Meet
Craig Morford, Esq.
Executive VP and Chief
Compliance Officer,
Cardinal Health
PAGE 14

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HEALTH CARE BOARDS OF DIRECTORS’ LEGAL RESPONSIBILITIES FOR QUALITY
PAGE 9

Feature Focus:
What every compliance officer should know about M&A due diligence
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On-call coverage payments to physicians: In the spotlight by Jen Johnson
Health care facilities that pay physicians for on-call duty should make sure their arrangements meet fair market value requirements.

CEU: Health care boards of directors’ legal responsibilities for quality
By Cheryl L. Wagonhurst and M. Leann Habte
Governing boards have fiduciary responsibility and obligation to ensure quality of care.

Meet Craig Morford, Executive VP and Chief Compliance Officer, Cardinal health
An interview by Gabriel L. Imperato

Newly Certified CHCs

Letter from the CEO By Roy Snell
Closer to the edge

Assessing need in health care arrangements
By David M. Hyman and Nicole DiMaria
Guidance from OIG and CMS is useful when defining terms such as “reasonably necessary” or “legitimate business purpose” to assess fraud and abuse risks.

Laboratory Compliance: Taking the deep dive into laboratory auditing and monitoring
By Jeff Sinaiko
Inappropriate charges/false claims and issues that impact quality, prompt payment, and utilization pose significant risks for labs.

What employers really want from employees
By Maurice Gilbert
Whether you are looking for a new job or seeking a promotion on the job you already have, these skills and character traits are essential.

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CEU: Feature focus: What every compliance officer should know about M&A due diligence
By Greg Brock, John Gilbertson, Vanessa Griggley, Terri Kraemer, and Karolyn Woo
Five key areas the compliance officer should focus on before a merger or acquisition deal is signed.

Compliance 101: Your first 100 days By Jay P. Anstine
A road map to help you get started on the right foot as a new compliance officer and help you manage the seemingly overwhelming responsibilities.

The what, why, and how of Medicare Coverage Analysis – Part II By Kristen Pawlowski
Six “how-to” steps for conducting an MCA to ensure accurate billing of clinical trials.

CEU: The revised PhRMA Code: Implications for provider conflict-of-interest policies
By Sara Kay Wheeler and Michael Paulhus
Health care providers should regularly assess the nature and extent of their relationships with vendors to identify and manage conflicts of interest.

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December 2008
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Adequate on-call emergency coverage is a real issue for hospital emergency departments and inpatients who require urgent specialist consultation. Sullivan Cotter and Associates’ 2008 Physician On-Call Pay Survey Report¹ states that 85% of survey respondents have experienced difficulty finding physicians to provide on-call coverage.

The problem has been severe enough, in some instances, that 16% of respondents reported the discontinuation of service lines due to lack of on-call coverage. Sullivan Cotter’s survey provides several statistics which support the trend in providing payments for on-call coverage:

- 86% of the survey respondents reported they currently provide compensation to non-employed physicians for call coverage.
- 70% of the respondents stated they provide additional pay for on-call services, or consider on-call duties in determining total compensation for employed physicians.
- Nearly two-thirds of those surveyed reported their on-call pay expenditures have increased in the past 12 months, with 15% of these respondents reporting increases of more than 50%.
- 28% of the respondents indicate they plan on implementing on-call pay within the next 6 months for physicians not currently receiving pay.

With physician compensation activity such as this, it is no surprise the Office of Inspector General (OIG) has brought on-call coverage payments to the spotlight by issuing its first advisory opinion related to on-call coverage last Fall. The following discusses the reasons for the growth of on-call coverage payments, compensation options, and what organizations should consider when determining if their arrangement meets the Fair Market Value (FMV) requirements.

Reasons for the rise of on-call payments

A shortage of physicians are willing to take on-call duty for several reasons, including reluctance to go without pay for uninsured patients, fear of malpractice lawsuits, disruption of personal lives and practice, and the fact that fewer physicians are working for hospitals.

In addition, a pure physician–supply issue is expected to worsen. Richard Cooper, MD, Director of the Health Policy Institute at the Medical College of Wisconsin in Milwaukee and a national expert on physician–workforce issues, projects a shortage of 50,000 physicians by 2010 and up to 200,000 physicians by 2020.²

Adding to the shortage of physicians’ availability for on-call duty is the fact that the physician workforce is aging, and many medical staff bylaws allow older physicians to opt out of on-call duty. From a demand perspective, no relief is in sight, because the elderly population...
Another major reason for the on-call physician shortage is a fundamental change in the industry. Historically, physicians provided on-call coverage in exchange for privileges at a hospital, which allowed them to help build their practice. Today, many physicians are shifting away from hospital settings to freestanding ambulatory surgery centers or specialty hospitals that don't have emergency departments (EDs). The growth in physician-owned surgery, imaging, diagnostic, and other facilities is expected to continue, which will provide more alternatives to physicians who don't require on-call duty to build their practices. In 2005, The American College of Emergency Physicians survey polled 4,444 US hospital ED medical directors. When asked if their on-call coverage problems were due to physicians relinquishing privileges to pursue practices elsewhere, 51% responded yes.

Several other economic reasons contribute to the shortage of physicians who are willing to provide on-call coverage and the increased need for on-call payments. Because patients seen in the ED are often uninsured or underinsured, payments are inadequate, and this patient population is on the rise. In addition, malpractice insurance for those who provide ED coverage is higher than for those strictly in private practice. Plus, work-life balance is more important to the newest generation of physicians. Reasons for on-call coverage payments, cited by hospitals, include physicians threatening to cease on-call coverage and the desire to create equity among all physicians. For all of these reasons, many organizations are currently contemplating on-call payments for the first time, and are struggling with how to structure the arrangements and determine the payments.

**On-call payment models**
The most common solution for retaining physicians to provide on-call coverage is by providing a stipend or hourly rate. The Sullivan Cotter survey notes that 90% of organizations utilize this methodology for employed physicians and 97% use this methodology for non-employed physicians. Other options used in the industry include:

- Providing payments for "excess" on-call duty (typically more than 3-5 shifts per month)
- Fee-for-service payments
- Paying professional fees for uninsured patients (typically based on Medicare rates)
- Paying the physician's malpractice insurance premium
- Unique compensation plans, including 457fs, which are deferred compensation plans that allow eligible employers to contribute money to investments on a pre-tax basis, and company-owned life insurance plans
- Physicians dedicated to on-call coverage and unassigned patients. These new roles are often referred to as laborists (obstetricians) and surgicalists (general surgeons and orthopedists)
- Contracting with an entire physician group to provide on-call coverage
- Utilizing residents and physician "extenders"
- Using locum tenens agencies
- Technology driven on-call, whereby the physicians call in remotely and through live video/audio feed, they can review imaging scans and on-site reports to direct the on-site physician.

All of the above on-call payment models could be viable options for obtaining on-call coverage. The following discussion addresses compliance considerations under the most common model for on-call compensation, the hourly rate or stipend. Before analyzing the appropriate method for determining on-call compensation under this payment model, it is important to understand the on-call coverage opinion issued by OIG in September of 2007.

**The first on-call opinion**
On September 20, 2007, OIG issued Advisory Opinion number 07-10 (Opinion), the first advisory opinion to address an on-call arrangement. The Opinion stipulated several guidelines for health care organizations that were considering compensation for physicians who provided on-call coverage. Specifically, OIG found a certain arrangement to be low risk for fraud and abuse, based on several factors, including:

- An independent third-party analysis which concluded that the compensation reflected FMV for the services furnished
- The per diem rate was designed to compensate each physician for the burden of being on-call and it considered the likelihood that the physician would be required to provide subsequent inpatient services.
- On-call physicians were obligated to provide continuing care to ED patients, regardless of their ability to pay.
- Physicians in each specialty received the same per diem payment without regard to the individual physician’s referrals to, or business generated for, the hospital.
- The medical center had a legitimate, unmet need for on-call coverage and indigent care services as demonstrated by the fact that the medical center was previously forced to outsource emergency care and related treatments to other facilities.

OIG’s Opinion also warned of a substantial risk that improperly structured payments for on-call coverage could be considered unlawful remuneration if the payments exceed fair market value.

**Fair market value guidelines**
In addition to the Opinion discussed above, the federal government has presented guidelines for determining physician compensation. Most notably, the Stark regulations

Continued on page 7
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state specific methods for determining FMV. Although the Stark regulations may not be directly applicable to an on-call arrangement, they provide insight into what federal authorities consider appropriate methods in determining FMV within the health care arena:

We will continue to scrutinize the Fair Market Value of arrangements as Fair Market Value is an essential element of many exceptions. Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating Fair Market Value. (Stark II, Phase III, Fed Reg Vol. 72, No. 171)

The methodology must exclude valuations where the parties to the transactions are at arm’s length but in a position to refer to one another. (Stark II, Phase II, Fed Reg Vol. 69, No. 59)

Based on the above regulatory language, reference to multiple, objective, independently published salary surveys and limited reliance on information produced from referral relationships should be guidelines in determining the FMV for on-call payments.

Unfortunately, the market does not offer multiple surveys for on-call compensation, only the Sullivan Cotter survey. In addition, this survey data is based on referral relationships. Therefore, it is prudent to look to other methods when determining the FMV for on-call compensation. The following discussion addresses the pros and cons of the Sullivan Cotter survey, as well as alternative methodologies for determining on-call compensation.

Although relying on the Sullivan Cotter survey alone has its drawbacks, it does provide the most relevant data available. In addition, based on the experience and observations of a national health care valuation firm (VMG), the median per diem payment data for certain specialties, such as orthopedic surgery, are in line with FMV analyses for on-call coverage. Specifically, a review of the Sullivan Cotter survey data for orthopedic surgery on-call coverage compensation shows the median per diem payments for 2006, 2007 and 2008 were $975, $968, and $1,000, respectively. VMG has concluded similar results in valuing on-call arrangements in the orthopedic surgery specialty. However, it is important to note that a FMV analysis should consider additional valuation methods and other factors, such as the burden of on-call duty. For example, if an arrangement’s circumstances included an exceptionally poor payer mix or very low volume, market indications could warrant an adjustment up or down.

Another issue with using the Sullivan Cotter survey is reliability. Specifically, of the 36 reported specialties, two-thirds of those specialties have less than 20 respondents for on-call compensation. In addition, some specialties show questionable year-over-year growth, such as anesthesiology, which shows per diem median payments jumped 50%, from $500 to $750 in 2008; and gastroenterology, which shows per diem median payments rose 42%, from $300 to $425 in 2008. Other red flags with certain data in the survey include the decrease of median per diem payments for specialties such as neurosurgery, which dropped 15% to $1,000, and psychiatry, which dropped 50% to $200 in 2008.

Fortunately, the Medical Group Management Association, a leading provider of health care survey data, is currently conducting an on-call compensation survey which is expected to be released in the Spring of 2009. Although survey data alone does not appear to be enough to fully support FMV payments for on-call coverage, considering two surveys will be a step in the right direction.

Alternatives for determining the FMV for on-call payments include adjusted locum tenens rates and beeper rates. The locum tenens approach provides a proxy for the cost of on-call coverage by adjusting a market locum tenens quote by an industry margin and patient contact time. The beeper rate methodology is based on what a provider would earn, as a percent of base pay, for being on call. If conducted appropriately, this method can reference multiple surveys for the specialty and provide an on-call rate based on non-referring provider data.

Once the various market costs for on-call coverage are understood, it is important to show that the agreement terms and burden of on-call duty were considered in determining the on-call payments. This will document due diligence in ensuring that the organization considered regulatory guidance in its compliance policies.

**Bottom line**

If health care organizations are not careful in determining FMV compensation for on-call coverage, they risk being non-compliant with health care regulations. In addition, it is expected that authorities may start to pay more attention to these arrangements, because of their growth and FMV challenges. The critical components to compliance include understanding the recent OIG opinion when drafting on-call agreements, documenting factors to show the burden of on-call duty, and following the regulations that surround health care valuations.

This article is not to be construed as legal advice; it is to provide insight to valuation guidelines related to FMV.

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Health care boards of directors’ legal responsibilities for quality

By Cheryl L. Wagonhurst, Esq, CCEP and M. Leeann Habte, Esq.

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This is the third in a series of articles by Foley & Lardner LLP published in Compliance Today designed to address the compliance risks associated with quality of care in the hospital setting. This article explores and explains the legal responsibilities of health care boards of directors and how compliance officers can educate and assist boards in fulfilling their legal responsibilities.

The Institute of Medicine’s landmark report,1 which documented that medical errors were one of the leading causes of death in the United States, served as a wake-up call for the health care industry. In response to growing concerns about health care quality and patient safety, federal and state governments, purchasers, and health plans began launching new initiatives to increase quality and accountability in the health care system. This emerging quality movement has shifted the focus on accountability for health care quality and patient safety from individual practitioners to the health care system itself. Consistent with this shift in perspective, the government has charged governing boards of health care organizations with the overall responsibility for the quality of care delivered at their organizations. As this article will show, health care boards of directors are increasingly being held accountable for quality failures. It would not be a surprise if, eventually, this accountability translated into legal liability for board members in enforcement actions for quality failures.

The Centers for Medicare and Medicaid Services (CMS) clarified its intent to hold hospital leadership responsible and accountable for quality in the 2003 revisions of the hospital Conditions of Participation (CoP), which included the Quality Assessment and Performance Improvement Program (QAPI).2 The revised QAPI CoP sets forth a standard, titled "Executive Responsibilities," which emphasizes the role of the hospital’s governing body, medical staff, and administrative officials in establishing a culture of safety and quality and defining the importance of QAPI activities throughout the institution.3

Under the pre-existing QAPI standards, the hospital leadership was responsible for ensuring that QAPI addressed priorities for improved quality of care and patient safety and that all improvement actions were evaluated. The revisions strengthened the standard by additionally requiring the hospital’s governing body to set expectations for safety and to allocate adequate resources for measuring, assessing, improving, and sustaining the hospital’s performance and for reducing risks to patients.4 These defined responsibilities are just one aspect of the hospital governing board’s general oversight duty to ensure that the hospital’s QAPI reflects the complexity of the hospital’s organization and services, involves all hospitals departments and services, focuses on indicators related to improvement of health outcomes, and the prevention and reduction of medical errors.5

Fiduciary responsibilities of the board

The emergence of the quality movement (accompanied by a myriad of new regulatory and payment provisions that impact health organizations) prompted the National Quality Forum to issue its groundbreaking “Call to Responsibility” to health care organizations. This Call urged health care boards to make serious efforts to ensure quality of care and outlined principles that boards should follow in ensuring health care quality.6 To inform and educate board members about their new roles and responsibilities, the Department of Health and Human Services’ Office of Inspector General (OIG) and the American Health Lawyers Association (AHILA) issued three joint reports on corporate responsibility, compliance, and health care quality.7 According to the most recent OIG/AHLA white paper, oversight of quality has become a core fiduciary responsibility of health care organization boards.8

 Continued on page 11
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Duty of care. The board of directors’ legal obligations with respect to the duty of care arise in two distinct contexts: (1) the decision-making function, and (2) the oversight function. In fulfilling its duty of care, the board is obligated to conduct due inquiry, make responsible decisions, and provide appropriate oversight to the health care organization. Generally, the duty of care is satisfied when directors act:

- in “good faith,”
- with the care an ordinarily prudent person would exercise in like circumstances, and
- in a manner that they reasonably believe to be in the best interests of the corporation.9

In recent years, the “reasonable inquiry standard” has been interpreted to require directors to actively inquire into aspects of corporate operations where appropriate.10

With regard to health care quality, boards exercise their decision-making function when they review and approve or disapprove medical staff credentialing recommendations. Boards exercise their oversight function when they assess emerging issues of quality of care and patient safety, review quality data reporting by their organization, and evaluate the effectiveness of the corporate compliance program. Although directors are not expected to serve as compliance officers, they are responsible for oversight of management’s operation of the compliance program. In carrying out their duty of care, boards are also obligated to exercise general supervision and control with respect to corporate officers. If information is presented—either through the compliance program, through complaints, or otherwise—that causes or should cause concerns to be aroused, the director is obligated to make further inquiry until such time as the concerns are satisfactorily addressed and favorably resolved. Given the recent government interest in quality of care, the OIG/AHLA white paper instructs boards to take a more active role in overseeing quality issues within their organizations in order to satisfy the duty of care.11

The seminal Caremark case established the legal liability of the board members for breach of fiduciary duty. In the Caremark case, the court found that the board did not breach its fiduciary duty, but the court’s opinion also stated that:

“[A] director’s obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards.”12

In accordance with this decision, health care boards might be susceptible to legal risk, in extreme circumstances, if they fail to reasonably oversee the organization’s compliance program or act as mere passive recipients of information.

Duty of obedience. A health care entity/board also is subject to the duty of obedience to corporate purpose and mission.13 For nonprofits, the board has a particular duty to ensure that the organization is acting in the furtherance of the defined purpose and mission of the organization as set forth in the corporate charter and bylaws.

As the OIG/AHLA white paper indicates, “perfection” is not required in order to discharge the duty of care or duty of obedience to corporate purpose and mission obligations.14 Instead, it is recommended that boards exercise general oversight of patient safety and quality of care issues by:

- Understanding the emergence of quality-of-care issues, challenges, and opportunities;
- Overseeing the development of specific quality-of-care measurement and reporting requirements (including asking the executive staff for periodic education); and
- Requesting periodic updates from the executive staff on organizational quality-of-care initiatives and how the organization intends to address legal issues associated with those initiatives.15

If these efforts uncover quality-of-care issues, then additional inquiry may be required in order for boards to satisfy their duties to their organizations.

Government regulation and enforcement

Governing boards must be conversant in the clinical, operational, and policy issues associated with quality of care to respond to the increasingly expansive and complex federal and state regulatory scheme governing health care quality. New policies that affect reimbursement and payment, efficiency, and collaboration among organizational providers and individual and group practitioners require the governing board to closely monitor the activities of their organization as part of their oversight responsibility. Clearly, Medicare CoP require hospital boards to monitor quality through credentialing of medical staff and to maintain effective quality assessment and performance improvement programs; that is just one strand in the web of quality regulations. New financial incentives, such as Pay for Performance, gain-sharing, and other financial arrangements are regulated under state and federal law. Federal quality reporting initiatives and state adverse-event reporting regulations also apply to health care providers and expose them to legal risk for non-compliance.

Continued on page 12

December 2008
The government is developing a variety of means to identify quality-of-care issues that run afoul of the complex regulatory requirements. State certification surveys are the traditional mechanism of identifying quality deficiencies; however, federal government agencies have developed new data mining methodologies to apply to health care claims, hospital adverse-event reports, and physician quality reports to identify quality problems. Because the data submitted to government agencies and third-party payers is being used for determining reimbursement, inaccurate submission of such data could result in the misrepresentation of the status of patients and residents, the submission of false claims, and potential enforcement action under the False Claims Act (FCA). Quality issues also can be brought to the government’s attention through whistleblower lawsuits or qui tam actions.

When quality problems are identified, the regulatory scheme includes a range of progressive administrative sanctions and monetary penalties that may be imposed against providers that fail to comply with the legal requirements. In addition to the administrative penalties, OIG, Department of Justice, state Attorney Generals, and state fraud control units are working together to enforce quality for beneficiaries of federal health care programs. The consequences of quality violations range from a requirement to repay any improperly received reimbursement amount with interest, to the imposition of severe financial penalties, criminal prosecution, and exclusion from participation in any federal health care program for the corporation or organization.

Increased government scrutiny and enhanced enforcement create new risks for corporate compliance, but they may also increase risk for individual board members, owners, and high-ranking executives, who may, in certain circumstances, be held liable for quality-of-care failures. Hospitals have been held liable for failure to investigate and act on medically unnecessary care provided by its medical staff. Administrators and chief executive officers (CEOs) also have been subject to civil and criminal liability where the facility has provided substandard or inadequate care or where the executives have restricted the budget to such an extent that adequate care could not have been provided. The following examples of quality-of-care investigations that have resulted in significant settlements and convictions illustrate the government’s focus:

- A Michigan hospital and individual members of the Medical Executive Committee were indicted in federal court on charges of criminal conspiracy, mail fraud, and wire fraud by billing for medically unnecessary pain procedures. The government’s case centered on the hospital’s allegedly deficient peer review procedures, which failed to properly investigate and curtail the unnecessary pain procedures. The hospital pled guilty to wire fraud, and the case resulted in a settlement agreement of $1 million, $750,000 in restitution, and an agreement by the individuals to plead guilty to state charges.

- In another case focusing on deficient peer review procedures, a northern California hospital and its parent corporation paid $59.5 million to settle civil FCA allegations that the hospital inadequately performed credentialing and peer review of cardiologists on its staff. Administrators and chief executive officers (CEOs) also have been subject to civil and criminal liability where the facility has provided substandard or inadequate care or where the executives have restricted the budget to such an extent that adequate care could not have been provided. The following examples of quality-of-care investigations that have resulted in significant settlements and convictions illustrate the government’s focus:

- A long-term care facility management company, its CEO, and three nursing homes were found guilty of conspiracy and health care fraud based on their imposition of budgetary constraints that prevented the facilities from providing...
adequate care to residents. In 2007, the CEO was sentenced to pay $29,000 in criminal fines and to serve an 18-month sentence. The management company and nursing homes were each sentenced to pay $182,250 in criminal fines. In a related civil case, the corporate defendants paid $1.25 million to resolve FCA allegations, and agreed to be excluded from federal health care programs.21

On June 10, 2008, the owner of a personal care home in Philadelphia agreed to pay the United States $700,000, close the facility, and also agreed to lifetime exclusion from the Medicare and Medicaid programs for providing grossly inadequate housing and care for residents. The owners agreed never again own or operate a patient, personal, or residential care facility or a program or facility that participates in any federally funded health care program.22

**Implications for boards of directors**
The new emphasis on quality raises the stakes for health care organizations, both financially and legally. In light of the severe consequences that might result from a lack of adherence to applicable legal requirements, it is essential for the board of directors to be cognizant of its evolving responsibilities. Health care organizations are required to be mindful of the Anti-kickback Statute, the physician self-referral (Stark) law, civil money penalty statutes, the Health Insurance Portability and Accountability Act, federal tax exemption standards, antitrust law, fraud laws, and other legal compliance standards.23 Boards must exercise oversight of the organization’s compliance programs and must reasonably inquire whether appropriate control mechanisms are in place to monitor the associated legal risks.

To fulfill their responsibilities and avoid legal risk, board members must take action. An action plan for the board of directors should involve the following steps:

- **Fiduciary duty.** Boards of directors must recognize quality of care as a core fiduciary duty. Health care quality must be established as a key component of corporate mission and elevated to the same level of fiduciary obligation as financial viability and corporate compliance.

- **Education.** Boards of directors must be educated on quality of care policies, laws, and issues as they relate to their oversight responsibilities. Recognizing the importance of an informed and educated board, the American Hospital Association’s Center for Healthcare Governance has developed a Quality Curriculum for Trustees,24 which was developed to increase hospital board member knowledge of the quality imperative. This curriculum was created and piloted with the Massachusetts Hospital Association. Blue Cross Blue Shield of Massachusetts has supported the initiative and is offering incentives to hospitals after their trustees complete the six-hour quality improvement course.25

- **Risk assessment.** Health care boards must assess organizational risk. The board needs to review the quality of care provided by the organization and identify any quality of care failures. To help identify issues that could signal legal liability, the board should begin with an inquiry into the following issues:
  - Has there been a systemic failure by management and the board to address quality issues?
  - Has the organization made false reports about quality, or failed to make mandated reports?
  - Has the organization profited from ignoring poor quality, or ignoring providers of poor quality?
  - Have patients been harmed by poor quality, or given false information?

Although the federal and state regulations governing quality continue to grow, directors do not have to address these issues on their own. Enlisting the aid of outside attorneys or consultants to evaluate quality-of-care risk areas within their organizations can help boards to fulfill their fiduciary duties for quality of care.

- **Integrated analysis.** Boards must encourage the development of an integrated quality improvement and assessment system, which moves beyond case-by-case evaluation of past problems (e.g., a “bad apples” approach) to integrated analysis and use of retrospective data to identify high-risk patterns. As part of this analysis, boards should assess any medical necessity issues. In so doing, boards must be careful not to violate any state laws, including but not limited to all appropriate peer review protections. Therefore, it is imperative that an organization involve its counsel in this assessment process. To fulfill their leadership responsibilities, boards should frame and agenda for quality of care and communicate it throughout the organization by working collaboratively with senior management and health care practitioners. Quality improvement is likely to involve significant restructuring of key departments and processes to integrate quality compliance throughout organization. Therefore, joint planning with board members and medical staff

Continued on page 56
Editor’s note: This interview with Craig Morford was conducted in September 2008 by HCCA Board member Gabriel L. Imperato, Esq, CHC, Managing Partner, Fort Lauderdale offices of Broad and Cassel. Mr. Imperato may be reached by telephone at 954/764-7060 or by e-mail at gimperato@broadandcassel.com.

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GI: Craig, thank you for agreeing to this interview with Compliance Today. Please tell our readers a little about your background and the road you traveled to become the Chief Compliance Officer at Cardinal Health?

CM: After a brief stint as a trial attorney with the IRS, I was recruited in 1987 by the Department of Justice Organized Crime Strike Force to help prosecute international porn czar Reuben Sturmon in one of the largest criminal tax cases ever prosecuted. I spent the next 16 years prosecuting a wide variety of organized crime, white-collar fraud, and public corruption cases, including the RICO [Racketeer Influenced and Corrupt Organizations] prosecutions of Youngstown mob boss Lenny Strollo and U.S. Congressman James Traficant. After the Traficant case, the Department began assigning me to a series of ‘problem-management’ assignments.

In December 2003, I was appointed special counsel to the Attorney General when a federal district judge in Detroit ordered a comprehensive, independent review of the first post-9/11 terrorism case to go to trial. Based on my team’s review and recommendation, the court dismissed the convictions in that case, due to the government’s multiple failures to disclose exculpatory evidence. Nine months into that assignment, I was appointed to serve as interim United States Attorney in Detroit, where I helped assess and restructure that office.

In 2005, I returned to Cleveland, where I served as the First Assistant U.S. Attorney, overseeing all prosecutions in the northern district of Ohio. In 2006, I was appointed Interim U.S. Attorney in Nashville to address management and morale issues in that office.

Finally, in July 2007, during the time when the Department of Justice [DoJ] was besieged with allegations regarding controversial hiring and dismissal practices, I was appointed to serve as Acting Deputy Attorney General. In that role, I oversaw the day-to-day operations of the Department, acted in the capacity of the Attorney General during his absence, and supervised the 100,000+ employees of the Department and its subordinate agencies, including the FBI, DEA, and 93 United States attorney’s offices. Taking office at such a turbulent time, it was my top priority to foster public confidence in the Department and its policies, decisions, and actions.

In the spring of this year, I left the Department to join Cardinal Health as Executive Vice President/Chief Compliance Officer [COO]. In my current position, I oversee the areas of ethics and compliance, regulatory compliance, anti-diversion, pharmaceutical supply chain integrity, global trade, environmental health and safety, business continuity, and enterprise risk management.

GI: Tell us some of the ways your experience at the Department of Justice helped to prepare you for your duties as a corporate compliance officer.

CM: My experience with the Department of Justice was an ideal training ground for my duties and challenges as chief compliance officer of a Fortune 20 company. Indeed, I have found the corporate compliance field to be a perfect place to leverage the decision-making and leadership skills I developed over my 20+ years at the Department of Justice.

For example, as acting deputy attorney general, I generally confronted issues that fell into
one of two categories: (1) issues so significant that they required a decision at the highest level; and (2) issues so challenging that they could not be resolved at lower levels. A large portion of these were thorny ethical issues which frequently had no good answer and required a “least worst alternative” analysis. My experience dealing with these types of issues on an almost daily basis was ideal preparation for the analogous types of issues I deal with as chief compliance officer.

In addition, my deputy duties required me to represent the Department of Justice in matters involving multiple departments through the White House’s “interagency process.” Whenever an interagency issue arose, I would meet with my relevant division chiefs to gain an understanding of the issue and determine the DoJ’s institutional interests and equities. I would then weigh our equities and perspectives against those of the other departments (e.g., the Departments of State, Treasury, Homeland Security, Health and Human Services, etc.).

It was critical to understand the unique perspectives of each department in order to determine the best course of action for the nation as a whole. There is a powerful analogy between the interagency process and the things I do here as Chief Compliance Officer. Just as I was at the DoJ, I am regularly confronted with ethical, legal and regulatory issues that impact multiple departments – legal, human resources, finance and a variety of business units. In addressing these issues, I work collaboratively with the leaders of those departments to understand their siloed perspectives and arrive at solutions in the best interests of our customers, investors, employees, and the public-at-large. The context is different, but the drill is the same.

GI: What attracted you to the compliance profession in general and to Cardinal Health in particular?
CM: Let me start with the compliance profession. I receive a great sense of fulfillment knowing that I work for an organization dedicated to helping others and committed to doing the right things the right way for the right reasons. That sense of fulfillment attracted me to and kept me working at the DoJ for over 20 years. When it came time to move to the private sector, it was important for me to find a position that captured that same spirit. At the DoJ, I took great pride in knowing that I literally got paid to do the right thing. The same is true of corporate compliance. As compliance officers, we are paid to do the right thing and to equip and empower others to do the right thing.

I also view the Chief Compliance Officer position as a logical extension of my dedication to service. I believe that the economic well-being of our country and our communities is dependant upon our ability to maintain responsible companies that conduct themselves in an ethically compliant and appropriate manner. Chief compliance officers have the opportunity to promote corporate responsibility from the inside of a company in a way that is even more effective than a prosecutor who can only chip away at ethics from the outside.

Having decided to pursue a position in compliance, I chose to work at Cardinal Health because I embrace its mission; share our senior leaders’ vision of making Cardinal Health an ethics and compliance leader; and believe this position provides me a great opportunity to not only impact our company, but the health care industry as a whole.

With regard to mission, Cardinal Health is dedicated to making health care safer and more productive. It is a sad reality, but every one of us at some point will find ourselves standing in a hospital at the bedside of a loved one: a parent, a spouse, a child, a friend. And as we stand at that bedside, we want to know that the goods and services maintaining their lives are working properly. It matters that the IV drip delivering medication to our loved one is functioning properly. It is essential that the supply chain that delivers the medicine being given to our loved one is free of counterfeit and defective products. It is critical that our loved one doesn’t pick up an infection or mistakenly receive the wrong kinds or quantities of medication – two of the biggest risks plaguing hospitals today. I take great satisfaction in knowing that I work for a company dedicated to addressing these important issues.

Cardinal Health distributes one-third of all medicines and medical supplies used in the United States every day. We develop cutting edge technologies that help hospitals reduce the incidence of infection and medication errors. And we help health care providers throughout the chain of care operate as efficiently as possible, to free up their time to focus on patient care.

I take great satisfaction in knowing that I can impact the integrity of our medication supply chain and the quality of our medical devices. I also take great satisfaction in knowing that Cardinal Health’s senior leadership is committed to creating and sustaining a culture of ethics and compliance. In my first meeting with Cardinal Health’s CEO, Kerry Clark, we spoke for hours about the importance of
Meet Craig Morford  ...continued from page 15

this company’s mission and his desire to be a leader in ethics and compliance.

I was impressed by Kerry’s passion for the difference our company makes in peoples’ lives and his personal commitment to ensuring the company does the right things the right way. My interactions with our segment CEOs, our Board and our employees have only reinforced those first impressions. Cardinal Health is a company that wants to get it right and is looking for strong leadership to help ensure that we get it right. It is a tremendous opportunity to be able to help provide that leadership.

Cardinal Health’s powerful mission and strong commitment to enhancing our compliance culture provides the opportunity to build something special in the areas of ethical, regulatory, and legal compliance. In addition, because we’re a $90 billion health care company that touches virtually every facet of health care, we have a unique opportunity to impact the entire healthcare industry.

For example, in the last six months we have invested over $20 million to develop a premier system to monitor and block suspicious orders of controlled medications like hydrocodone and oxycontin. Our goal is to work with regulators and our competitors to develop consistent, effective, industry-wide standards that will effectively balance our industry’s duty to ensure that patients receive necessary medications in a timely, affordable, and safe manner, and our duty to protect our children and communities from the diversion of controlled medications by criminals.

**GI:** What were the circumstances which led you to prepare the Morford Memo at the Department of Justice on the selection and use of federal monitors in Deferred and Non-Prosecution Agreements with corporations?

**CM:** We developed the so-called “Morford Memo” because we needed to assure the public that our process for selecting corporate monitors in deferred prosecution cases was merit-based, avoided conflicts of interest, and was designed to select the most highly qualified and effective professionals possible.

A number of people were criticizing the existing process for selecting monitors. Some were calling for wooden, one-size-fits-all approaches. Others correctly noted that a one-size-fits-all approach would never work, because the facts and circumstances differed in each case. The nature and egregiousness of the misconduct and pervasiveness of the problem within the leadership of an offending corporation needed to dictate the qualifications of the monitor, and the degree to which an offending corporation could play a role in the selection process. Simply put, there had to be a flexible process to allow the selection of the right type of monitor in every case, while limiting the appearance of conflicts of interest, cronyism, or other improper selection factors.

The Memo outlined a process that provides maximum flexibility to select the right kind of monitor in every circumstance, while protecting the system from actual or apparent conflicts of interest, unnecessary bureaucracy, waste, and inefficiency. The purpose of appointing monitors is to protect shareholders and the public from waste, fraud, and abuse. The last thing we wanted to do was create a selection process that itself subjects those stakeholders to waste and abuse. Under the procedures set forth in the memo, monitor candidates are screened by teams of career prosecutors in field offices and then reviewed at the highest level in the deputy attorney general’s office in Washington to avoid potential conflicts at either end. The exact process used and extent of participation of the company is determined by the local office, based on the facts of each individual case. The system is flexible, practical, effective, and efficient.

**GI:** What advice would you give to someone who is just starting out as a compliance professional and implementing or maintaining a compliance program?

**CM:** First, I would emphasize the importance of focusing on the purpose behind compliance processes. When you deal with process, it is easy to become wooden in your approach and lose sight of the goals and purposes for which the process was created. This reduces compliance to mere “box-checking,” and promotes legalism and a mindset that compliance is merely a necessary evil that brings little value to the company. When you focus on the purpose behind a compliance process, compliance becomes goal-oriented and dynamic. People come to understand the value of the goal and are more likely to embrace the process.

Second, I would emphasize the need to remember that companies are made up of people. People are human. Humans make mistakes—all of us, all of the time. At Cardinal Health, we employ over 40,000 employees globally, so we are going to make mistakes.

The key is developing a corporate mindset in which people understand that complying with our ethical, regulatory, and legal obligations is a corporate priority from the highest levels to the most entry-level positions.

At Cardinal Health, we conduct business in a highly regulated industry, offering products and services that carry the potential to accomplish tremendous good or grievous harm. While we realize mistakes will sometimes be made, our goal is to minimize error by fostering a compliance culture and corporate mindset where people are dedicated to doing the right thing, are empowered to do the right thing, and, when mistakes are made, are quick to elevate those mistakes to the appropriate decision makers, so those mistakes can be promptly corrected.

Third, I would emphasize the importance of defining a clear mission, philosophy, role,
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GI: Are you a member of the Health Care Compliance Association or have you attended any of its numerous educational and networking conferences? If so, has this benefited you professionally and in what ways?

CM: I am a member and attended the 2008 HCCA Compliance Institute in New Orleans. As a new CCO, the Institute provided a great opportunity to network with other health care industry CCOs and provided a valuable overview of the varied issues I would soon face in my new position.
Closer to the edge
I have always tried to be careful in these articles. I have tried to minimize the number of calls from board members or members at large asking, “What were you thinking?” That has been difficult, because I feel that this column should be about substantive issues and not all about the CEO hyping the next conference or telling everyone about how great our organization is. I have written a few of those columns, but they have been limited. I have spent as much time as possible talking about issues and giving my opinion about the job of the compliance professional. It is hard to have an opinion about this stressful profession that does not bother someone. A lot of the details have not been worked out as to what professional or compliance program standards we will have. Some issues are very controversial. I often feel quite passionately, because I have held the role of compliance officer and spent the last twelve years of my life immersed in this profession.

I read an article about blogs today. Because our new Social Networking software has a blog feature, I was interested in what the article had to say. It said that CEOs of associations failed to get comments to their blogs because they did not talk about substantive issues. The author said the reason was obvious: the CEO was boring. All the CEO did was dither on about the next conference or how great the members and the board are. I worry a great deal about creating controversy every time I write an article. Now I am thinking about starting a blog. Do I need to get closer to the edge of controversy to make it work? Our board made a strategic decision to implement a social network for compliance professionals. I am going to participate; however, I am concerned that I may get too close to the edge in an effort to avoid being boring. Wish me luck. I hope that we get a number of members starting blogs or contributing questions and answers on the e-group list serves. A link to the Social Network is on the front page of our website. Check it out.

CEOs of associations failed to get comments to their blogs because they did not talk about substantive issues.

Our board made a strategic decision to implement a social network for compliance professionals.
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Assessing need in health care arrangements

By David M. Hyman, Esq. and Nicole F. DiMaria, Esq.

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Health care fraud and abuse compliance is often marked with uncertainty. Many aspects of fraud and abuse law are ill-defined, and those seeking to achieve compliance can be left with the uncomfortable task of making subjective judgment calls. One such ill-defined aspect of the law is the requirement that a health care arrangement be “reasonably necessary,” “commercially reasonable” or serve a “legitimate business purpose.” These and similar terms are often used in the federal Anti-kickback Statute safe harbors and federal Stark Law exceptions, but without regulatory definition. Formal governmental guidance and expert commentary with respect to the meaning of these terms are sparse.

In an industry that is constantly challenged to balance business and humanitarian motives with strict legal requirements, application of the “reasonably necessary,” “commercially reasonable” or “legitimate business purpose” tests in certain arrangements may be problematic. For example, in some arrangements with physicians, it may be difficult to differentiate between what may be beneficial for a medical center and its patients and what is “necessary.”

Compensation arrangements between hospitals and physicians for on-call coverage—which have greatly proliferated in recent years—may present such a scenario. Payment for on-call coverage can inherently incentivize physicians to make referrals to the hospitals with which they have such arrangements and can, therefore, present some difficult compliance issues. Certain on-call coverage may be mandated by law (and may be deemed “necessary” for that reason alone), but what about on-call coverage that is not clearly required by law? Such arrangements may increase the value and quality of the services offered by the hospital, but are they “reasonably necessary” as that term is used (e.g., in the Anti-kickback Statute safe harbor for personal services and management contracts)?

In order to make such a determination, it is helpful to review guidance/commentary from the Department of Health and Senior Services Office of Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) with respect to its interpretation of “reasonably necessary,” “commercially reasonable” and similar terms. This article highlights such guidance/commentary, with a focus on the OIG’s recent Advisory Opinion regarding on-call coverage.

**Anti-kickback Statute safe harbors**

OIG discussed the “commercially reasonable business purpose” test of the safe harbors for space and equipment rental and personal services and management contracts in its November 19, 1999 Final Rule. It clarified the initial OIG safe harbor provisions and established additional safe harbor provisions under the Anti-kickback Statute. OIG stated that “commercially reasonable business purpose” means the “purpose must be reasonably calculated to further the business of the lessee or purchaser,” and that purchased services must “have intrinsic commercial value.” OIG identified three factors to further demonstrate the meaning of this standard: the purchaser must (1) need, (2) intend to utilize, and (3) in fact, utilize the services in furtherance of commercially reasonable business objectives.

**OIG hospital compliance guidance**

In its Supplemental Compliance Program Guidance for Hospitals, OIG explained that hospitals should review the following factors (among others) to assess fraud and abuse with respect to their physician compensation arrangements:

- Are the items and services obtained from a physician legitimate, commercially reasonable, and necessary to achieve a legitimate business purpose of the hospital (apart from obtaining referrals)? Assuming that the hospital needs the items and services, does the hospital have multiple arrangements with different physicians, so that in the aggregate the items or services provided by all physicians exceed the hospital’s actual needs (apart from generating business)?

**Stark 1998 Proposed Rule**

CMS discussed the “commercially reasonable” standard of the Stark compensation-related exceptions in the Stark 1998 proposed rule, stating that it interprets the term 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.”

**Stark II, Phase I Preamble.**

CMS stated the following in the Stark II, Phase I Final Rule with respect to the “commercially reasonable” standard of the fair market value exception:

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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. In addition, we strongly suggest that the parties maintain good documentation supporting valuation.8

Stark II, Phase II Preamble

CMS provided the following explanation of the “commercially reasonable” standard of the personal service arrangements exception in the Stark II, Phase II preamble:10

An arrangement will be considered “commercially reasonable” in the absence of referrals if the arrangement would make commercial sense if 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 [designated health services] referrals.11

Advisory Opinion No. 07-10

OIG favorably analyzed a medical center’s arrangement for physician on-call coverage in Advisory Opinion No. 07-10. OIG explained that legitimate reasons exist for physician on-call arrangements, such as “compliance with EMTALA obligations; scarcity of certain physicians within a hospital’s service area; or access to sufficient and proximate trauma services for local patients.” Notwithstanding these legitimate purposes, OIG stated that “on-call coverage compensation potentially creates considerable risk that physicians may demand such compensation as a condition of doing business at a hospital, even when neither the services provided nor any external market factor (e.g., a physician shortage) support such compensation.” OIG clearly viewed the medical center’s need for the services to be of particular importance in issuing a favorable opinion. OIG found that the medical center demonstrated a “legitimate, unmet need” for the on-call coverage, stating that the medical center’s emergency department was “understaffed for lack of capable and willing physicians” and that the medical center consequently “resorted to the outsourcing of emergency care and other related treatment to other medical facilities.”12

Conclusion

The commentary above may be helpful, but it certainly does not exhaust the numerous questions that may arise in certain arrangements, especially those that are outside the context of a clear need created, for example, by a physician shortage or understaffing. In spite of the uncertainty in construing “reasonably necessary,” “commercially reasonable” and similar terms, it is quite clear that OIG and CMS expect assessments of need in health care arrangements to be made without regard to referrals or the generation of business between the parties. It is also clear that documentation of the need, particularly in the case of on-call arrangements, is invaluable. When faced with an absence of documented need, providers may find it useful to engage outside consultants to review an arrangement and provide a needs assessment report. ■

A special thanks to Wolff & Samson associate Nicole K. Martin, MPH, Esq. for her research and writing assistance.

1 See 42 U.S.C. § 1320a-7b (Federal Anti-Kickback Statute); 42 C.F.R. § 1001.352 (Federal Anti-Kickback Statute safe harbor).
3 See 42 C.F.R. § 1001.352(b).
4 See 42 C.F.R. §§ 1001.952 (b) (space rental safe harbor), (c) (equipment rental safe harbor) and (d) (personal services and management contracts safe harbor).
8 See 42 C.F.R. § 411.377(d) (fair market value compensation exception).
10 See 42 C.F.R. § 411.375(e) (personal service arrangements exception).

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Taking the deep dive into laboratory auditing and monitoring

By Jeff Sinaiko

Editor's note: Jeff Sinaiko is president of Sinaiko Healthcare Consulting, one of the nation’s leading independent healthcare management consulting firms. He works with healthcare organizations nationwide on a diverse range of compliance issues. For more information, please email jeff@sinaikohc.com or go to www.sinaikohc.com.

Having taken a brief break from this year’s series of columns on laboratory compliance to address some concerns with respect to organizational compliance culture, I want to return to the theme. The intent of this article is to build on the basics of laboratory auditing and monitoring previously discussed, and to provide additional thoughts and guidance on the deeper, more complex and unique aspects of laboratory compliance that are significant challenges for many organizations and their laboratory operations.

To recap the basics that we’ve already covered:

- Laboratory compliance auditing and monitoring is unique from other aspects of provider operations, requires specific experience and expertise to audit and monitor, and necessitates work plans that differ from other ancillary services;
- Laboratory coding and auditing require a level of knowledge and laboratory operations experience not generally maintained by most coders and compliance auditors;
- Laboratory compliance is fundamentally dependent on the “foundational” aspects of the process and operations, such as the Physician Request Forms or laboratory charge tickets, Physician Acknowledgement Forms with respect to custom panels, and the integration of such data with the intake and laboratory processing systems; and
- An even greater level of consistent physician and staff education is required to ensure both compliance and appropriate utilization of laboratory services.

With these tenets previously recommended as a base, I want to expand the discussion to include issues that all organizations and compliance officers should integrate into their ongoing compliance auditing and monitoring programs. These issues generally fall into two broad categories:

- Additional reimbursement compliance issues that can lead to receipt of inappropriate reimbursement and/or false claims risk; and
- Issues that impact quality and utilization or prompt payment.

Laboratory reimbursement compliance

In addition to the inappropriate use of custom panels and unbundling—which are clearly the most common and likely risks that we discussed in the previous article—the most common issues for compliance to address, audit, and monitor include the following.

Overuse/overbilling of panels

It is necessary to ensure that panels including multiple constituent tests are not being performed and billed repeatedly. This is essentially a medical necessity issue. It is only appropriate for physicians to re-order and for the laboratory to repeat and bill for the components of a given panel that are still of concern or that are abnormal. In fact, this is why the Office of the Inspector General (OIG) specifically recommends that all constituent analytes in a panel be separately identifiable on the requisition form, so a physician can order only those specific components.

This is an area that requires significant education and monitoring, because it is quite common and easy for physicians to simply continually reorder the same panel in its entirety, even when many of the components are not clinically necessary. Billing for such panels results in higher reimbursement than what would have been received for just the medically necessary components.

Charge Description Master (CDM)

Compliance should audit and monitor IT and/or the Reimbursement departments to ensure that reflex testing protocols are not “hard coded” into the system via the CDM, and therefore ensure that they are not billing for tests which were not actually needed or performed based on such hard codes in the system. In the “inside baseball” of the laboratory world (as our laboratory compliance leader, Dinh Nguyen, tells me), this is called “non-permissible pairing of driver and passenger CPT codes.” Payments may be denied if a Current Procedural Terminology (CPT) code in the CDM does not accurately describe or correspond to the particular methodology used to perform the test in question.

Professional services

An ongoing and somewhat controversial debate continues in the industry over whether or not hospitals and hospital-based pathologists can bill professional services for most hospital-based laboratory and pathology services. Until a significant change to the

Continued on page 24
Laboratory Compliance: ...continued from page 23

regulations is made, it should be clear that it is not permissible to bill for normal and routine review of laboratory results, which are otherwise part of the pathologists’ quality assurance obligations for hospital-based pathology. It is permissible to bill for surgical pathology, complex or borderline test interpretations, and/or for the reading of certain permissible high-complexity diagnostic tests.

Quality management
The Compliance department of any provider organization can and should have the ability to make a broader contribution to the organization. In this particular area of laboratory operations, Compliance can monitor issues that will be apparent in the data being otherwise reviewed (e.g., utilization data), but also can highlight other issues that need to be addressed.

For example, if tests are not precise, sensitive, or accurate enough, medical decision making can be impacted, treatment decisions can be erroneous, and the overall quality of medical care can suffer. As part of ongoing educational sessions and communications regarding the laboratory, physicians should be polled with respect to their experiences with the accuracy and consistency of test results, specifically identifying concerns they may have with respect to test accuracy and quality.

Moreover, laboratory directors should monitor the frequency of repeat or confirmatory tests because of poor accuracy, unreliable results, and the like. Deficiencies in this area may result in inappropriate or unnecessary confirmatory tests that could have been avoided through continuous evaluation of available test methodologies. Additionally, the ideal test menu should eliminate those methodologies known to result in an unacceptable level of false positive or false negative laboratory values. Otherwise, medical decision making may be adversely affected or result in unnecessary repeat testing.

For example, if a particular test methodology for total cholesterol and its fractions is not accurate or precise enough, falsely elevated levels may result in inappropriate or unnecessary prescribing of cholesterol-reducing medications with unwanted side effects. Conversely, a test methodology that results in falsely reduced levels may place the patient at risk of conditions associated with hypercholesterolemia.

In closing
As a final summary note to this series of articles, it is clear that ongoing interaction between the laboratory and the medical staff—as well as the Finance, Billing, and Quality Management departments—is crucial to optimal compliance, reimbursement, quality, and the mitigation of potential regulatory exposure.

I would be remiss if I did not thank Dinh Nguyen, our Senior Director of Compliance Services and resident laboratory expert, whose advice and guidance on these issues have been invaluable this year.

I appreciate all of your comments and responses to the columns this year. Hopefully, we have come a long way in the specialized field of laboratory compliance, yet it is clear we have a number of opportunities for improving the way this important component of health care is managed in the future.
What employers really want from employees

By Maurice Gilbert, CPA

Editor’s note: Maurice Gilbert is the Managing Director of Conselium, an executive search firm with a core expertise in corporate compliance. He can be reached by e-mail at Maurice@conse-lium.com or by telephone at 972/934-8444.

What’s the secret to being the perfect job candidate? I get this question a lot, and after more than a decade in the executive search field—a time that has seen economic boom and bust—the answer hasn’t really changed.

There’s no one thing employers are looking for in their ideal employee. Rather, they’re looking for a combination of skills and, just as important, character traits that when combined, make for a productive valued employee.

Of course, individual jobs have different requirements, and the skills and traits listed below won’t be of equal importance in every job (leadership may be more important than computer literacy, or vice versa, depending on the position). Nevertheless, the skills and traits listed below are a good run-down of what my corporate clients are seeking.

Skills

The items in this section are skills that can be honed and developed over time and with practice. I’ve included at the bottom of this article some of my favorite resources for boning up on some of the more critical skills. I highly recommend that job candidates focus as much time on making sure they bring the proper skills to the table as they do polishing their résumé. The skills most employers look for are:

- **Communication.** There’s no job for which good communication skills aren’t absolutely critical. The ability to present your ideas clearly and persuasively, whether in writing or orally, is fundamental to just about any great job. And what many people might not tell you is that excellent writing and speaking skills—which contribute so much to making a good first impression—can make up for less-than-sparkling credentials in other areas. Unfortunately, this is also the skill that many otherwise qualified candidates frequently lack.

- **Organization.** Employers want to know that the candidate they’re interviewing has his/her act together, that appointments won’t be forgotten, balls won’t be dropped, and important tasks won’t fall through the cracks. They want to know, in essence, that their potential employee is organized. This means having the ability to manage several projects at once without getting flustered, and the ability to prioritize tasks and obligations.

- **Interpersonal skills.** How many times have you said to yourself “I wish I could spend more time with boring, self-involved, tedious narcissists?” Me neither. Employers are pretty much the same. They like to hire people they like, plain and simple. This means being a good listener, being genuinely interested in others, and being able to make small talk when appropriate and “big talk” when the time comes.

- **Problem-solving.** The ability to problem-solve is the gift that keeps on giving. Problem-solvers are go-to employees. They’re the ones who have the ability to look at any problem, from the mundane to the truly vexing, see it with fresh eyes, and come up with the solution that is at once painfully obvious, but one that eluded everybody else in the room. Employers, clients, everybody loves problem solvers.

- **Research/analysis.** With so much information coming at us every day—from the Internet, magazines, newspapers, television, and other sources—the ability to locate, sort through, and synthesize information is highly valued. Employers are looking for candidates who have the ability to discern what’s important, disregard what’s not, and make decisions based on the information available.

- **Computer literacy.** Unless the job is a highly technical one—like an IT manager or a computer programmer—“computer literate” doesn’t mean the candidate needs to be able to write code or answer every computer question thrown at them. It does mean, however, a basic familiarity with standard word processing, spreadsheet, and possibly database and desktop publishing software. Additionally, the ability to send e-mail and navigate and research the Internet is a must.

- **Flexibility/ability to multi-task.** They say the only constant is change, so a good job candidate is one who can move easily from one game plan to another without getting flustered. Additionally, employers want workers who can handle more than one (or two or three) tasks at a time without dropping balls.

- **Leadership skills.** Granted, not every employee needs to be CEO material, but nobody wants a shop full of order-takers either. An ideal job candidate is one who has a proven history of “taking ownership” of projects and the ability to motivate teammates and subordinates to do their very best.

- **Diversity awareness.** Regardless of your skin color, gender, or religious background, chances are you are going to be working alongside or for someone of a different skin color, gender, or religious background. An ideal employee doesn’t just tolerate those with different backgrounds from his own; he embraces diversity and the benefits it can bring to the finished product.

- **Ability to work as part of a team.** Everybody loves a star performer, but it’s just as important to be a valuable team-

Continued on page 28

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What employers really want from employees  ...continued from page 25

mate, the one who sets up the shot or keeps the quarterback from being sacked. The ideal job candidate has a history of helping those around him do their best.

I’ve met very few candidates who score one hundred (or even ninety) on every one of the skills I’ve listed. Most everybody can use some brushing up on one thing or another. After all, very few people are born computer literate or as polished public speakers. Those things come only with time and practice. Below are some or my favorite resources for improving the skills employers are looking for:

■ The 7 Habits of Highly Effective People, by Stephen Covey
■ Leadership, by Tom Peters
■ How to Win Friends and Influence People, by Dale Carnegie
■ Getting Things Done, by David Allen
■ Toastmasters, a non-profit organization that meets in small groups to help members improve their communication (particularly speaking) and leadership skills, www.toastmasters.org.

Character traits

Good character is arguably more important than any skill set a job candidate can put on his/her résumé. After all, what use is an experienced corporate compliance officer if she never gets to work on time or never does what she says she’ll do? Unfortunately, I can’t direct you to a great book or executive training program that can instill good character. I’m afraid these things typically start long before candidates enter the job market. If you suspect, for example, that you’re irresponsible or lack integrity, that’s probably something you’ll want to work on, independent of any job search. Nevertheless, these are the qualities employers look for in a strong job candidate:

■ Responsibility: This is everything from consistently being at work on-time to taking responsibility for your own actions. Although we’re more likely to use this word when talking about teen-age drivers and babysitters, responsibility is a quality every employer wants in an employee.

■ Positive attitude: The late Randy Pausch, in his recent bestseller The Last Lecture, put it best when he said we all have the choice to be either positive, glass half-full Winnie the Poohs or pessimistic, down-in-the-mouth Eeyores. Not only is life more fun for the Poohs, but they’re more productive employees and more inspiring leaders.

■ Strong work ethic: Employers aren’t slave drivers (at least most of them aren’t), but they want to know that their workers are putting in an honest day’s work for an honest day’s pay. If you’re spending more time on Facebook than you are preparing your quarterly report, or if you’re shopping you when you should be meeting with clients, you’re not a good bargain in anyone’s eyes.

■ Professionalism: This includes everything from dress and demeanor to language and behavior. An ideal job candidate is one who looks polished and can hold her own at cocktail parties and expensive restaurants, not one who tells off-color jokes around the office and makes a spectacle of himself at the office holiday party.

■ Integrity: Do you do what you say you’re going to do? Can you be trusted with confidential information? Are your expense reports truthful and reasonable? Employers want someone who can honestly answer questions like these with a resounding, “Yes.”

■ Adaptability: An ideal job candidate is one who can quickly shift gears and be resilient and thoughtful in the face of multiple, shifting priorities and even crises.

■ Loyalty: Employers want workers who will stand by them, even when times are tough. They want employees who don’t badmouth them or their co-workers, who believe in the company’s mission—whether it’s providing healthcare or building cars—and who bring that passion with them to the office every day.

■ Self-confidence: Call it poise, confidence, or charisma, but the ideal job candidates carry themselves with a certain something that inspires others to trust them. Granted, much of this comes from actually being good at your job. But even the most competent workers can be undercut by their own lack of confidence.

■ Self-starter: Companies are always on the hunt for workers who don’t need to be told what to do before they do it. In a tough economy, in particular, employers want employees who see a need and fill it, who think “outside the box,” and who don’t wait around for a problem to become a crisis before they act on it.

■ Hungry to learn. As any teacher will tell you, the best students are those who can’t wait to sink their teeth into something new. The ideal job candidates aren’t afraid to work outside their comfort zone. They are always looking for the next challenge, and are anxious to dive into new projects and learn new things.

Now, I’ve thrown a lot at you, and you’re probably wondering if anybody can fill all these requirements. I can tell you with confidence that, if that person exists, I have yet to meet him or her. I share this information with you, not to overwhelm you, but to tell you what qualities employers are looking for.

Smart job candidates will examine the list, see where they are strong, and play to those strengths. They won’t ignore their own weaknesses, however. It doesn’t matter if you’re young or old, with thirty years under your belt or fresh out of graduate school—there’s always room for improvement.
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One might think that the current financial market turmoil has slowed mergers and acquisition (M&A) activity; however, M&A activity in the health care industry still remains quite active, especially with the middle market transactions of less than $500 million. Not surprisingly, analysts expect for-profit health system M&A activity to begin to take a back seat to not-for-profit organization activity, in part because there is less credit available from private equity firms for the for-profit systems. Thus, the large not-for-profit health systems with strong credit ratings are expected to continue to be strategic acquirers.

Whether your organization is in an aggressive, slow, or planning mode of expansion (the buyer), or whether your organization is in the process of being acquired (the target), the compliance officer is a key member of the due diligence team and should play a central role in a variety of due diligence activities in the M&A process. We have selected five areas the compliance officer should consider focusing on during an M&A transaction: compliance program, relationships with health care professionals, cost reports, third-party reimbursement, and documentation, coding, and billing.

**Compliance program**

The more traditional areas of due diligence focus (e.g., financial performance, debt ratios, accounts receivable, market share) are typically addressed with a good deal of scrutiny. Unfortunately, the compliance program rarely receives the same level of scrutiny before a merger or acquisition decision is made, even though an ineffective compliance program that fails to identify regulatory non-compliance can significantly affect the outcome of a merger or acquisition and can create financial risk. Oftentimes, compliance program issues can be just the tip of the iceberg and suggestive of greater issues that are below the surface. Failure to properly focus on non-financial, broader concepts such as governance, ethics, culture, and compliance—before a merger or acquisition deal is inked—can pose substantial risk to the buyer.

Compliance program due diligence procedures should include performing an assessment of the effectiveness of the target organization’s compliance program by focusing on the compliance program’s operations as they relate to compliance program guidance from the Federal Sentencing Guidelines and the Office of Inspector General (OIG). The Federal Sentencing Guidelines instruct that the following seven elements are fundamental for an effective compliance program. OIG has supported these elements in its compliance program guidance issuances:

- Developing and implementing written policies, procedures, and standards of conduct;
- Designating a compliance officer and compliance committee;
- Conducting annual training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.

Although not all inclusive, when conducting compliance program due diligence, consider starting with the following activities:

- Review the target organization’s most recent Securities and Exchange Commission (SEC) filings (if the organization is publicly traded) and identify the disclosed regulatory compliance risks. If the target is a not-for-profit organization, require the target to
If the compliance function is de-centralized, is there a dotted line or informal reporting mechanism to a chief compliance officer?

Determine if the compliance function is centralized or de-centralized. For example, is there one compliance function that has oversight and board reporting responsibilities for the entire health system? Or is there an independent compliance function for each entity that is responsible for its own independent reporting of compliance activities and board reporting.

If the compliance function is de-centralized, is there a dotted line or informal reporting mechanism to a chief compliance officer?

Review compliance program-related documentation and conduct interviews with key personnel involved with the compliance program. The structure of the M&A transaction and the structure of the target’s compliance program will dictate the focus of the compliance review. Things to consider include:

- Evaluate the compliance program resources—fiscal and personnel—including whether the program has adequate fiscal resources and whether the personnel are qualified.
- Review the compliance programs annual compliance plans for the past two years, including how robust the plan is and whether the plan was adequate and met.
- Review the internal and external compliance auditing and monitoring results, including the effectiveness of corrective action.
- Review federal and state investigation results and survey results and the target’s handling of investigations and survey findings.
- Review the types and frequency of hotline calls and the target’s process and outcomes of investigating calls.
- Read the Compliance Committee minutes and board reports to evaluate the effectiveness, leadership, and stature of the compliance officer and the effectiveness of the Compliance Committee and reporting structures for the compliance officer.
- Evaluate the completeness of the compliance program policies and procedures, code of conduct, and training and education programs.
- Confirm board and senior leadership commitment to a culture of compliance.
- If your organization is planning on purchasing a health system with more than one entity, consider reviewing the compliance programs for all entities to be acquired and the home office or corporate program.

Determine if the compliance function is centralized or de-centralized. For example, is there one compliance function that has oversight and board reporting responsibilities for the entire health system? Or is there an independent compliance function for each entity that is responsible for its own independent reporting of compliance activities and board reporting.

If the compliance function is de-centralized, is there a dotted line or informal reporting mechanism to a chief compliance officer?

In general, the buyer should do sufficient due diligence to obtain a solid level of comfort that the target has an effective compliance program so that the target has or would have identified compliance issues, if such issues exist. Compliance program issues identified during due diligence, in particular issues that have financial implications, should be vetted with legal counsel and addressed by the target to the satisfaction of the buyer prior to finalization of the merger or acquisition.

**Relationships with health care professionals**

The proper delivery of medical care generally requires health care companies to enter into a broad range of financial and other relationships with health care professionals and/or providers (HCP). The evaluation of a potential M&A transaction may be significantly influenced by potentially material and complex legal issues that may arise from the arrangements by and between a health care company and HCPs. Thus, the compliance officer for both the buyer and the target should ensure that the M&A due diligence process includes an appropriate evaluation of the relationships of the other party with HCPs and other practitioners or businesses that are in a position to influence the volume or value of the business generated by the target.

The evaluation of significant compliance issues that may arise under arrangements with HCPs should constitute a key element of the compliance officers’ performance of due diligence activities during both the M&A decision-making process and the post-closing integration of the target’s compliance function with the buyer’s compliance program. The regulatory framework imposed on HCP arrangements includes state and federal laws relating to anti-kickback, self-referral, false claims, and other related laws, rules, and regulations. These are all areas typically under the watchful eye of the compliance officer, who is well positioned to conduct the due diligence activities in this area.

The buyer’s failure to properly identify HCP-related compliance issues during the due diligence phase may result in severe financial and regulatory consequences which can include:

- repayment of prior collections,
- Are compliance policies, procedures and other compliance-related documents standardized, based on one compliance program manual and code of conduct, or are there different manuals and codes of conduct for each entity?
- How is compliance-related information (e.g., internal and external audit results, hotline calls, government investigations, training content) shared and communicated across the entities?

Continued on page 33
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What every compliance officer should know about M&A due diligence  ...continued from page 31

- fines for each claim that is improperly submitted,
- exclusion from the Medicare or Medicaid programs,
- loss of tax-exemption or imposition of intermediate sanction excise taxes for tax-exempt organizations, and
- numerous other contractual, administrative, civil and criminal fines and penalties and other sanctions.

The potential consequences resulting from improper HCP arrangements may adversely affect both the buyer and the target. For example, the failure to properly identify issues relating to the buyer’s HCP relationships may hinder the buyer’s ability to participate in the transactions and/or otherwise expose the target (or the assets of the target) to the buyer’s contingent liabilities. The target’s HCP relationships may create significant exposure for the buyer with respect to any relationships that are assumed by the buyer and/or otherwise imposed on the buyer following the M&A transaction under various legal theories (e.g., successor liability, piercing the corporate veil, etc.).

Recent legislative developments and enforcement efforts further emphasize the potential conflicts of interest and compliance issues that may arise from financial relationships by and between HCPs and health care or life science companies. Accordingly, the need of the compliance officer to carefully review HCP relationships takes on even greater significance in light of potential increased regulatory scrutiny of such arrangements.

In order to evaluate compliance risk, the compliance officer should carefully coordinate with it’s legal counsel, professional advisors, and other members of the due diligence team to assure that the M&A due diligence properly identifies and evaluates the HCP arrangements. This review should include a consideration of the following items relating to HCP arrangements:

- Effectiveness of the target’s compliance function relating to HCP arrangements such as: (1) policies and procedures; (2) monitoring and auditing activities; (3) investigation of compliance issues, including the conduct of internal investigations; (4) disciplinary actions and/or implementation of corrective action plans; and (5) use of attorney client privilege in connection with the exercise of the compliance function (i.e., broad use of attorney-client privilege may indicate the lack of independence of compliance and legal functions or that compliance function may be subordinate to Legal).

- Ongoing management and administration of HCP relationships, including assessment of practices relating to: (1) review and approval of relationships process; (2) fair market value determinations; (3) conducting needs assessments; (4) budgetary oversight of payments to HCPs; and (5) ongoing management and administration (e.g., review of time keeping records to verify services rendered, existence of a contract management system).

- Meeting disclosure and reporting requirements relating to HCP arrangements, including those imposed by the IRS with respect to employment or independent contractor settings (Form 1099).

- Addressing legal and compliance issues identified by legal counsel and professional advisors in connection with the review of the HCP agreements.

- Assessing loss contingencies relating to (1) litigation or threatened claims relating to HCP arrangements; (2) current or planned internal investigations; or (3) other items identified during other phases of due diligence (e.g., billing, coding and collection practices, and coding practices).

- Identifying and addressing conflicts of interest arising from relationships by and between HCPs and the company (and any potential conflicts that may arise between HCPs and the other party as a result of the proposed M&A transaction).

- Understanding the nature of any unwritten arrangements that provide a benefit for HCPs (e.g., provision of meals, travel, or lodging; provision of management or other services at no charge or below market; etc.).

- Other evidence or documentation relating to the level of compliance relating to HCP arrangements (e.g., statements of management).

**Cost reports**

A health care provider’s direct financial ties to cost reporting have diminished over the years. However, compliance and financial risks related to the provider’s cost reporting function still remain, and the compliance officer is typically very knowledgeable with these risks. The government’s reliance on cost report data to develop and update payment rates is one reason the Centers for Medicare and Medicaid Services (CMS) requires accurate and timely filing of provider cost reports. For some providers, significant reimbursements continue to flow through the cost report. With the retrospective nature of those reimbursement components, settlement adjustments and their effects on future cash flows can be difficult to predict.

A buyer’s due diligence should include a review of the compliance risks associated with the target’s cost reporting function. The compliance risk generally applies to all provider types (e.g., hospitals, skilled nursing facilities, home health agencies, etc.). The financial risk will vary

Continued on page 34
by provider type based on the reimbursement system employed. With many prospective payment systems in place for most provider types, the cost reports for providers other than hospitals may not have a direct impact on the provider’s revenue. However, many hospitals still receive significant reimbursements through various add-on formulas that continue to have a retrospective settlement component.

When conducting due diligence, the first step is to gain an understanding of how the provider’s cost report function is organized. If the provider is part of a system, the cost report responsibilities may reside at a corporate level.

Stand-alone facilities may have a dedicated department at the provider site. In either case, their responsibilities could vary, but may include compiling the cost report, monitoring settlements with Medicare and other payers, and recording financial entries to reflect this activity. Interviews with target management personnel who are responsible for the cost reporting function are necessary to assess the organization’s overall cost reporting compliance efforts, to gauge the level of attention to the review and monitoring process, and to help the buyer develop a strategy to integrate these responsibilities into their own operations.

Other topics to include in target personnel interviews include the number of open cost reports subject to settlement, the number of appeals and amended cost reports pending, and any regulatory investigations that may be underway. It is common for the Fiscal Intermediary to issue its final settlement for a specific cost report two years after the related fiscal year end. If the Fiscal Intermediary is three or more years behind in issuing settlements, there may be higher risk that issues are in dispute over certain reimbursement principles. Further investigation by the buyer may be necessary to determine how the financial impacts of any disputed items are reflected in the provider’s financial statements.

Providers with more complex reimbursement components may have a number of appeals related to their prior year cost reports. The backlog on appeals may be substantial. If a hospital prevails in its appeal, the result may be significant revenue recognition in the year the appeal is settled. Providers may also have other amended settlements pending that are outside the formal appeal process and may also be significant. Evaluation is necessary to determine the implications on other cost report settlements, or on future reimbursement rates. For example, if a base-year cost report is amended to correct an error, the amended base year could result in a change in expected reimbursement for future years, even though the change in reimbursement is not yet reflected in subsequent cost reports. All of these issues can affect target’s future revenue stream.

### Third-party reimbursement

The general financial risk associated with a provider acquisition can be better managed by gaining an understanding of the future revenue streams expected from government payers. An accurate picture of future earnings is necessary to evaluate the purchase price for the transaction. Even if the transaction is not a formal purchase, or the purchase price is fixed, the acquiring entity will need an accurate picture of future cash flows in order to develop any meaningful financial planning which may include initiating new or refinancing existing debt.

Future revenues are usually estimated based on the provider’s historical financial results adjusted for anticipated changes in volumes and payment rates. Adjustments are also necessary for one-time or unusual events. For example, if a provider settled a number of prior cost report appeals resulting in significant revenue recognized in the most recent fiscal year, it will be important to remove the prior year revenue from the baseline, because similar amounts will not be expected in future years.

A good baseline for revenues received from governmental payers is dependent on the accuracy of the provider’s estimate of settlements on open cost reports. Year-to-date settlements are more subject to management judgment because many of the year-end cost report factors are not compiled until the fiscal year is complete. Many complex reimbursement formulas are associated with some Medicare add-on payments. The buyer’s due diligence should include analytic comparisons and testing on all of the formulas and factors used in management’s estimates.

The analysis should include all cost report years that are open and subject to settlement, including the current year-to-date accrual.

Cost reports settlements are generally reported in the general ledger “due to/due from” accounts and consolidated into one amount on the balance sheet. Activity within these accounts can be generally categorized in two ways:

- **Lump sum payments.** These are payments made to or from the provider during the year and are generally balance sheet-only transactions that have no effect on revenue recognized in the income statement.
- **Changes in estimates.** These transactions will usually have an effect on the income statement. For example, CMS may update a factor used to compute a Medicare add-on payment which will change the expected settlement on a cost report. If the update increases the expected reimbursement, then a larger receivable will be recorded on the balance sheet and an increase in revenue will be recognized on the income statement.
Buyer’s due diligence should include a review of all activity in the “due to/ due from” accounts to identify the net changes in estimates that may be reflected in the baseline revenues. Changes in estimates related to prior year activity must be removed from the baseline, or “pushed back” to the related year in question. When revenue has been reclassified into the years in which it should have been recognized (based on hindsight analysis), trending forward to estimate future revenues will be more accurate.

In addition to reviewing the activity within the “due to/due from” accounts, the ending balance should also be reviewed for reasonableness. This review should include a general assessment of the level of conservatism built into the balances. It is common in the health care provider industry for estimates of settlement to include a certain level of conservatism to account for unknown adjustments that the Fiscal Intermediary may include in their final settlement. A reserve amount may be reported based on historical error rates in general or for each open cost report. Reserve policies will vary for different providers based on their complexity or based on management’s judgment. A significant change in the reserve policy must be assessed to determine if it represents a change in estimate which may also result in adjustments to the baseline.

After adjusting for prior year revenue issues as described above, the buyer will have a better reference point for future revenue projections. However, it is also important to be able to estimate the revenue effects related to changes in legislation that may affect future government payment systems. For example, a state Medicaid agency may revise or discontinue their supplemental payments for charity care or medical education. The revised level of funding will need to be reflected in the future revenue projections.

The due diligence process described above will help address the financial risks associated with the cost reporting function. In addition to risk mitigation, the due diligence process may also identify areas of opportunity not previously recognized by the target’s exiting management. Opportunities are more likely to be uncovered through a more detailed analysis, including in-depth interviews with management to fully understand the variables they have used in their historical cost report claims.

Documentation, coding, and billing

Services provided at any health care entity are reimbursed based on documentation, coding, and billing. The compliance officer is often keenly aware of the requirements in this area and is well positioned to lead the due diligence activities necessary to assess the target’s knowledge and compliance with documentation, coding, and billing rules and regulations as set forth by various governmental entities.

Inadequate documentation, inaccurate coding, and inaccurate billing place an entity at risk for legal exposure. Inappropriate coding and billing can be linked to fraud and abuse, leading to overpayments from the government and insurance companies. Coding and billing errors that are determined to represent a fraudulent claim can subject an entity to penalties that include treble damages and civil fines that range from $5,000 - $10,000 per false claim under the False Claims Act (FCA).

Although the basis for reimbursement (documentation, coding, and billing) is the same across all health care entities and all types of services, the guidelines, restrictions, and applicable laws will differ depending on the type of entity and/or service. Regulatory requirements, as well as payment systems and/or methodologies, correspond to the type of entity where services are provided, as well as to the types of services provided. When planning the documentation, coding, and billing due diligence, it is important that the buyer has a clear understanding of the types of services that the target provides, so that the due diligence process includes the application of the appropriate rules and regulations.

The due diligence process is consistent across the various types of services and/or entities being evaluated. The process begins with selection of a pre-determined set of paid claims. Many insurance companies follow Medicare guidelines regarding coverage and reimbursement for services. As such, the documentation, coding, and billing evaluation for M&A transactions often focus on an evaluation of Medicare paid claims.

Once the claims sample is decided upon and selected, a request is made for all documentation associated with the selected claims. The documentation request should include all patient care record documentation, the detailed bill generated by the provider of service, the health insurance claim forms completed and submitted to third-party payers for reimbursement, and the remittance advice (RA) that details reimbursement information per payer.

Patient care record documentation is evaluated to determine whether services have been appropriately documented as required by regulatory guidelines. Documentation is also evaluated to determine whether the services in question met medical necessity requirements as mandated for reimbursement.
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The focus of the coding and billing analysis is to assess the degree to which:

- Charges billed on the insurance claim form are consistent with the charges on the detailed bill and with the physician orders and documentation in the patient care record;
- Diagnoses described in the patient care record are appropriately coded with ICD-9-CM diagnosis codes;
- Procedures described in the patient care record are appropriately coded with CPT-4/HCPCS and/or ICD-9-CM procedure codes, charged, and billed;
- Appropriate coding guidelines are utilized and consistently applied to the types of services provided; and
- Expected reimbursement has been received from third-party payers.

If issues are identified, root causes and unfavorable trends can be revealed by conducting interviews with key stakeholders. The director of Health Information Management (HIM), the director of Patient Financial Services and representatives from the professional coding staff can provide insight into an entity’s documentation, coding, and billing practices as well as into issues that may be discovered during the assessment. Discussions can reveal whether staff responsible for the coding and billing process have received adequate training and have access to the proper resources to perform their jobs properly.

The due diligence effort may seem herculean, but with a seasoned compliance officer leading the due diligence in the areas under his/her purview, the buyer should be in a much better position to understand the compliance risks, and resulting financial implications of those risks that the buyer would be inheriting from the target. Furthermore, the buyer would have a better understanding of the level of effort that will be needed to integrate the target into the buyer’s business. All these factors should be components in determining the purchase price, which is ultimately negotiated.

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1 “M&A Trend: No Big Deal; Tight Credit Could Make It Tougher to Finance Large For-Profit Acquisitions Like Those That Made Headlines the Past Two Years,” Modern Healthcare, January 21, 2008.
Your first 100 days

By Jay P. Anstine, JD

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Starting a new job is often a little overwhelming, especially when you are new to a profession. With constantly changing regulations and never ending operational adjustments, the world of a compliance officer seldom has time for rest. Added to that is the fact that when joining an organization, you pretty much need to hit the ground running. “What do I do first? Where do I begin? This should be a breeze—oh wait, this is more work than I thought. What was that person's name again?”

If those are at least some of the thoughts you are having, you are not alone. Whether you are joining an existing compliance program or establishing a new one, this article will assist you in prioritizing those first 100 days as a new compliance officer.

Brainstorm

Regardless of whether you are joining an existing program or creating a new one, the first thing you will want to do is spend some time brainstorming. Generally speaking, you should think about: the organization, your role as compliance officer, and what information you need to review in order to get up to speed. These main topics will provide you with a good starting point.

In brainstorming, you will want to sit down and literally put pen to paper (or use a computer) and evaluate what you will need to know. Because brainstorming can often be random in nature, make sure you capture fleeting thoughts as you think of them. To accomplish this task, it might be a good idea to make several categorized files or folders in which to jot down information. Some examples of categories might include:

- Operational questions to ask other staff members
- Areas to research further to determine risk
- Possible work plan projects
- Documents to be reviewed

For existing programs, you want to evaluate the current program, including thinking about who to talk to within the organization to help with your evaluation.

While brainstorming, there are specific questions you may want to ponder including:

- What is the business structure and culture of the organization?
- What services does your organization provide? (e.g., hospital inpatient, outpatient radiology, cardiology, neurology, etc.)
- With what payers does the organization have contracts?
- What are the various departments in the organization?
- Do we provide services in more than one state?
- What federal, state, and local regulations do I need to know?
- Does the organization have operational policies or do they need to be created?
- What compliance-related education has been done in the past (HIPAA, safety, harassment, etc.)?
- Do employees know how to report a compliance issue?
- Are there any past or current investigations or issues with regulatory agencies (e.g., any Corporate Integrity Agreements [CIAs], Joint Commission violations, State violations, etc.). CIAs are often negotiated between healthcare providers and the Department of Health and Human Services-Office of Inspector General (DHHS-OIG) as part of the settlement of federal health care program investigations. A provider typically consents to compliance obligations as part of the civil settlement and in exchange for the OIG’s agreement not to seek an exclusion of that health care provider from participation in Medicare, Medicaid, and other federal health care programs.

This is not an all-inclusive list, but these are just a few questions to get you started.

If you are joining an existing program, some of this information should be readily accessible. If you are establishing a new program, some information may require further research and discussion with other key staff members. Keep in mind that it will take some time before all these questions can be answered, so you will need to be patient and prioritize your “need to know” information. Also, be cautious about the accuracy of the information you receive when relying on discussion with staff members. Some information could be skewed when taking into account prior history and relationships.

Get to know the organization

After brainstorming, focus on understanding as much about the organization as possible. Even if you are familiar from past experience with the services offered, each organization is different logistically in how they provide those services.

To accomplish this task, you will need to get to know the operations and the people.

Continued on page 41
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Because a health care entity could employ 15 people or 15,000, your approach to learning the organization will vary. As your schedule permits, you should identify the key players within the organization who can provide useful information (e.g., the CFO, business office director, HR director, clinic manager, etc.). You will need to understand what their roles are in the organization and what influence they have within the scope of compliance. Have them walk you through their job responsibilities and the functions within their departments. Because your eventual concern will be whether the organization’s processes are compliant, taking the time now to learn how the organization does business and who the key players are will assist you later. It will also aid subsequent one-on-one communications to effectively address staff concerns as they are presented to you, and in conducting any future auditing, monitoring, and investigations.

When meeting with organizational staff, you may find it helpful to outline or flowchart the various operations. This endeavor will give you a better understanding of the relationships between departments within the organization. Lastly, if time allows, you may find shadowing some staff members helpful, particularly if you are new to the services offered by the provider or you have little or no clinical background.

The old adage of “you truly don’t know a person until you have walked a mile in his/her shoes” certainly applies here.

**Document review**

As part of getting to know the organization, you will also need to juggle your time, engaging in extensive document review. In addition to expanding your knowledge of the organization itself, this endeavor will also benefit you in formulating questions to ask staff as you move through departments. You will want to focus on two primary areas: operational documents and regulatory guidance. Specifically, some generic documents to consider reviewing include:

- A compliance plan (if available)
- A code of conduct (if available)
- Any compliance educational materials
- Any Corporate Integrity Agreements (CIAs) or violation documentation submitted by regulatory authorities (e.g., Joint Commission, OIG, DoJ, etc.)
- Organizational charts
- Business entity documents (articles of incorporation, partnership agreements, etc)
- Service agreements
- Payer agreements (commercial and government)
- Operational policies and procedures
- State, local, and federal regulations

Additionally, you will want to become familiar with any applicable Fiscal Intermediary (FI) and Carrier websites for guidance on medical necessity, billing, and coding issues. FIs are for hospitals/facilities (Medicare Part A); Carriers are for Medicare Part B. Steps are being taken to integrate FIs and Carriers in the future, so eventually both may be housed under the same website. You will also need to become familiar with the CMS website (http://www.cms.hhs.gov/), the OIG website (http://www.oig.hhs.gov/) and your specialty’s association/society website(s).

Although the above list is not intended to be all-inclusive, it will give you a starting point from which to work, relative to your organization’s size and operations. Reviewing this information will give you insight into the structure of your organization, the services offered, the reimbursement policies in place, and the regulatory guidance applicable to your facility.

The appropriate executive director or high-ranking financial officer should be able to provide these operational documents and help you locate others. Regulatory guidance information can likely be provided for you, if you are coming into an established compliance program. You should conduct your due diligence though, in making sure you have all the applicable regulations. If you are establishing a new program, you will need to do some research to identify what regulations apply to your organization. To save time, a great starting place would be visiting applicable trade association websites, especially if you work in a specialized area. Often these associations will have listed all applicable regulations that affect a particular trade. From there you can go to whatever website (federal or state) that has the official listing of regulations to ensure your research is accurate. You can also try searching online through general search terms.

With an existing program, you will also want to evaluate the status of the various measures in place to meet the requirements of the OIG Compliance Program Guidance for an effective compliance program (a.k.a, the Seven Elements). For example, was there a compliance officer previous to you and a compliance committee in place? Likewise, if you are creating a new program, you will want to make your first efforts to establish a compliance program that follows the seven elements.

**Establish a reference library**

In addition to learning the organization and reviewing documents, you will also need to establish a reference library, both hard copy and electronic. If you are creating a new program, determining what resources you will need should also be part of your brainstorming process. If you are joining an existing program, some of that information should be readily accessible. Below are some useful reference materials; depending on your available budget, some of the items mentioned can be found for free on the Internet.

*Continued on page 44*
Health Care Compliance Association’s
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Baltimore, MD | Renaissance Baltimore Harborplace Hotel

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Kim Brandt, Director of Program Integrity
Centers for Medicare & Medicaid Services

Cynthia Tudor, Medicare Drug Benefit Group
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For hard copy reference materials, some useful resources include:

- A medical dictionary, a basic anatomy and physiology book so you can understand clinical processes, and a legal dictionary.

- You should also review the OIG compliance guidances as applicable. Additionally, if you are creating a program, you can obtain hard copy manuals for establishing a compliance program through organizations like HCCA. These manuals provide everything from discussion about major health care regulations to sample policies and other documents common to the compliance officer profession.

Joining trade associations, such as HCCA, can also be invaluable resource for networking and communicating with colleagues about compliance-related issues.

For establishing an electronic library, you will want to bookmark websites that are relevant to your healthcare entity’s line of business. There are five primary sources for information to keep in mind:

- Federal regulatory agencies (e.g., Centers for Medicare and Medicaid Services (CMS), Internal Revenue Service (IRS), Centers For Disease Control and Prevention (CDC), National Institutes of Health (NIH), the Food and Drug Administration (FDA), OIG, and the US Department of Justice (DoJ))
- Congressional websites (e.g., Senate Finance Committee; US Senate Committee on Health, Education, Labor and Pensions; the House Ways and Means, and the House Energy and Commerce Committees; Subcommittee on Health)
- State and local websites (e.g., your state’s legislature, Department of Health, Professional Licensing Boards, and Medicaid program, Medicare Fiscal Intermediaries and Carriers; any local or municipal agencies, governing bodies, and local regulations)
- Trade associations (e.g., HCCA, American Health Lawyers Association [AHLA], Healthcare Financial Management Association [HFMA]); and
- Law firms and publications (e.g., Horts, Springer & Mattern, PC; Kaisernetwork.org; Health Leaders; and Modern Healthcare)

Some of these websites have free e-mail services to notify you automatically anytime a regulatory update becomes apparent. You can also set up trackers through Google Alert to automatically notify you anytime your search terms appear in an article or other document on the internet.

Lastly, compliance-related list-serves can also be an invaluable source of information. Some government websites, such as the Department of Health and Human Services (http://www.oig.hhs.gov/mailinglist.html) offer free list-serves. There are also fee-based list-serves through trade associations such as AHLA, HFMA, or HCCA. How you tailor your electronic library should be unique to your organization’s structure, services offered, and the role the compliance officer plays within the organization.

Establish a work plan

If you are establishing a new compliance program and have done a thorough review and analysis of the organization’s operations and policies, you should be in a position to begin putting together a tentative work plan. This is where previous hotline calls or reports regarding prior investigations will be most useful. Your work plan should identify the compliance-related projects you plan to identifying and reporting any trends in the future. You should also think about how a system for reported issues will function, both when the identity is known and when reports are anonymous. Anonymous reporting systems can be as simple as locked black boxes (e.g., “suggestion boxes”), or a hotline, or as complex as using a third-party vendor.

If you are joining an existing compliance program, you will want to research whether the previous compliance officer maintained such a database and read through some of the past issues that were raised. This will give you valuable insight into the types of issues reported and the history of reported concerns regarding certain staff members or certain departments. It may also give you an initial basis on which to establish future compliance monitoring programs.

Issues can be logged as simply as creating an electronic spreadsheet, or logging may be as advanced as using a purchased tracking system from a compliance product vendor. Compliance hotline vendors often have tracking systems available as an option to record not only hotline calls, but to record other reported compliance issues as well. As you create your tracker, think about the kinds of information you want to capture, how to keep the information confidential and secure (e.g., who will have access to the tracker, etc.), and what types of information you envision reporting to your director and/or governing board.

Create an issue tracker

If you are establishing a new compliance program, you should also set up a database to track compliance-related issues that are reported to you. At a minimum, the tracker should document when the issue was reported, who reported (if known), what the issue was, and the outcome. This will assist you with identifying and reporting any trends in the future. You should also think about how a system for reported issues will function, both when the identity is known and when reports are anonymous. Anonymous reporting systems can be as simple as locked black boxes (e.g., “suggestion boxes”), or a hotline, or as complex as using a third-party vendor.

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work on for the remainder of the year. In order to finalize this process (and depending on the size of your organization), you may need to perform a compliance risk assessment. You may want to combine with other areas, such as HR or Finance, to do a formal organization-wide risk assessment to determine what particular issues present the greatest risk to the organization. To accomplish this task, you will need to meet with your appropriate middle-to-upper management (directors and higher) to get their input.

If you are joining an existing compliance program, you will want to make sure the work plan is on your list of documents to review. Additionally, be sure you are familiar with your compliance program’s risk assessment and work plan development process and what is expected of you in that process.

Assuming your program is new and depending on your organization’s structure, once you have finalized your work plan, you may need to take it to the governing board or the compliance committee for approval or at a minimum, obtain approval from your leading executive officer. Depending on the state of your new compliance program, board approval of the work plan may have to wait until the board has approved a resolution establishing the compliance program and approved your corporate compliance plan (discussed below). Nevertheless, you will want to move forward with the work while seeking approval, because it may take several months between draft revisions, legal counsel approval, and governing board approval. This process can also vary depending on the size and structure of the organization.

**Create a corporate compliance plan**

Saving the best and most time-consuming for last, depending on the state of your compliance program, you may need to develop a corporate compliance plan (CCP) for your organization or restructure an existing CCP. A CCP memorializes the structure and responsibilities of your compliance program and how the program will meet the seven elements.

If a CCP has been created, you will want to make sure that it is included in your document review, discussed above. If one has not been created, you will need to consult with your organization’s appropriate legal counsel to first draft a board resolution that directs management to establish a compliance

Continued on page 50

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Seven of the top 15 healthcare organizations as ranked by *US News & World Report* are using MDaudit to automate the administrative tasks of compliance auditing. Using strategic, risk-based audit methodology, they:

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The what, why, and how of Medicare Coverage Analysis – Part II

By Kristen Pawlowski

Effective and accurate billing for clinical trials is a critical part of maintaining a compliant clinical research operation. As the Office of Inspector General (OIG), U.S. Department of Justice, and other agencies are increasingly becoming aware of the issues related to billing for clinical trials, it is important for academic medical centers, community hospitals, health systems, and other health care entities that conduct clinical research to develop processes to meet the requirements of accurate research billing.

The foundation of compliant billing for clinical trials is a Medicare Coverage Analysis (MCA), which is the systematic review of clinical trial documents to determine the items and services that may be billed to Medicare during the course of the trial. By applying current Medicare coverage rules, benefit policies, and federal guidelines, an MCA can be used to identify the study-related items and services that may be billed to Medicare, and those that cannot. Many third-party payers follow Medicare’s rules and regulations; therefore, the issues outlined in this article can be generally applied to coverage analyses for clinical trials on the whole, not just those with Medicare participants.

Part II of the series outlines a basic process for conducting an MCA. The following components are included in the basic process:

- a review of when in the life-cycle of a study an MCA should be conducted,
- the documents necessary to complete a review,
- the fundamental questions that must be considered,
- the sources to identify billable costs, and
- methods for documenting the MCA results.

In 2000, President Clinton signed an executive memorandum directing the Secretary of the Department of Health and Human Services to “…explicitly authorize [Medicare] payment for routine patient care costs…and costs due to medical complications associated with participation in clinical trials.” As a result, the Health Care Financing Administration, now called the Centers for Medicare and Medicaid Services (CMS), created a National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). In July 2007, CMS issued an update to NCD 310.1, naming it the Medicare Clinical Trial Policy (CTP). The NCD was the culmination of a legislative process that commenced with the Balanced Budget Act of 1997 which directed the Secretary of the Department of Health and Human Services to request an analysis from the National Academy of Sciences regarding the expansion or modification of benefits to Medicare beneficiaries for “[r]outine patient care costs for beneficiaries enrolled in approved clinical trial programs.” This request resulted in the Institutes of Medicine (IOM) report titled “Extending Medicare Reimbursement in Clinical Trials.”

The consequences of over-billing Medicare for clinical trials-related costs may be significant. One of the best known settlements in this area was in December 2005 when Rush University Medical Center agreed to enter into a three-year Certification of Compliance Agreement with the OIG and repay monies to the federal and state health care programs. For the next three years, Rush was required to certify the efficacy of its compliance program, report overpayments, and conduct extensive clinical trials billing auditing and monitoring.

In addition to facilitating billing compliance, coverage analyses may also be beneficial for the development of the clinical trial budget and provide an assessment of the actual research costs prior to finalizing the contract with the trial sponsor. The research organization may also improve the overall integrity of research, earn the trust of sponsors and research participants, and appropriately and effectively use available research dollars.

MCAs may be developed before the development of the trial or after the initiation of the trial. When possible, it is preferable to complete a coverage analysis prior to finalizing the trial budget, particularly to facilitate
negotiations with the trial sponsor, to ensure that all patient care costs of conducting the trial are covered by one of the available resource streams.

The party responsible for conducting the MCA varies by organization. The local environment, available resources, and the institution’s level of risk tolerance are all factors that may determine who will conduct the analysis. The Principal Investigator (PI) or the PI’s support staff may be responsible for completing the MCA. However, because there is increased scrutiny on clinical trials billing, additional resources should participate in the process to confirm that the correct Medicare benefit policies, NCDs, Local Coverage Determinations (LCDs), and routine care guidelines are being properly applied. Additionally, MCAs may also be used by schedulers, charge capture professionals, billing personnel, and others involved in the administration of clinical research. As such, many institutions have developed a hybrid approach that uses the knowledge base and skill sets of both the clinical research personnel and the centralized research administration or health care coding professionals to complete the MCA.

Six steps to conducting an MCA:

1. Documentation. Assemble and review all of the appropriate documents to determine if they include the requisite information to complete the MCA. The minimally necessary documents include the study protocol, protocol-specific informed consent document, study budget, and clinical trial agreement (CTA) or notice of grant award (NOGA). It is also helpful to have documentation of FDA approval, if applicable, and the Carrier and/or Fiscal Intermediary (FI) approval letter, if available. The availability and completeness of some documents may vary depending on the timing of the coverage analysis; if conducted prior to or in conjunction with budget development (as recommended), documents may be in draft form or not available. The details of how to use each of these documents are:

   - **Study protocol:** The protocol should include the study objectives, study procedures, schedule of events, and the patient population. All four items are necessary to complete the coverage analysis.
   - **Protocol-specific informed consent:** For the coverage analysis, three main sections will provide the most beneficial information. They are the patient cost section, the benefits/therapeutic intent section, and the section that outlines for the enrollee what services will be provided over the course of the trial.
   - **Study budget:** If the MCA is conducted in the early stages of the consideration of the research, the study budget may only be available in draft form. Because the MCA can provide valuable information regarding the actual costs to the institution for a trial, conducting the MCA prior to study initiation will aid in the development of an accurate study budget. If a draft of the budget is being used, make sure to track the version of the budget and update the MCA accordingly to align with the final budget.
   - **The clinical trial agreement/contract or notice of grant award:** The CTA or NOGA provide detail on the compensation the institution will receive for conducting the trial. If the financial details in the contract differ from the financial details in the budget, the contract should prevail.
   - **Documentation of FDA approval:** For drug and biologics studies, the Investigational New Drug (IND) number is potentially needed to meet the ‘deeming’ status of the trial. Although the FDA approval letter is the best evidence of an accurate IND number, the number can be located in other documents and correspondence (e.g., the protocol).

2. Billing grid. Create a billing grid to document the study-specific items and services. For an easily interpreted coverage analysis, a billing grid should be created that lays out each item and service to be provided to the research participants over the course of the trial and the date of service that they are intended to be provided. An Excel-type spreadsheet has proven to be a valuable tool for the creation of the grid. The Y-axis, or first column of the spreadsheet, should delineate each and every item or service to be provided over the course of the research trial, with the dates of services from the study schedule outlined on the X-axis or first row of the spreadsheet. Once these two main axes are completed, each cell of the spreadsheet can then be used to identify the dates on which each item or service will be provided. For example, if the research participant receives chemotherapy every four weeks, then there should be cells in the Y-axis for the chemotherapy drugs, pre-meds, administration charges, etc. These items and services would then be indicated as provided at week four, eight, twelve, etc. in the relevant columns that align with these dates of service from the X-axis. A more thorough and detailed MCA would be very specific on the X-axis such that both the cycle and day would be included, rather than simply indicating ‘monthly’. Use the study protocol’s schedule of events and procedure section to fill in each item or service on the billing grid.
3. Qualifying. After completing the billing grid, the next step is to determine if the trial is a “qualifying” clinical trial. In a Qualifying Clinical Trial (QCT), the “routine costs” provided to the research participants over the course of the research study can be billed to Medicare. The first step to determining if the trial is qualifying is to identify the type of trial (e.g., drug, biologic, device, etc.). This information may be easily found in the protocol; the title and study objectives should clearly identify what is being studied. After completing the billing grid in Step 2, this should be clear.

For non-device trials, the trial must meet four criteria to be qualifying. If the trial is not a QCT, then none of the items or services provided as part of the trial are billable to Medicare. The four criteria are:

- The investigational item or service falls into a Medicare Benefit Category
- The trial has therapeutic intent
- The trial enrolls patients with the diagnosed disease, and
- The trial meets the seven desirable characteristics.

The CTP does not apply to Investigational Device Exemption (IDE) device trials. Approval for IDE device trials needs to comply with the applicable regulations at 42 CFR Part 405, subpart B. However, an MCA should be conducted for all types of trials in order to determine and document that the study has the requisite approvals in place for billing and to ensure effective internal communication regarding which items and services are billable to Medicare and which items and services should be charged to the study budget.

Identifying a study as “deemed” is not synonymous with being a QCT. Deemed trials meet the seven desirable characteristics, and therefore, only one of the four necessary criteria to be a QCT. The other three criteria must also be met for the trial to be qualifying. Furthermore, there does not seem to be any other means of meeting the fourth and last prong of the qualifying analysis than to meet one of the deeming criteria. As mentioned in Part I of this series, although the NCD included an intention to have a self-certification process, this process has never been implemented by CMS.

4. Non-billable costs. Determine the non-billable costs of the trial. After determining if the study is qualifying or may possibly have some costs that are billable to Medicare, review the documents gathered in Step 1 to begin completing the billing grid.

- Identify the items and services the sponsor has agreed to pay.
- Review the informed consent document and identify the items and services for which the patient is not financially responsible.
- Indicate these determinations on the appropriate cells in the grid.

5. Billable costs. Review the remaining items and services on the billing grid and identify if they are billable to Medicare.

Items and services that are included as billable to Medicare, are: 

Continued on page 50
Generally available to Medicare beneficiaries,
Typically provided for the patient’s diagnosis outside of a clinical trial,
Solely for the provision of the investigational item or service or to monitor the effects or to treat complications, and
For the diagnosis or treatment of a complication. Note that even if a trial is not qualifying, as determined in Step 3, items and services provided for the diagnosis or treatment of a complication are billable to Medicare.

Identifying the billable or “conventional care” items and services can be challenging. Several sources are beneficial to determine if items and services provided as part of a trial are billable. These sources include:

- Medicare benefit policies,
- NCDs and LCDs,
- The current index of laboratory NCDs, and
- Medical association guidelines and/or professional journals.

A special coding system is often used to easily identify the decision-making in the MCA process. For instance, an “S” can be used to indicate that the item should be billed to the study budget, an “M” used to indicate that the item is billable to Medicare. Some grids are simple and may only use these two types of codes to categorize the charges. Other grids can be more sophisticated to accommodate data gathering (as in the case of tracking and trending for clinical research items and services) or to depict the underlying basis for why the item is billable or not billable (as in the case of an item being promised for free in the informed consent, coded as “ICF”).

After completing Step 5, all items and services provided in the protocol should be on the billing grid with an indication of whether or not they are billable to Medicare.

6. Coverage analysis. Finally, document the coverage analysis. To complete the coverage analysis, a document, memo, or second tab of the billing grid should cite the documents reviewed for the analysis, including the version and dates, where available, as well as the logic of the QCT analysis (Step 3).

This two-part series on MCAs has provided detail on the statutory background for the clinical research billing rules, the benefits of conducting MCAs as well as the how-to steps to conducting a MCA. An overview of the basic process has provided the essential groundwork to conduct an MCA. A thorough understanding of clinical research and application of Medicare benefit policies, coverage rules and federal guidelines is necessary to complete a comprehensive and accurate MCA.

1 The IOM report can be found at http://www.iom.edu/CMS37945528.pdf
2 Boyd, Cynthia and Meade, Ryan D: Clinical Trial Billing Compliance at Academic Medical Centers. Academic Medicine; 82.7 (July 2007): 646.
3 “Routine costs” are defined in the Clinical Trial Policy, July 2007, and can be found at http://www.cms.hhs.gov/transmittals/downloads/R131OTN.pdf
4 The seven desirable characteristics can be found in NCD 310.1, Version 2, Section A.
5 Medicare Benefit Policy Manual 102, Chapter 14.
6 42 CFR § 405.207 (b)(2).
7 See Change Request 3548, December 17, 2004 which can be found at http://www.cms.hhs.gov/transmittals/downloads/R131OTN.pdf

Your first 100 days

...continued from page 45

If you have never drafted a compliance plan, you should first spend some time familiarizing yourself with what a CCP looks like. You can obtain copies of other CCPs through online research. After you become familiar with the content, you will need to defer to your organization’s legal counsel to draft a CCP for you, or at a minimum, have them review and approve a draft you have put together. One thing to keep in mind is that due to resources, the size of the organization, and the services offered, CCPs are not a one-size-fits-all endeavor. What works for large health system ideally, won’t work for a small physician practice.

Conclusion

The above information is certainly not intended to be all-inclusive, but at least it gives you a starting point for determining what would be best to focus on during your first few months in your new position. As you transition into this new profession, it is important to keep a couple of thoughts in mind. First, not all compliance programs are created equal. If one option does not work, be prepared to switch gears. Secondly, your approach does not necessarily need to follow the order in which the above information was presented. In fact, most items will likely be carried out simultaneously. Lastly, just remember it will take some time before all these steps can be carried out to completion. Although the title of this article is “Your First 100 Days,” it will likely take much of your first year before all these steps are finalized. Patience and organization are important. If you prioritize your objectives and set goals accordingly, you will have a solid road map for transitioning smoothly into your new role.
The revised PhRMA Code: Implications for provider conflict-of-interest policies

By Sara Kay Wheeler, Esq. and Michael Paulhus, Esq.

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In July 2008, the Pharmaceutical Research and Manufacturers Association (PhRMA) published its revised PhRMA Code on Interactions with Healthcare Professionals (Revised Code), which will govern the interactions of pharmaceutical sales representatives with health care providers, effective January 1, 2009.¹ The publication of the Revised Code comes in the midst of increased focus by federal and state legislators, regulators, trade associations, the press, and the public on relationships that may raise potential conflicts of interest among pharmaceutical, medical device, and biotechnology manufacturers (collectively vendors) and health care providers.

Although conflicts of interest are by no means a new issue in the health care industry, the scrutiny of such issues has escalated in recent months. For example, the Senate Finance Committee and the press recently have focused attention on compensation paid to pharmaceutical manufacturers to three prominent child psychiatrists who practice at Massachusetts General Hospital.² In addition to physician payments, the rigor with which Massachusetts General Hospital monitors compliance with its conflict-of-interest policies has been questioned.³ Conflicts of interest also have drawn the attention of the United States Food & Drug Administration (FDA), which in August 2008 announced new policies and procedures governing its management of advisory committees and conflicts of interest.⁴ Additionally, the Institute of Medicine (IOM) has stated that financial conflicts of interest “raise concerns about the objectivity and trustworthiness of research conduct and publications, the prudent management of scientific investigations and other activities in the public interest, and the commitment of health care professionals to the best interests of patients.”⁵ The IOM is conducting hearings and is expected to issue a report addressing conflicts of interest.

Attention concerning potential conflicts in the health care industry traditionally has been focused on the interaction between vendors and individual health care providers, such as physicians. However, the focus on conflicts of interest is evolving, making it critical for institutional health care providers, such as academic medical centers, community hospitals, ambulatory surgery centers, nursing homes, and physician practices (collectively, institutional providers) to reexamine and, if necessary, revise their conflict-of-interest policies. As illustrated in the timeline on page 53, the approach to conflicts of interest by various stakeholders has been a moving target. Given this constant movement, it is important for institutional providers to revisit regularly the nature and extent of their relationships with various industry stakeholders and to assess whether internal controls and processes are adequate to effectively identify and manage potential conflicts of interest.

A review of the concepts articulated in the newly-revised PhRMA Code serves as a helpful starting point in the review of institutional conflict-of-interest policies.

Consideration of relevant stakeholders

Institutional providers have a myriad of structures and serve different needs. Thus, in reviewing and revising conflict-of-interest policies, it is critical for institutional providers to consider the depth and breadth of relationships with stakeholders relevant to the institution and to carefully monitor industry developments to the extent such developments are germane to operations. As a general matter, institutional providers seek to avoid any perception that their organizational mission to provide the highest level of quality patient care has been compromised. Negative publicity distracts management from its patient care focus and harms relationships with patients and the community. For example, the coverage of the Massachusetts General psychiatrists’ conflict-of-interest issues with the pharmaceutical industry has resulted in negative press, including editorials in the New York Times and Boston Globe, as well as congressional interest questioning the hospital’s enforcement of conflict-of-interest policies regarding National Institutes of Health (NIH) grants. This case demonstrates the importance for all institutional providers to consider the need to both implement and enforce robust conflict-of-interest policies tailored to the institution with an eye to the potential reaction if the policy and implementation are exposed to public scrutiny.

When reviewing this issue, institutional providers also should consider the growing

Continued on page 53
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trend in recent years for institutional providers to employ a greater number of physician medical staff members. Although this movement may have many salutary features, institutional providers should be cognizant of respondeat superior liability theories applicable to employed physicians and other employed individual health care practitioners. As a matter of employment law, an institutional provider has the right and obligation to control certain acts of its employees, and violations of laws prohibiting conflicts of interests by employees can be imputed to the employing institution. Moreover, even non-employed health care providers in positions to influence purchasing decisions within hospitals can implicate conflict-of-interest issues for institutional providers. Therefore, the extent to which institutional providers employ physicians and other individual health care providers should influence the content of institutional conflict-of-interest policies.

Academic medical centers and institutions that host clinical research provide examples of entities with interests that may require a different approach to conflicts of interest. Academic medical centers have been leading the way in enacting stringent conflict-of-interest provisions. In 2006, an article in the Journal of the American Medical Association called for academic medical centers to revise the manner in which these entities permit interaction with vendors, including complete bans on all gifts and meals, prohibitions on serving as speakers, and additional transparency concerning consulting relationships.

In June 2008, the Association of American Medical Colleges (AAMC) addressed the issue of conflicts of interest and published detailed guidelines governing the interaction of industry representatives with faculty, students and staff of academic medical centers. The AAMC recommendations included:

- prohibitions on acceptance of any gifts;
- prohibitions on acceptance of food, except in compliance with Accreditation Council for Continuing Medical Education (ACCM) guidance;
- limitations on site access for vendors;
- participation in only accredited Continuing Medical Education (CME) programs;
- strong discouragement of participation by faculty in industry-sponsored speakers’ bureaus; and
- disclosure of financial interests and recusal by individuals involved in purchasing decisions.

Institutions that host clinical research also have unique conflict-of-interest issues.

Continued on page 54
Specific conflict-of-interest requirements govern grantees and investigators in research grants administered by NIH. These regulations require institutional providers to “maintain an appropriate written, enforced policy” and to “[e]stablish adequate enforcement mechanisms and provide for sanctions where appropriate.” Failure to implement and follow conflict-of-interest policies can result in the denial of participation in NIH grants or refusal to continue to pay for research in process. In February 2008, a joint advisory committee of AAMC and the Association of American Universities (AAU) issued a report making various recommendations for conflict-of-interest policies at institutions that conduct clinical research. Institutional providers that host clinical research should consider the standards set forth in NIH regulations and the AAMC/AAU report in composing their conflict-of-interest policies.

All institutional providers must be cognizant of the implications of the growing trend in legislation to require public disclosure of vendor gifts to health care providers. For example, bills titled the Physician Payment Sunshine Act of 2008 currently are pending in the US House and Senate. The Senate version would require manufacturers to report to the United States Secretary of Health and Human Services all gifts valued over $500 in the aggregate to physicians, clinicians, and other prescribers. Moreover, depending upon the state in which an institutional provider is located, the amount of gifts made to the institutional provider or affiliated individual health care providers may already be publicly available, because Maine, Minnesota, Vermont, West Virginia, and the District of Columbia each have laws requiring gift reporting by certain vendors.

This trend in favor of publishing information about industry gifts shows no sign of slowing down. In August 2008, Massachusetts passed legislation that requires the state Department of Health to adopt a standard marketing code for pharmaceutical sales and device manufacturing representatives that is no less restrictive than the most recent versions of the PhRMA and Advanced Medical Technology Association (AdvaMed) Codes. Significantly, the new law will require disclosure for publication on a website of “…the value, nature, purpose and particular receipt of any…economic benefit with a value of at least $50, which the company provides, directly or through its agents, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner or other person…authorized to prescribe, dispense, or purchase prescription drugs or medical devices…”

The increased level of public disclosures has the potential to lead to lawsuits against institutional providers, based on conflict-of-interest theories, because plaintiffs’ attorneys and regulators are likely to examine the disclosures included in these databases.

In addition to the specific issues raised by public and media scrutiny, employed health care providers, academic medical centers, clinical research integrity, and the publication of vendor gifts, there is a real risk that state and federal prosecutors as well as the plaintiffs’ bar will turn their attention to institutional recipients of payments from vendors to allege claims based on Federal Anti-kickback Statute and False Claims Act theories of liability. The Anti-kickback Statute covers not only the offer of remuneration to induce referrals, but also extends to the solicitation or acceptance of such remuneration. Moreover, courts have permitted the government and private plaintiffs to bootstrap False Claims Act claims based on violations of the Anti-kickback Statute. The cases have alleged that because of relationships prohibited by the Anti-Kickback Statute, providers are not entitled to reimbursement for services, thus making the submission of claims to federal health care programs for these services “false claims.”

To the extent that institutional providers receive direct support from vendors in the form of educational programs and direct grants, evolving theories of liability could bring institutional providers into the sweep of government investigations and suits by False Claims Act relators. The theory of liability might look something like this: Institutional providers or individual health care providers receive significant payments from vendors; the payments influence pharmacy and therapeutics committees to approve the use of certain drugs or devices promoted by the vendors who make the payments. Alternately, vendors may make payments to encourage individual health care professionals to increase utilization of drugs or devices at the institution. "Respondeat superior" liability for the acts of employed physicians or other employed individual health care providers is also of concern in the enforcement context.

Revisions to PhRMA Code

In 2003, the Office of Inspector General of the Department of Health and Human Services (OIG) published the OIG Compliance Program Guidance for Pharmaceutical Manufacturers (CPG), which discusses the Anti-kickback Statute and “focuses on relationships with physicians, but [notes] the same principles would apply when evaluating relationships with other parties in a position to influence referrals…” The CPG addresses conflicts of interest and states "Although compliance with the PhRMA Code will not protect a manufacturer as
a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.”21

This guidance by OIG suggests that institutional providers would be well-served to monitor changes to the PhRMA Code and consider the implications for their conflict-of-interest policies.

The following discussion provides an overview of the most significant changes introduced in the Revised Code from the original version released in 2002 that are relevant to relationships between institutional providers and vendors. Institutional providers should consider revisiting their conflict-of-interest policies to determine whether revisions are needed to be consistent with the Revised PhRMA Code. Institutional providers should consider extending policies to cover interaction with medical device and biotechnology manufacturers, because anecdotal evidence suggests the AdvaMed Code, which governs interactions between medical device manufacturers and health care providers, may itself be revised in the near future to follow the Revised PhRMA Code. Depending upon an institution’s circumstances, it also may be important to consider addressing relationships between non-employed health care professionals and vendors. For example, although an institutional provider has less control over a non-employed physician than an employee, it should consider the value of restricting non-employed physicians who conduct clinical research at the institution or those who serve on a procurement committee from having certain relationships with vendors, including accepting entertainment or recreational items, that could raise conflict-of-interest concerns.

**Gifts to health care professionals**

The Revised Code prohibits entertainment, recreational items and vacation trips to any health care professional (HCP) who is not a salaried employee of the pharmaceutical manufacturer. This removes an exception from the 2002 Code that allowed entertainment and recreation for advisory boards, consultant meetings, and speaker programs. The Revised Code further prohibits the distribution to HCPs of minimal value, practice-related items (e.g., pens, clipboards, note pads, mugs, and other reminder items). The Revised Code limits gifts to modest gifts for the education of patients or HCPs. For example, permissible gifts would include medical texts, scientific journal subscriptions, clinical treatment guidelines, anatomical models, patient starter kits (all capped at $100 value).

**Practical tips for compliance programs:**

- Ensure no entertainment or recreational items are provided by vendors to employed HCPs, in any context.
- Prohibit employed HCPs from attending vendor events or activities at resorts.
- Eliminate “reminder” items entirely. The PhRMA Code would permit the receipt of items designed for the education of patients or HCPs valued at $100 or less; however, the Revised Code’s definition of “educational” items is subject to interpretation and monitoring such gifts imposes an administrative burden on institutional providers. Therefore, some institutions may find it more manageable simply to prohibit all gifts from vendors.
- Develop policies to address the receipt by the institution or individual departments of educational grants, industry programs, or other compensation from vendors.

**Meals**

Occasional meals may be offered in connection with informational presentations, if they are modest as judged by local standards, are not part of entertainment or a recreational event, and are conducive to informational communication. The Revised Code provides that meals in connection with informational presentations by sales representatives or their immediate managers must be in-office or in-hospital only. The Revised Code provides an example of modest meals as sandwiches or pizza. Meals hosted by sales representatives or their immediate managers at restaurants are prohibited.

**Funding of Continuing Medical Education**

It is still the case under the Revised Code that pharmaceutical manufacturers cannot provide financial support for travel, lodging, or personal expenses of non-faculty HCPs who attend the CME. In addition to these prohibitions, manufacturers may no longer provide meals directly at CME programs (e.g., by sponsoring or hosting the meal directly or being identified as the sponsor of the meal). Manufacturers may provide general funding to the CME provider, which the provider can use at its discretion to provide meals for all participants. Additionally, under...
...continued from page 13

Health care boards of directors’ legal responsibilities for quality leadership can help facilitate development and implementation of a new agenda for quality.

**Oversight.** The board must improve its oversight of quality. The board must support executive leadership in quality and patient safety initiatives, regularly review reports to the board on quality, patient safety, utilization review, reimbursement, risk management, quality data reporting, peer review, and corporate compliance. Effective oversight of the compliance program will require an evaluation of compliance with regulations that govern hospital acquired conditions, the Reporting Hospital Quality Data for Annual Program Update, state adverse event reporting requirements, gainsharing, physician incentives, and outcomes management initiatives.

**Conclusion**

Boards of directors must act swiftly to address their responsibilities for quality of care in light of the onslaught of government initiatives. The evolving public reporting and pay-for-performance initiatives, coupled with increased government efforts to uncover quality failures through data mining and to enforce quality through the FCA, highlight the necessity of leadership on the part of health care boards of directors in ensuring quality of care. ■

1. Institute of Medicine, To Err is Human: Building a Safe Health System (2000).
3. Id. see also 42 C.F.R. § 482.21(c).
4. Id.
5. 42 C.F.R. § 482.21.
9. Id.
10. Id.
11. Id.
14. Id.
15. Id.
16. Id.
17. In a qui tam action, a private individual, or “whistleblower”, with knowledge of past or present fraud committed against the U.S. federal government brings a lawsuit on behalf of the United States.
19. Testimony of Gregory E. Demmke, Assistant Inspector General for Legal Affairs, U.S. Department of Health and Human Services before the U.S. Senate Special Committee on Aging on the Role of OIG in Identifying and Preventing the Abuse of the Elderly (July 18, 2007).
25. Training Program for Hospital Trustee, Adapted, White Coat News (March 21, 2008).
The revised PhRMA Code: Implications for provider conflict-of-interest policies ...continued from page 55

the Revised Code, manufacturers are expected to follow ACCME Standards for Commercial Support and standards of other accrediting entities, which include independence of the CME provider in selection and presentation of content, educational methods, and evaluation of the program.22

Practical tips for compliance programs
- Ensure employed HCPs attend programs accredited by ACCME or another appropriate accrediting body. This can be accomplished by requiring employed HCPs to notify the institution of the CME programs they attend and by checking on the accreditation of the programs.
- Ensure that no meals are provided directly by vendors at CME events to employed HCPs.

Consultants and speakers
Pharmaceutical and medical device manufacturers have come under attack recently in enforcement actions and civil litigation for alleged sham consulting arrangements.23 Accordingly, PhRMA has pursued steps to revise the sections of the Code addressing consultant and speaker relationships. The Revised Code emphasizes that decisions regarding the selection and retention of HCPs as consultants should be based on defined criteria such as expertise, reputation and knowledge in a specific area. Consultants’ compensation and reimbursement for reasonable travel, lodging, and meals must be based on reasonable fair market value, and the Revised Code recommends the arrangement be in writing. As noted above, the Revised Code prohibits the provision of entertainment and recreational items during manufacturer-sponsored consultant meetings, and it explicitly prohibits holding such meetings at resorts. In addition to consultants, the Revised Code addresses the treatment of HCPs who serve as speakers for manufacturers. It imposes many of the same requirements as those for governing consultants (e.g., selection based on defined criteria, fair market value compensation memorialized in writing) and it adds a requirement that manufacturers impose caps on the annual amount of compensation paid to any individual HCP for speaking.

Practical tips for compliance programs
- Consider the imposition of an annual compensation cap per employed HCP in connection with vendor speaking arrangements.
- Require compensation of consultants and speakers by vendors to be reasonable, based on fair market value, and documented in writing.
- Consider training for employed HCPs on institutional expectations regarding vendor speaker programs and consultant relationships.
- Develop policies and periodic reporting to monitor employed HCP participation in vendor speaker programs and consultant relationships.

Formulary and clinical guidelines committees
Under the Revised Code, HCPs who are pharmaceutical company speakers or consultants and who serve on institutional formulary or guideline committees must disclose their affiliation with the manufacturer. Disclosure should continue two years after termination of speaker or consultant agreement. HCPs must follow the committee’s procedures, which may include recusal from decisions about the manufacturer’s products.

Practical tips for compliance programs
- Develop policies to govern HCPs (both employed and non-employed) who serve as members of formulary committees or committees that set clinical practice guidelines and/or serve as vendor consultants and speakers.
- Require disclosure of financial relationships with vendors by HCPs (both employed and non-employed) who serve as members of formulary committees or committees that set clinical practice guidelines.
- Develop policies to govern and potentially prohibit relationships between vendors and individual HCPs (both employed and non-employed) engaged in making procurement decisions on behalf of the institution.

Annual certification and verification
The Revised Code provides that manufacturers who agree to abide by the Code must require their Chief Executive Officer and Chief Compliance Officer to execute an annual certification to that effect, whereupon the manufacturer will be identified on PhRMA’s website. Manufacturers are also encouraged to secure external verification of their compliance policies and procedures every three years, which also will be published on PhRMA’s website.

Practical tips for compliance programs
- Consider the use of data mining by the institution to confirm that amounts reported internally to the institution by individual health care providers comport with publicly available data released by vendors (e.g., on state websites).
- Review PhRMA’s website to determine whether the pharmaceutical manufacturers for which employed health care providers speak or serve as consultants certify their compliance with the PhRMA Code and have participated in the external verification process. If not, an institution may want to consider additional restrictions on relationships with vendors that are not PhRMA compliant.
- In addition to reviewing and revising...
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conflict-of-interest policies to make them consistent with the standards included in the Revised Code, this is a good time to make sure that conflict-of-interest policies are robust, not only on paper, but also in application. From a perspective of defending allegations of wrongdoing, a detailed compliance policy that is not enforced is often more problematic than an anemic paper policy that receives enforcement attention. Providers also should consider the implementation of auditing procedures and disciplinary measures for the failure to comply with conflict-of-interest policies.

Conclusion

It is appropriate and necessary in many instances for institutional providers and affiliated individual health care providers to interact with pharmaceutical, medical device, and biotechnology manufacturers. These contacts provide important educational information to providers and feedback to manufacturers. Given the breadth of these contacts and the current enforcement environment’s focus on conflict-of-interest issues, there is no guarantee that an institutional provider’s policies can entirely prevent conflict-of-interest issues from arising. Accordingly, it is important to recognize that the bar is constantly moving and to (1) adopt a reasoned approach to conflict-of-interest issues, and (2) periodically review that approach. Revising conflict-of-interest policies consistent with the Revised PhRMA Code is a prudent step toward reducing risks arising in this area.

3 The authors do not intend to suggest any inappropriate action by Massachusetts General Hospital. Rather they reference this case as an example of recent government and media focus on conflicts of interest.
9 Id.
11 42 C.F.R. §§ 50.604(a) & (f).
15 Id.
16 42 U.S.C. § 1320a-7b.
18 42 U.S.C. § 1320a-7b.
21 Id.
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Denver, CO

November 16–19, 2009
Orlando, FL

November 30—December 3, 2009
San Diego, CA
New HCCA Members

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

Illinois
- Virginia L. Cooper, JD, So. IL Univ Sch of Med
- Lucas Crater, JD, So. IL Univ Sch of Med
- Debra Finch, Southern IL Healthcare
- Susan E. Gutjahr, RHIT, CCS, CPC, Sparta Community Hospital
- Shirley Nash, CHC, Chicago Dept of Public Health
- Claudia Niersbach, Elmhurst Memorial Hosp
- Douglas Niska, UnitedHealthcare
- Joanne O’Malley, AthletiCo
- Doris Ronge, Centegra Health System
- Jennifer Ruocco, Huron Consulting Group
- Lisa Snow, Huron Consulting Group

Indiana
- Chartlay McMaster Bondurant, Indiana University
- Lora Fortenberry, Decatur Vein Clinic
- Patrick Hogenbirk, DePuy Orthopaedics
- Michelle L. Killasy, Indiana University
- Lariann Musgrove
- Jason D. Schultz, Baker & Daniels LLP
- Janice Simonelli, AmeriChoice
- Daniel Stephens, RN, JD, South Bend Clinic

Kentucky
- Crystal Clevinger
- Susan Dawson, SeniorCare
- Rebecca Englehardt, Roper Saint Francis Healthcare
- Patti Insko, Harrison Memorial Hospital
- Glena Jarboe, University of Kentucky
- Loretta LeBar, Stoll Keenon Ogden
- Robbin Nelson CHC, RN, BS, MBA

Louisiana
- Geri Abadie, St. James Parish Hospital
- Richard MacMillan, Mr., LHC Group, Inc.

Maine
- David Russell, Univ of New England -ITS

Maryland
- Adriana Brigatti, JD, MPH, LLM, CIP, MedStar Research Institute
- Tiffany W. Edwards, Washington Adventist Hosp
- Cary Gates, HealthCare Enterprises, Inc.
- Kristina Kahan, Navigant Consulting
- David McDade, Institute of Human Virology
- Barbara Spence, AmeriChoice
- Donald Tannenbaum, XLHealth Corp

Massachusetts
- Ann Marie ArsenaULT, RN BSN CPC, Dana Farber Cancer Institute
- Monica Baggio Tormey, BS, RHIA, CHP, NE & Braintree Rehabilitation Hospitals
- Ralph Barisano, Jr., Tornier
- Maureen Broms, RN, MS, New England Baptist Hosp
- Jennifer Hutton, Fresenius Medical Care NA
- Marcia Jones
- Erin Prophet, PMP, New England Baptist Hospital
- Anthony B. Shull, Attorney at Law
- Caroline Ward, Caritas St. Elizabeth’s Medical Center

Continued on page 62

Update Your HIPAA Staff Training With:

**THE HCCA HIPAA Training Handbook**

Written by compliance expert Marti Arvin, this new 36-page handbook covers:
- Who must comply with the HIPAA?
- When 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 for the security of PHI?
- Which safeguards are required, which are recommended, and what’s the difference?

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FYI ...continued from page 61

Michigan
- Becky E. Gebhart, Cherry Street Health
- Diane Hilfinger, Transplant, University of Michigan
- Lauri Oakes, AmeriChoice
- Lisa Selski, Garden City Hospital
- Scott D. Tuma, Superior Care Partners/MGHS

Minnesota
- Steven Heil, Jefferson Wells Intl.
- Chris Palme-Krizak, AmeriChoice
- Taya Peterson, Fairview Health Services
- Jack Radke, Chief Ethics Officer, UnitedHealth Group
- Thomas Schumacher, Medtronic, Inc.

Missouri
- Morgan Byron, Washington University
- Heather Cobb, North Kansas City Hosp

New Jersey
- Michele Kennett, University of Missouri-Columbia
- Kathleen E. Murray, Comtrex, Inc
- Carla D. Neff, Air Evac Lifeteam

Nebraska
- Dawn Carpenter, NE Heart Institute

Nevada
- Ms. Tammie L. Bain, BS, JD, Univ of NV Reno
- Judy S. Hatch, HCA
- Maria Pearson, Carson Valley Medical Center

New Hampshire
- Eileen F. Fehskens, Dartmouth-Hitchcock Medical Center
- Timothy C. Hogan, JD CHFP, Elliot Health System

New Mexico
- Patrick Collins, Carlsbad Mental Health Center

Your HCCA Staff

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