court rejects False Claims Act quality-of-care theory

By Lisa Estrada

Editor's note: Lisa Estrada is a Partner in Arent Fox's Regulatory and Litigation Departments and serves as practice group leader for the Health Care Group. She may be contacted by telephone in Washington DC at 202/828-3424 or by e-mail at estrada.lisa@arentfox.com.

In January, the US District Court for the Northern District of New York dismissed a False Claims Act (FCA) case brought by a whistleblower against Dialysis Clinic Inc. (DCI). The dismissal was based on the relator's failure to plead fraud with particularity. This means that the relator made generalized allegations that did not include enough specific information to allow DCI to effectively defend the claims. But, the court didn't stop with the dismissal, deciding instead to signal its view that the allegations that DCI failed to abide by the health, safety, and quality of care standards set forth in Medicare's end stage renal disease (ESRD) Conditions for Coverage should not be actionable under the FCA.

The decision in *U.S. ex rel. Blundell v. Dialysis Clinic Inc.*[1] is the latest in a string of recent defense victories on the question of whether Medicare conditions of participation should be considered conditions of payment with which health care providers impliedly certify compliance each time they submit a claim for payment.

The relator, a former DCI charge nurse, relied on a laundry list of DCI's purported deficiencies vis-à-vis the ESRD Conditions for Coverage, including serious allegations that the company failed to provide adequate and appropriately qualified personnel, failed to prevent cross-contamination, permitted patient care technicians to perform nursing functions and administer medications, and falsified records. The relator also included some allegations of a seemingly less serious nature, including that DCI failed to provide comfortable temperatures within the facility. The relator argued that, by submitting claims for services rendered in violation of each of these regulatory requirements, DCI violated the FCA.

Relying heavily on the analytical framework set forth in the Second Circuit's 2001 decision in *Mikes v. Strauss*[2] and the Tenth Circuit's 2008 Decision in *U.S. ex rel. Conner v. Salina Regional Health Center*,[3] the DCI Court concluded that the ESRD Conditions for Coverage are conditions of participation, not prerequisites to receiving reimbursement from the government. As a result, failure to comply with the requirements cannot supply the basis for an implied certification claim. In so finding, the Court focused on the fact that the ESRD Conditions for Coverage are quality-of-care standards that, when they are not met, may be sanctioned by expulsion from the Medicare program, but not recoupment of particular payments. The Court also rejected the relator's "worthless services" claim, because the allegations of deficient care fell well short of pleading that DCI failed to provide any service to their patients.

The Court's decision is welcome news for health care providers who are concerned that the FCA may be used to federalize malpractice liability. However, in the long run, the case and others like it may provide little protection, given the ease with which CMS can eliminate the regulatory distinction between conditions of participation and conditions of payment. In fact, in the ESRD context, CMS may have already accomplished this by adding the following provision at the tail-end of the recently released final rule

Continued on page 72

 ...continued from page 71

implementing the ESRD bundled payment system: "Qualification for Payment. To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter." Thus, going forward and in light of the deference courts are likely to pay to CMS' interpretation of its own regulatory scheme, ESRD facilities may face difficulty in combating a quality-of-care false certification allegation by arguing that ESRD Conditions for Coverage are not conditions of payment. ■

1. 2011 WL 167246 (NDNY Jan. 19, 2001)
2. 274 F.3d 687 (2001) in which the U.S. Court of Appeals held that a claim for reimbursement is not legally false simply because the particular service furnished failed to meet accepted standards.
3. 543 F.3d 1211 (10th Cir. 2008), in which the U.S. Court of Appeals for the Tenth Circuit held that a hospital's failure to meet all of the regulatory conditions for participation in Medicare does not necessarily create a basis for liability under the FCA.

An interview with Diana Adams - HCCA's own Regional Conference groupie

...continued from page 56

to a specific question, you at least now know where to look and who to ask. Compliance is a growing field with many opportunities.

Q: Do you take advantage of HCCA's Social Network and if "yes," why? What feature do you find most beneficial?

DA: Yes, I receive the messages and e-mails, and it is another way of staying current. By the way, "The Social Network" was an interesting topic presented at the Regional Conferences last year. Sometimes us "old folks" have a hard time transitioning to the new way of communication, but at least I am open to learning.

Q: Diana, how long have you been a member of HCCA, and what do you feel is the best benefit of your membership?

DA: That is a good question, and you would think that I would know that answer. I joined HCCA first when the organization was about two years old, then dropped out for a bit, but came back as I was needing an organization where I could research and gain further compliance knowledge. So, I would say I've been a member at least seven years. The benefits: networking, the informative **Compliance Today** journal, research capabilities, and overall, growing in my profession.

Q: What do you think HCCA does well, and what do you think HCCA could improve on?

DA: HCCA is good at getting information out to those working in the field, keeping us current with the good and bad. And HCCA needs to keep focusing on their goals for growth in a field of health care that is never going to go away, giving those of us in compliance the opportunities of meeting the people who are doing the government and private audits. And this year, if all goes as planned, I will be attending nine Regional Conferences, and loving every minute of them! ■

New HCCA Members

Alabama
- Judy A. Allen, Advanced Surgeons
- Vicki Britt, Pickens County Medical Center
- Peggy Panos, Children's Health Syst
- Alice Teal, Troy Regional Medical Center

Alaska
- Tara J. Hutson, Cornerstone Home Health
- Michelle Iniguez, Cornerstone Home Health
- William Kost, Eastern Aleutian Tribes

Arizona
- Jacqueline Bloink, Jacqueline Nash Bloink Healthcare Consulting
- Robert Coyle, Vanguard Health Syst
- Ralph Green
- Mary A. Kimmel, ABC Medical Billing Consultants
- Roxane Tompkins, Cancer Treatment Centers of America

Arkansas
- Larry Davis, SBRMC
- Janie McKinney
- Dana H. Williams, Baptist Health

California
- Bruce Anderson, Health Net, Inc
- Tina Buop, Muir Medical Group
- Maria Calderon, Molina Healthcare Inc
- Robert Coe, Placentia-Linda Hosp
- Jessica Dunphy, Providence St. Joseph Medical Center
- Paige Fretwell, New Century Health
- Cea Ishikawa, Planned Parenthood of the Pacific Southwest
- Marion Reeves, Butte County
- Regina Richard, Palo Alto Medical Foundation
- Harry Shore, McGladrey

Colorado
- Aygul Gumerova, Denver Health Medical Plan
- Heather Swanson, EthicsPoint, Inc

Connecticut
- Diane H. Bouffard, Bristol Hosp & Health Care Grp
- Andrew F. Braver
- Sandra L. Coppola, Medical Oncology & Hematology

Delaware
- Patricia Gam Simpson, Aetna

Florida
- Bob Cunniff, Orthopedic Specialists of SW Florida
- Angela D'Anna, Lee Memorial Health System
- Emylene Egusquiza, Acevedo Consulting Inc
- David Graham, Kforce Healthcare
- Richard A. Hood, Omnicare
- William Kuzbyt, CHS
- Christian Lops
- Susan Roberts, The RobertGroup
- Anthony M. Stahl, Florida Hospital Heartland Medical Center
- Autumn Wiley, CCS Medical

Georgia
- Nancy Brannon, Piedmont Healthcare, Inc
- Valorie Carnes, Piedmont Healthcare, Inc
- Brandy Fournet, PSS World Medical, Inc
- D'Andrea Morning, Alston & Bird
- Angela Belinda Powell, Appling Health Care System
- Amanda Winters, Highland Rivers Center

Illinois
- Patricia DiFiglio, La Rabida Children's Hospital
- Stephanie Johnson, University of Chicago Hospital

Indiana
- Elizabeth S. Hall, Indianapolis Osteopathic Hosp/Westview Hosp
- Patti J. Hunker, Methodist Sports Medicine / The Orthopedic Specialists
- Virginia Nelson, Aspire Indiana

Iowa
- Cathi Scharnberg, Avera Holy Family Hospital
- Lana Christine Sohn, RegionalCare Hospital Partners

Kentucky
- Laura Kelley, Humana

Lousiana
- John F. Derenbecker, North Oaks Medical Center
- Linda M. Ellis, MedAdvise
- Michele P. Kane, Audobon Healthcare

Maine
- Jennifer A W Rush, Norman Hanson & DeTroy

Maryland
- Paula Polek, Johns Hopkins HealthCare LLC
- Vernisha L Robinson, CMS
- Caroline Rufino
- Philip Sherfey, CMS
- Brenda J. Tranchida, CMS

Massachusetts
- Steven L. Biles, Invacare Supply Grp
- Crystal Bloom, Donoghue, Barrett, & Singal
- Andrew Ferrer, Donoghue, Barrett & Singal
- Elizabeth-Ann Foley, Donoghue Barrett & Singal
- Myra Green, DentaQuest
- Kelly McGee, Donoghue, Barrett & Singal
- Barbara O'Neill, Hallmark Health
- Matthew Smith, Massachusetts Eye & Ear Infirmary

Michigan
- Kevin W. Carlson, Upper Peninsula Health Plan
- Gail F. Einhaus, Trinity Health
- Phil Reed, CTSI-Michigan State University
- Diane Wilson, Univ of Michigan Medical School

Mississippi
- Amy Tolliver, Magee General Hospital

Neveda
- Mona Kaul

New Jersey
- Gary A. Weiss, VHA, CBF

New Mexico
- Edward Young, Hidalgo Medical Services

New York
- Heather E. Berg, Recovery Center
- Izetta Briggs-Bolling, Recovery Center
- Valerie Campbell, Health Quest Systems, Inc
- Judy Doria, Central Nassau Guidance & Counseling
- Laura M. Forster, MVP Health Care
- Sandra Gonzalez, Puerto Rican Family Institute, Inc
- Rose Marie G. Grave, MJHS - Menorah Home & Hospital
- Patricia Hajnosz, St Francis Hospital
- Jeff Holloway, Family and Children's Assoc
- Sandra Maliszewski, NuHealth System
- Linda Martin, Aging in America
- John Navarra, Town Total Health
- Renee Nesheiwat, Health Quest Systems, Inc
- Evan J. Sacks, Bluemark, LLC
- Rochelle Saks, Phoenix Houses of New York
- Nicole Sexton, Donoghue, Barrett & Singal
- Fausto Uceta, Rockaway Manor Health Care
- Norman S. Werner, Continum Health Partners

North Carolina
- Linda Coye, Transylvania Health System

Ohio
- Peggy Beat
- Beverly Brouse, Akron General
- Tammie Campton, Communicare Family of Companies
- Jeremy Corsmo, Cincinnati Children's Medical Center
- Teresa Crenshaw, The Christ Hospital Cardiovascular Assoc
- Katy Davis, Fairfield HC Professional
- Melinda J. McQuesten, Modern Medical Inc
- Barb Metcalf, Stein Hospice
- Suzanne Neuber, Omnicare, Inc
- Lisa Renaker, Communicare Family of Companies
- Kim E. Watson, Wellpoint Inc

Oklahoma
- Amy Balsiger, Logan Medical Cntr
- Kathy L. Jones, Duncan Medical Assoc
- Bobby Mason, OUHSC

Oregon
- David Childers, EthicsPoint, Inc
- Tom Monterossi, EthicsPoint, Inc
- Bill Piwonka, EthicsPoint, Inc

Pennsylvania
- Stacy L. Abebe, Gateway Health Plan
- Debbie Baer, Saint Mary's Home of Erie
- Lynann Casagrande, Allegheny HealthChoices, Inc
- Noelle Conners, St. Christopher's Hospital for Children
- Henri-Alexandre Lauer, Compliance Concepts, Inc
- Richard E. Reilly, Genesis HealthCare LLC
- Linda Schneider, GlaxoSmithKline

Rhode Island
- Kathleen Kenny

South Carolina
- Rebecca C. Marigliano, Palmetto Health
- Preston Wilson, Select Health of South Carolina

South Dakota
- Crystal Gruetzmacher, Rapid City Regional Hospital, Inc

Tennessee
- Catherine A. Badger-Rodriguez, Church Street Health Mgmt
- Vinnie Dam, Medex BioCare
- Dana Fields, HealthSpring, Inc
- Teresa Kidd, Frontier Health
- Michelle Marsh, LifePoint Hospitals
- Laurie L. Newlun, Hospice of Chattanooga
- Leanne Patterson
- Angie Rogers, Fresenius Medical Care
- Sheron Salyer, VA Tennessee Valley Healthcare System
- Garry Smith, Wright Medical Technology
- Fran Sorrell, American Esoteric Laboratories
- Ronette Adams Taylor, Meharry Medical College
- Carol Wesson, Tennessee Health Management
- William D. Wright, The Little Clinic

Texas
- Cassandra Blair, Universal American
- Heidi Bragg, Cardinal Health
- Carole Hackett, The Methodist Hospital
- Charles Harrison, Austin Travis County Integral Care
- Jodi Jackson, Children's Medical Center
- Juliet H. Lane, Brazosport Regional Health System
- William LeMaistre, Univ of North Texas Health Science Center

Continued on page 76

New Members ...continued from page 75

- Salome Lofty
- Kathy Mace, T-System, Inc

Texas (continued)

- Tracy J. Masson, Texas Health Presbyterian-WNJ
- Caroline Murphy, HCA
- Phuong D. Nguyen, Health Texas Provider Network
- Nichola S. Oka, Baylor Health Care System
- Michael Rabie, Family Care
- Kristina Ramos, QMACS, Inc
- Sonya Reyes, WellMed Medical Management
- Janie M. Schumaker, T-System, Inc
- Natalie L. Welborn, Seton Family of Hospitals
- Deborah L. Ziegler, Law Office of Deborah Ziegler

Utah

- Summer Davis, Univ of Utah

Vermont

- Kenneth Beattie, Northeast Kingdom Human Services
- Charles Lief, Amida Care

Virginia

- Lisa Allnutt, Carilion Health System
- Gwen M. Avery, Southside Regional Medical Center
- Todd Bejian, IBA
- William Forte, Norfolk Community Services Board
- Ellen D. Harrison, Western State Hosp
- Robert Horne, Norfolk CSB
- Carrie Kusserow
- Elizabeth A. Leff, Chesapeake Regional Medical Center
- Mark T. Morrell, Hancock, Daniel, Johnson & Nagle
- Mark Moser, Norfolk Community Services Board
- John D. Uecke, Nova Medical Billing, Inc
- Maureen Womack, Norfolk Community Services Board

Washington

- Molly Brown, PeaceHealth
- Jeffrey Grice, Group Health Physicians
- Jennifer Hall, RS Medical
- Deborah D. Kobelansky, Harrison Medical Center
- Rebecca Ruecker, Ruecker Healthcare Consulting
- Timothy Schut, Providence Health & Services

Wisconsin

- Richard D. Andersen, Wheaton Franciscan Healthcare
- Ann Fiala, Westfields Hospital
- Meghan C. O'Connor, Von Briesen & Roper
- Michael Peer, Brookdale Senior Living
- Jessica M. VanderZanden, Network Health Insurance Corp
- Kirsten R. Wild
- Adam Zunker, UnitedHealth Group

Guam

- Tammy Jeffcoat

Your HCCA Staff


Sarah Anondson
Graphic Artist
sarah.anondson@hcca-info.org


Lizza Catalano
Conference Planner
lizza.catalano@hcca-info.org


Gary DeVaan
IT Manager/Graphic Artist
gary.devaan@hcca-info.org


Margaret Dragon
Director of Communications
margaret.dragon@hcca-info.org


Darin Dvorak
Director of Conferences and Exhibits
darin.dvorak@hcca-info.org


Wilma Eisenman
HR Director/Office Manager/ Compliance Officer
wilma.eisenman@hcca-info.org


Jodi Erickson Hernandez
Conference Planner
jodi.ericksonhernandez @hcca-info.org


Nancy L. Gordon
Managing Editor
nancy.gordon@hcca-info.org


Melanie Gross
Marketing Coodinator/ Conference Planner
melanie.gross@hcca-info.org


Karrie Hakenson
Receptionist
karrie.hakenson@hcca-info.org


Elizabeth Hergert
Certification Coordinator
elizabeth.hergert@hcca-info.org


Patti Hoskin
Database Associate
patti.hoskin@hcca-info.org


April Kiel
Database and Member Services Administrator
april.kiel@hcca-info.org


Meg Kosowski
Certification Specialist
meghan.kosowski@hcca-info.org


Katie Luitjens
Conference Planner
katie.luitjens@hcca-info.org


Amy Macias
Member Services
amy.macias@hcca-info.org


Patricia Mees
Communications Editor
patricia.mees@hcca-info.org


Eric Newman, Esq.
Social Media Manager
eric.newman@hcca-info.org


Tracey Page
Member Services
tracey.page@hcca-info.org


Jennifer Power
Conference Planner
jennifer.power@hcca-info.org


Marlene Robinson
Web Conference Planner
marlene.robinson@hcca-info.org


Beckie Smith
Conference Planner
beckie.smith@hcca-info.org


Roy Snell
Chief Executive Officer
roy.snell@hcca-info.org


Charlie Thiem
Chief Financial Officer
charlie.thiem@hcca-info.org


Adam Turteltaub
VP Member Relations
adam.turteltaub@hcca-info.org


Allison Willford
Accountant
allison.willford@hcca-info.org

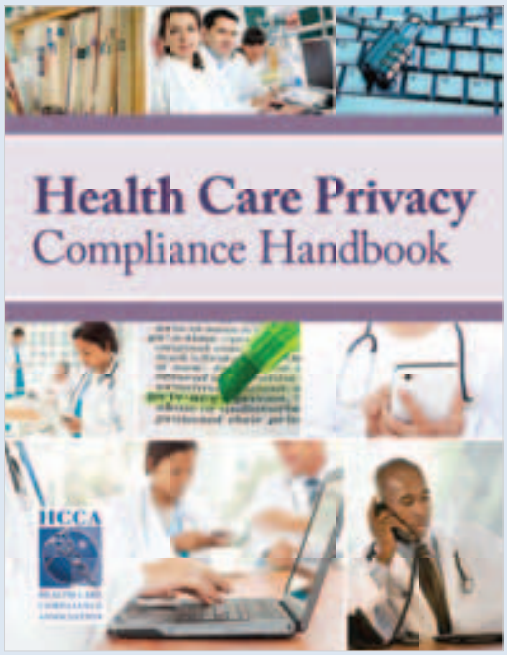

Julie Wolbers
Accountant
julie.wolbers@hcca-info.org

6500 Barrie Road, Suite 250
Minneapolis, MN 55435
Phone 888-580-8373
Fax 952-988-0146
www.hcca-info.org
info@hcca-info.org

Health Care Privacy Compliance Handbook

This book will help you sort through the complex regulatory framework and significant issues about privacy facing health care organizations. Written by the faculty of HCCA's Basic Privacy Compliance Academy, it covers:

- HIPAA
- HITECH
- FERPA
- The Federal Privacy Act
- Privacy and Research
- Vendor Relations
- Payor Privacy Issues
- Auditing & Monitoring



ORDER NOW

HEALTH CARE PRIVACY COMPLIANCE HANDBOOK

Qty **Cost**

_____ HCCA Members: $149 ..... $ _____

_____ Non-Members: $169 ..... $ _____

_____ Join HCCA: $200 ..... $ _____

Non-members, add $200 to join HCCA, and pay member prices for your order (REGULAR DUES $295/YEAR)

Total $ _____

Prices subject to change without notice. HCCA will charge your credit card the correct amount if the total above is incorrect. All purchases within the continental U.S. receive free FedEx Ground shipping. Additional charges apply for international orders: please contact HCCA for more information. HCCA is required to charge sales tax on purchases from Minnesota and Pennsylvania. Please calculate this in the cost of your order: PA = 8% and MN = 6.875%. *(Federal Tax ID: 23-2882664)*

PLEASE TYPE OR PRINT

HCCA Member ID

First Name M.I. Last Name

Title

Organization

Street Address

City State Zip

Telephone

Fax

E-mail

Make check payable to HCCA and mail to:

HCCA, 6500 Barrie Road, Suite 250
Minneapolis, MN 55435

Or fax order to: 952-988-0146

☐ *My organization is tax exempt*

☐ Check enclosed

☐ Invoice me | Purchase Order # _____

☐ I authorize HCCA to charge my credit card (choose below):

○ AmericanExpress ○ Diners Club ○ MasterCard ○ Visa

Credit Card Account Number

Credit Card Expiration Date

Cardholder's Name

Cardholder's Signature

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

6500 Barrie Road, Suite 250
Minneapolis, MN 55435
Phone 888-580-8373 | Fax 952-988-0146
www.hcca-info.org | helpteam@hcca-info.org

SAVE THE DATE

FRAUD & COMPLIANCE FORUM

September 25–27, 2011

Renaissance Harborplace Hotel | Baltimore, MD

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

Visit www.hcca-info.org to learn more

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION
www.hcca-info.org

AMERICAN HEALTH LAWYERS ASSOCIATION
www.healthlawyers.org

SPONSORS

HealthCare Appraisers

KPMG