

NEW PERSPECTIVES

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The Association of Healthcare Internal Auditors' mission is to be an international professional association dedicated to the promotion and advancement of the healthcare auditing and compliance professions.

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From the Editor



This issue of *New Perspectives* highlights practitioners audits and perspectives. We have coupled those with contributions and perspectives of professionals experienced in their fields. All this is geared to provide you with hands-on knowledge you can apply in your daily activities.

Please note that the annual conference in Nashville will occur before the next issue of *New Perspectives* is produced. The annual conference is your best opportunity to hobnob with healthcare internal auditors and compliance professionals, and to obtain current knowledge and skills. Consider attending.

We are always interested in comments, thoughts, and critiques of *New Perspectives*. If there are features you would like to see, let us know. You can communicate those electronically to the editor at: newkes@adelphia.net.

As always, some of the greatest member benefits come from the experiences of our peers. Your contributions are more important than you realize. Please consider sharing your audit and compliance experiences. Writing an article is easier than you think and it is certainly no more difficult than writing that last audit report.

I hope you enjoy this issue of *New Perspectives*. I wish you good reading.

Kenneth E. Spence, CFE
Editor, *New Perspectives*

AHIA MISSION STATEMENT

The Association of Healthcare Internal Auditors (AHIA) is an international organization dedicated to the advancement of the healthcare internal auditing profession, which includes auditing disciplines such as operational, compliance, clinical/medical, financial and information technology. AHIA is committed to:

- Providing for the continuing and specific professional education needs of healthcare auditors;
- Providing a forum for sharing information, experience and ideas related to healthcare internal auditing and the impacts of the healthcare business and regulatory environments on the profession
- Promoting the benefits of healthcare auditing to healthcare executives and trustees; and
- Representing the profession to other organizations, government agencies, and the public.

AHIA VISION STATEMENT

Healthcare leadership and the healthcare internal auditing profession recognize AHIA as the catalyst for continually elevating the quality of healthcare internal auditing and advancing the profession and its members. AHIA embodies 'excellence through sharing' and is the healthcare auditors first choice for education and leadership specific to this multi-disciplined profession and for information on best practices and industry and professional trends. AHIA is a leader in partnering with other organizations to expand professional resources.

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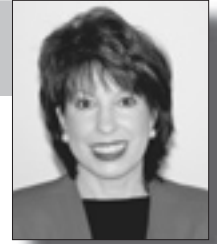
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Board Initiatives and Strategic Direction

By Debi Weatherford, CIA

I would like to update you on your Board's activities. I am happy to report that we have an action oriented Board interested in serving AHIA. A recap of several key initiatives and associated activities follows:

Select New Management Company

I reported in January, PB Consulting decided not to renew their three-year management contract, which expires December 31, 2005. AHIA started the RFP process to select a new management company. Karen Young, Vice Chairman, managed the Request for Proposal (RFP) process including interacting with interested vendors and compiling information for Board review. AHIA received an overwhelming response with 30 vendors submitting proposals!

Karen managed the process from an internal controls perspective. Karen opened all proposals from vendors with an independent person present from Postlethwaite & Netterville.

The entire Board has worked the systematic selection process. At the April Board meeting, the top three vendors were selected for in-person interviews and further evaluation. The goal is to make a final selection in June.

Expand Awareness by Exhibiting at HCCA and AAMAS

The AHIA Board of Directors continued to expand awareness of AHIA by exhibiting at the Healthcare Compliance Association's (HCCA) Annual Compliance Institute in April, and at the national conference of the American Association of Medical Audit Specialists (AAMAS) at the end of April.

Kelly Nueske and Mark Ruppert staffed the AHIA booth at the HCCA

Compliance Institute, with help from Mary Jo Flynn. Kelly Nueske and Debi Weatherford tended the AHIA booth at the AAMAS conference. We look forward to evaluating the impact of these awareness efforts.

Provide Quality Education

The AHIA initiative to provide quality education to members through annual conference, training seminars, *New Perspectives* (quarterly journal) and *E-Perspectives* (electronic newsletter) is receiving a lot of attention.

The AHIA Conference Committee has done a great job of planning the 2005 annual conference with 40 training workshops, great keynote speakers, and comprehensive optional sessions, all in a Nashville setting. We look forward to seeing all our members in Nashville come October.

The spring seminar occurred in May providing training for new auditors, construction auditing, and ACL training. Turnout for the spring seminar continues to grow each year. We encourage our members to take advantage of this specialized training.

The Editorial Committee has done a great job with *New Perspectives* and *E-Perspectives*. We encourage our members to consider contributing articles and information for publication to our Editor, Ken Spence at newkes@adelphia.net.

Continue Auditing and Monitoring Initiatives

A focus group of AHIA and HCCA members addressed compliance auditing and monitoring, and adopted the "seven component framework" initially developed by AHIA to support compliance auditing and monitoring.

They also completed a seven article series on this subject. These articles are available on the AHIA web site under the auditing and monitoring section. We encourage our members to review these articles.

Please note that one of the optional sessions offered at the AHIA annual conference is "Compliance Auditing & Monitoring HCCA/AHIA Focus Group Lessons Learned". Please consider attending this optional session to enhance your knowledge.

Continue Growing Relationships with Organizations

We strive to serve as the "voice" for healthcare auditing. As part of this process, we provided audio-conferences and speakers to communicate healthcare auditing information. Debi Weatherford, Glen Mueller, and Jan Coughlin presented at an audio-conference conducted by HCCA addressing "Auditing & Monitoring Three Aspects of the 2005 OIG Work Plan" on February 14. Mark Ruppert, Debi Weatherford, and Gloryanne Bryant on February 24 participated in an audio-conference presented by HcPro addressing "Auditing PFS: Strategies to Improve Billing and Collections". In addition, on May 17, Mark Ruppert and Debi Weatherford presented at an audio-conference presented by HFMA addressing "Auditing and Monitoring Patient Financial Services to Impact Performance".

Foster Strategy with Canadian Representatives

We are pioneering our efforts to reinforce our international presence by developing an effective strategy with our Canadian representatives and to

Chair, continued on page 19

Unlocking the Mysteries of Operational Auditing: A Focus on Efficient, Value-Adding Operational Audit

By Daniel Clayton

The United States 2002 Sarbanes Oxley Act (SOX) has created a widening stir in accounting. Its requirements of assessing and attesting to internal control quality have disturbed the peace of many comfortable armchair auditors. Traditional auditing models of sampling, audit program development and attesting must be reassessed. Some have dispatched their legal gurus to define the new law and the ranges of acceptable compliance, with the intent of building their accounting and auditing practices to meet that compliance. Others conceptualize about where accounting and auditing will be in the future, attempting to develop the next new standard. It is not easy to know where the solutions to future value and regulatory requirements will lie. However, quality internal audit and effective operational auditing is well positioned to stake its notable claim on the future. In order to stake that claim we must define quality operational audit that identifies the right issues at the right level in the most valuable efficient way.

Developing valuable and efficient operational audit programs is not an easy task. Most auditors will see their blank stare reflected in the vacant monitor as they wrestle with piecing together a highly subjective operational audit program. Even the most conceptual auditors seem to have periods of frustration as they confront ambiguity. However, our continued struggles to add value to management have surfaced a few key operational audit techniques, which can help us meet the tenets of the audit and add value at the same time. By leveraging Institute of Internal Auditors (IIA) Performance Standards and following key audit program development steps, operational auditing can be well positioned to meet any challenge.

Auditing can be an intimidating word not only for those being audited, but often for the auditor as well. What and how to audit presents a complex and subjective puzzle. The title of auditor is used in many different fields with many different purposes. Even within internal audit, there is a variety of ever-changing goals based

on the type of audit being performed. A *financial reporting audit* seeks to ensure that financial information is materially accurate. A *compliance audit* evaluates adherence to standards, regulations and laws, and an *operational audit* evaluates the efficiency and effectiveness of operational controls. Financial, Compliance and Operational audits all have expressed goals. Financial and compliance audits are fairly straightforward, and can generally have one audit program that is replicated in many different environments without losing the audit integrity. However, since operational audit is generally based on subjective terms like efficiency and internal control the very nature of the audit makes it dependent on specific client operations and its unique management environment.

Background

Outlining the historical goals of financial and operational auditing is important in understanding the value operational audit can add to an organization today. You will have to forgive the liberally defined audit

history, but this is best described through analogy.

When the first organization was built its owners wanted to know how well it was doing. They demanded reporting. This gave birth to the first clever manager who found a way to manipulate the reporting process. The owners then invented financial report auditing. The key focus for the auditors in the financial reporting process was to ensure that the statements in the report were "materially" accurate. Many more organizations were built and owners started to buy and sell ownership rights. Government entities decided that financial reporting and financial auditing were important enough to create standard reporting and mandated audit requirements.

Once financial reporting was in place, management desires evolved into wanting assurance that their operations were functioning according to policy and procedure. Management hired auditors and asked them to evaluate departments

for compliance to policy and overall progress toward meeting organizational goals. Modern internal audit was born. However, some organizations realized that the policies or management could actually be the issue. Internal audit began reporting to the board of directors.

In the United States during the 1980's the Committee of Sponsoring Organizations (COSO) defined internal control as a "process... designed to provide reasonable assurance regarding the achievement of objectives in the following areas: Effectiveness and Efficiency of Operations, Reliability of Financial Reporting, Compliance with Applicable Laws and Regulations." The IIA adopted COSO's definition of internal control. In IIA Performance Standard 2110, it states, "Auditors should evaluate the effectiveness of the organizations risk management [over these areas of internal control.]" In 2002, the United States Federal Government passed the Sarbanes-Oxley Act requiring that management assess the adequacy of their internal control structure, and have the external auditors attest to that assessment. Since that time management has been asking both internal audit and external audit for assistance in assessing their internal control structure.

Effectively designed and executed operational audits should meet both the requirements of IIA Performance Standards as well as management's need for assurance over the internal control structure in the area being audited.

Getting Started

Tackling an operational audit will, and should always be, a unique experience. Adding the most value through an operational audit requires a uniquely defined audit program. It is tempting to adopt an existing audit program for an operational audit. Although an existing audit program may provide a suggested audit approach, it should only be used as the foundation for building a program rather than the program itself. Simply adopting an existing audit program introduces the risk that the audit will not address critical issues related to your client's current operations and unique environment. In also introduces the risk that auditors will spend time reviewing well-controlled areas in detail and skipping areas of concern. Both situations do nothing to add value to the client. For example, a program focused on testing may never identify the actual broken

controls, or a program focused on defining controls may add no additional value to a well-controlled environment.

If an audit results in a listing of poor outcomes with no explanation as to why, or leaves management with a listing of findings and no clear strategy for addressing them, chances are the auditor began with an inappropriate audit program. Simply adopting an operational audit program does not meet the IIA planning Performance Standards 2201. Key steps need to be followed in building each operational audit program. The planning and audit program development for an operational audit takes significantly more time than that of a financial or compliance audit. Following a few key planning steps is critical to identifying how the Auditor can add the most value in an efficient way.

Key Planning Steps

1. *Understand and Document the Audit Source*

Reviewing and documenting the reason for the audit is the first important step in setting the scope. If the audit came from the annual risk assessment process, what risks lead to its inclusion in the annual audit plan? These risks should drive the initial unanalyzed scope of the audit. The same holds true for audits requested by management or through other sources. In this first step, it is necessary to understand the underlying concerns or risks that lead to it being considered for an audit. Understanding this initial scope will set the parameters on expected feedback and potential value that the audit can provide.

2. *Initial Risk Assessment*

Once the initial unanalyzed scope of the operational audit is defined, the next step is to perform a mini-risk assessment of the activities being audited. The IIA Performance Standard 2201 describes the first two planning considerations:

- "The objectives of the activity being reviewed and the means by which the activity controls its performance.
- "The significant risks to the activity, its objectives, resources, and operations and the means by which the potential impact of risk is kept to an acceptable level."

The objectives and risks of the initial unanalyzed scope are high level and are generally evaluated further through

detailed assessment of management controls. Management controls analysis is generally obtained through management interviews, and analysis of budget control, management oversight, and available metric reporting. The documented results of the initial interviews should identify key areas of high risk within the initial unanalyzed scope of the audit. Depending on the available time and resources, the auditor may choose to look only at the key areas of high risk. At the completion of the risk assessment we have taken the initial unanalyzed scope and defined detailed risks to address. The detailed risks now provide the audit program scope.

Developing the Audit Program

3. *Initial Area Assessment*

Now that the detailed risks to address have been defined, developing audit steps in each key area is the next piece of the audit program development process. However, prior to developing steps the Auditor must gain an initial understanding of the control quality and organizational impact of each key area. When an operational audit results in numerous errors and confused management, it is likely that little key area assessment was performed. The third and fourth planning considerations in the IIA Performance Standard 2201 emphasize control consideration and opportunity:

- "The adequacy and effectiveness of the activity's risk management and control systems compared to a relevant control framework or model.
- The opportunities for making significant improvements to the activity's risk management and control systems."

Initial interviews with key area managers or supervisors, and an evaluation of the policies and procedures can provide a good indication of internal control strength in the key area. Knowing how well controlled a key area is and how significant it is to the overall process or organization directly influences the nature of the audit steps. If a key area has weak or missing controls then it would be inefficient to test 25 items where we already know the likely issue. Instead, we would document the control deficiency and test five items to confirm the conclusion. In addition if we know an area is well controlled we may be wasting time by developing detailed flowcharts. Instead, we would document how controls are met in policy and procedure, and



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No stone unturned

Unprotected Health Information Security Gaps Are Being Found in Wireless Computer Networks

By Tom Tharp, CISA

Your physical and mental health is a private matter between you and your doctors. But don't forget to include anybody with a laptop computer and \$100. That is the going rate on eBay for a kit that allows someone to read private data of patients who have been treated at a healthcare facility that uses an unsecured wireless computer system.

The kit includes a "Yagi directional antenna," a wireless network card, and a connecting cord. The antenna is slightly larger than a canister of Pringles potato chips. Plug it into your PC and it shows whatever wireless computer signals are being transmitted within about a 600-foot radius. If used near a hospital and you might see treatment information about individual patients.

But take the Yagi to a healthcare facility with a secure wireless network and you'll see nothing but encryption—text converted into a code language that's undecipherable to outsiders.

The latter scenario is what healthcare administrators are hoping for, especially since most covered entities must comply with the HIPAA Security Rule by April 21, 2005. The Rule states that covered entities must have, among other things, technical safeguards in place to preserve the confidentiality of their electronic protected health information.

Some facilities have a long way to go to comply with this HIPAA Rule. Healthcare auditors have reviewed wireless networks at several of our mid-size to large hospitals and found significant security problems at all of them. This article reveals some of the more common security gaps being found, what causes them, why they're a threat to healthcare providers, and generally how they can be resolved.

Potential for Trouble

A growing number of healthcare facilities use wireless computer networks because they help employees become more efficient. Nurses transmit information from a patient's bedside regarding registration, charts, and the administration of medication. When patients press the call buttons in their rooms, the calls are routed to wireless Internet protocol phones that the nurses carry. Hospital administrators use wireless laptops in conference rooms.

One common wireless application is bar-coded medication administration. Before administering medication a nurse scans three bar codes: on their identification badge, on the medication, and on the patient's wristband. The system alerts the nurse if there are any discrepancies regarding patient, drug, dose, method of

administration, or time of day. If everything is verified, the nurse gives the patient the medication and the system logs a record of all medications administered.

All the applications mentioned above involve transmitting Personal Health Information (PHI) across the airwaves. If there are gaps in computer security, anybody with a Yagi antenna or a similar device can access that information.

The biggest reason for the security gaps is obvious: wireless radio frequency signals travel beyond the physical borders of a facility, thus making them accessible to outsiders. Other reasons include the following:

- Wireless devices are generally not securely configured by default.
- Free software is readily available that allows one to identify and exploit insecure wireless networks. Two of the most popular freeware tools are NetStumbler and AirSnort. They can be downloaded at no cost and used to hack into wireless networks.
- Wireless access points—the devices that receive and transmit radio signals and provide network connectivity—are easy to find and little cost or effort is required for a user to connect an unsecured access point to a hospital network.
- Existing encryption and authentication technologies are not effective or are proprietary. In the latter case, it might be necessary to make a considerable investment to replace computer hardware and software, and this isn't feasible for most organizations.
- The policies and procedures at many healthcare facilities do not address

Biggest Reason for Security Gaps ... wireless radio frequency signals travel beyond facility borders making them accessible to outsiders.

wireless security issues. Wireless is a relatively new technology and there has been a much bigger push to deploy it than to update policies and procedures that address its vulnerabilities. At some organizations, information technology personnel are aware of security issues, but lack formal procedures for addressing them.

Security Gaps Discovered

With so much potential for trouble, it is not surprising that security gaps are being found in healthcare systems wireless PC networks. Our wireless audits have uncovered the following:

- Access points that transmit patient bedside registration information in clear text rather than encrypted text.
- Unsecured access points that are installed for a specific purpose, but never removed. For example, an access point is installed in a conference room to provide network connectivity for a specific meeting, but after the meeting the access point is never disconnected.
- Access points that could be reconfigured without a password by any machine with a Web browser, whether the machine is wireless or conventionally connected to the network.
- Wireless clients set up in an unsecured peer-to-peer network. Such a network might consist of two laptop computers with wireless capability configured in a manner that allows one to access the other directly using wireless instead of connecting through the network conventionally. In these cases, anybody with a PC and a wireless network card could access the misconfigured laptop.
- Insecurely configured access points in physician offices that are connected to the hospital network. One such example auditors found was a wireless system that had been installed in a physician's office by a doctor's son.

An audit was performed at a healthcare system in the Midwest two years ago. Armed with a Yagi antenna and a laptop loaded with wireless security software, our auditors drove and walked

around the system's facilities looking for the broadcast of misconfigured access points. When a signal was picked up, they monitored its strength based on the antenna's location. Of the three insecure access points found, one was connected to the client's network. The other two were at a physician's office and at a police department office located within a hospital. The auditors also found issues that had arisen due to the lack of policies and procedures for using the wireless network, the lack of segregation of wireless network traffic, and an insecure authentication mechanism.



Such security gaps make PHI available not only to inappropriate individuals who are employed by the facility, but to contract staff, former employees, and even malicious focused outsiders such as private investigators, an individual's competitors, computer hackers, or even terrorists.

Failure to correct wireless network security gaps can have serious and even deadly consequences. If medical records are illegally manipulated, a patient's health could be compromised. Someone hacking into a payroll system could create financial losses. Lawsuits could result from legal liability. In addition, as mentioned before, HIPAA violations, at a minimum, could result in fines.

Filling the Gaps

A healthcare provider must determine exactly what its vulnerabilities are before it can address them. Therefore, assessment is the logical first step in ensuring the security of a wireless computer network. Whether the provider conducts a self-assessment or is analyzed by an outside party, the assessment must answer three major questions.

1. **Has administration approved, established, and clearly communicated appropriate wireless network policies, procedures, and standards?** Such policies must define the proper use of wireless technology and be approved by management, communicated to the right people, and periodically updated. Policies should also cover employees' home use of the organization's wireless technologies, as well as use by business partners.
2. **Is the wireless network infrastructure actively managed?** This includes having network diagrams of the infrastructure components, facility maps that document the physical location of access points, and an inventory of the components. It also includes having tools to monitor and manage the wireless infrastructure, conducting site surveys to identify unauthorized access points, and ensuring that a risk assessment has been performed.
3. **Have the wireless network components been securely configured?** This involves changing the setting on the wireless access points so that their presence is not broadcast, strong encryption is enabled, access logs are captured, and only authorized computers can access the wireless network.

If the provider is not able to answer affirmatively to all three questions above, an audit is in order to determine exactly what the wireless network's security gaps are and how to fill them.

Conclusion

The popularity of wireless computer systems at healthcare facilities is growing much faster than the development of wireless security and control capabilities. Healthcare administrators should assume that wireless devices are being used in their respective facilities, whether or not they or their IT personnel know about it.

A wireless network is not secure until it has well communicated policies, procedures, and standards in place, its infrastructure is actively managed, and its components have been securely configured. Until then, administrators should assume the security of their computer systems is at risk. ■

Tom Tharp, CISA, is the IT Audit Director for CHAN Healthcare Auditors in St. Louis, MO. He can be reached at ttharp@chanllc.com.

Performing the First Internal Audit: Do You Know Where Your Risks Are?

By Renee Jaenicke

In June 2004, Catholic Healthcare West (CHW) acquired two new facilities along the California Central Coast. Internal audits had not been performed previously at either of these facilities. CHAN Healthcare Auditors has a contract to perform audit services at all CHW's facilities. This article describes how the author determined the potential risks, the effectiveness of internal controls and educated the management and staff on the value of internal audit.

Arroyo Grande Community Hospital and French Hospital Medical Center were owned by two different organizations in the three years before their acquisition in June 2004. Upon completion of the acquisition, the Chief Financial Officer (CFO) requested the healthcare audit organization perform a General Controls Review of financial operations at the two new facilities to serve as an initial baseline and to prioritize areas that might require improvement. These facilities had not experienced any internal audits during their two previous ownerships. Therefore, the first audit project required establishing the purpose of an internal audit group and also educating staff how its daily activities contributes to strong controls for the organization.

Determining Potential Risks and Controls

The project timeline allowed five weeks for completion of this review. The review involved looking at financial areas at two different facilities. Therefore, clearly defined objectives and scope were crucial to a successful project. The auditors met with management and reviewed due diligence materials from the acquisition, to arrive at the following objectives:

- Obtain an understanding of financial processes and document the key financial processes.

- Identify key risks and controls in those processes.
- Perform limited testing to determine whether the controls are functioning as intended.

In consultation with management, the key financial processes referenced above were determined to be: payroll, cash receipts, billing, materials management, and accounts payable.

Each of the key processes above could easily result in a separate. Therefore, it was decided that only the key controls would be tested.

A scope document was developed and buy-in of the CFO was obtained (Exhibit 1). To keep the audit on track a project plan was developed (Exhibit 2). The project timeline allowed 260 hours (five weeks) to review financial operations at two different facilities.

Educating Management and Staff

Education was key to the successful completion of the audit. Since controls in the key financial processes has not been reviewed by an outside organization as far back as anyone could remember, this audit was sure to bring about changes. The individuals in department management and their staffs had already been through changes due to the prior acquisitions. Convincing them that more changes were

needed required showing them how these changes would benefit them. Two tools were used to provide this education: Flowcharts and the "Beat the Crook" game.

Meetings were held with the individuals who perform each step of the processes reviewed, and cross-functional flowcharts showing what steps are taken in the following process areas: payroll, cash receipts, cash posting, purchasing, and accounts payable.

The pictorial representations helped the individuals who perform the work to understand better their jobs, as well as the upstream and downstream step in each process. When individuals understand more about what happens to their work before and after they are finished with it, they tend to understand more about why they do things in a certain way and what might need to change. The flowchart also ensured that were had a solid understanding of what controls were already in place.

Once it was understood what controls were in place, the audit turned to determine which controls were not in place. This was accomplished by means of a "Beat the Crook" game (Exhibits 3 and 4). The games put the auditor in the place of the "crook" and the individuals interviewed played the role of someone returning from vacation during which

Exhibit 1

GENERAL CONTROLS REVIEW
 Arroyo Grande Community Hospital
 French Hospital Medical Center
Scope Considerations

AreaArea	In	Out
Cash Receipts and Posting	Analytical review Compliance with CHW P&P Cash collection (lockbox, mail, cashier, other) Cash receipting, deposits, and posting Cash drawer reconciliation Petty cash Physical security Unapplied cash	Cash account reconciliation Escheatment Unclaimed property Dietary Gift shop Cash equivalents (e.g., securities) Document retention Information systems
Payroll	Analytical review Compliance with CHW P&P Payroll master Timekeeping Overtime authorization Payroll processing Payroll distribution Check stock Payroll stamp	Wage and hours Tax submission to the IRS W-2 Document retention Information systems
Billing & Collections	Analytical review Compliance with CHW P&P Unbilled A/R Billing/claims processing (overview) Follow-up processing (overview) Credit balances/refunds and approval Bad debt write-offs and approval Administrative adjustments and approval	Pre-admission and authorizations Admitting/registration functions HIM Collection agencies Charge master Denial management Document retention Information systems
Accounts Payable	Analytical review Compliance with CHW P&P Vendor master requests Invoice receipt and approval Invoice coding Invoice entry and matching Check processing Check stock Returned checks	1099 processing Accrual G/L accounts Monthly cut-off Document retention Information systems
Materials Management	Analytical review Compliance with CHW P&P Purchase requisitions and approval Purchase order processing Receiving % Purchase order usage Returned goods	Inventory/Central Stores Volume discounts Consigned goods Sales tax Fixed assets Document retention Information systems

Exhibit 2

**GENERAL CONTROLS REVIEW
Arroyo Grande Community Hospital
French Hospital Medical Center**

Objectives

- To obtain an understanding of key financial processes performed by the above two facilities.
- To document these processes via high-level process maps.
- To identify key risks in these areas and key controls to mitigate those risks.
- To perform limited control testing to determine that controls are functioning as intended.

Scope

- Cash Receipts
- Payroll
- Billing and Collection (B&C)
- Accounts Payable (A/P)
- Materials Management (MM)

Excluded

- Substantive detailed testing will not be performed unless warranted by control testing.

Timing

Objective	Week Performed				
	Cash	Payroll	B & C	A/P	MM
Obtain overall understanding	8/9-8/13	8/2-8/6	8/9-8/13	8/16-8/20	8/16-8/20
Document processes	8/9-8/13	8/2-8/6	8/9-8/13	8/16-8/20	8/16-8/20
Identify key risks and controls	8/9-8/13	8/2-8/6	8/9-8/13	8/16-8/20	8/16-8/20
Limited control testing	8/23-8/27	8/23-8/27	8/23-8/27	8/23-8/27	8/23-8/27

Report writing	Week of 8/30-9/2
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the "crook" had attempted to steal from the facility. The games provided a series of scenarios and requested a response from those individuals in different areas of the process (i.e., cash receipts and cash posters, materials management and accounts payable). What made these games effective was:

- Department management suggested scenarios prior to staff interviews. These suggestions helped them buy into the game idea. Meetings were held with department management after completion of each game. These meetings alerted them to potential audit issues.
- The games looked at each process as a whole. For example, if a cashier thought that the cash poster provided a control that was not in place, all participants could see the breakdown.

- The games placed the "blame" on the interviewer, not the interviewee. The person interviewed was assumed to be honest. The interviewer was the crook. As a result, each person interviewed opened up more about their concerns.
- The individuals interviewed not only helped identify problems based on the responses to the scenarios, they also helped identify the solutions.
- When it was time to develop action plans, internal audit experienced virtually no resistance from the individuals responsible for carrying out the changes because they helped develop them.

The games were a hit! Staff talked about it at coffee breaks and in the lunchroom, asking if internal audit had been to their department yet. Department

management decided to keep the game on hand so it could be used to assess risks periodically.

Best Practices

Our audit organization maintains a database of best practices from over 300 facilities nationwide. A best practice is defined as a practice or process that strengthens the client's internal controls, could benefit another client if implemented, and is transferable by way of sharing methodology, tools, and templates. During this project, individuals requested information on how other facilities ensure strong controls in some of the process areas reviewed. However, they also had best practices to share. One of the collection locations had an excellent example of a cash-balancing template. This was recommended for use at both facilities, and it was submitted to CHAN's *Best Practice Committee* for

Exhibit 3

“BEAT THE CROOK” Disbursements Cycle

Hypothetical Scenario: You are on vacation for a month. I have taken your position on a temporary basis. When you return from vacation, I will be no longer be working for this facility and there will be no way to reach me. Consequently, you will be responsible for any actions I take on your behalf while you are away. Listed below are a series of scenarios. Please respond by advising how the process currently in place would detect these situations. For those situations that would not be detected, we will meet together to discuss what changes could be implemented to detect those situations should they occur in the future.

Scenario	Materials Management Response	Accounts Payable Response	Suggestions to Address
I am a buyer			
I created a bogus vendor with the address to my personal post office box. I issued a PO to this bogus vendor and then sent Accounts Payable (A/P) an invoice. Invoice was paid.			•
I issued a Purchase Order (PO) and received the goods. But I took some of the goods and adjusted the PO. Invoiced matched to adjusted PO and receiving report. Invoice was paid.			•
I created a PO with a ship-to address of my home. I input the receiving report. Vendor sent in invoice. Invoice was paid.			•
I entered a new item on the item master and ordered it from a vendor with whom we do not have a contract. Facility paid.			•
I am an Accounts Payable processor			
I entered a new item on the item master, ordered it, received it, and took it for myself. Vendor invoiced the facility and the facility paid.			•
I input a return PO indicating that items were returned to the vendor. Instead, I took these items for myself.			•
I keyed in a patient refund to someone other than a valid patient. This refund check was sent and cashed by my friend or by myself.			•
I keyed a non-PO invoice into the same vendor, same invoice number, but a different date. Invoice was paid.			•
I keyed a non-PO invoice into the same vendor but under a different vendor number. Invoice was paid.			•
I keyed a non-PO invoice to the same vendor, same vendor number, but I input the invoice number without the dashes. Invoice was paid.			•
Someone forged the manager’s signature for a non-PO invoice and took the items or used the service for themselves. I entered it and the invoice was paid.			•
Manager charged the invoice to a revenue account. I keyed this in and the invoice was paid.			•
A recurring invoice has been set up to pay monthly. I paid this recurring invoice, even though the contract had expired (e.g., rent).			•
I paid an invoice for an item that we no longer have (e.g., equipment lease), which was not set up as a recurring invoice.			•
I entered a new line on the PO, or I changed the per-unit \$ amount to force the invoice to match the PO. Invoice was paid.			•
I received a returned check and endorsed it to myself on behalf of the facility.			•

Exhibit 4

“BEAT THE CROOK” Cash Receipts

Hypothetical Scenario: You are on vacation for a month. I have taken your position on a temporary basis. When you return from vacation, I will be no longer be working for this facility and there will be no way to reach me. Consequently, you will be responsible for any actions I take on your behalf while you are away. Listed below are a series of scenarios. Please respond by advising how the process currently in place would detect these situations. For those situations that would not be detected, we will meet together to discuss what changes could be implemented to detect those situations should they occur in the future.

Situation	Cashier Response	Cash Poster Response	Suggestions to Address
I am a cashier			
Patient pays in cash or check and does not need a receipt. I take cash or endorse the check to myself.			•
Patient pays in cash or check. I prepare a receipt for the patient but do not log it on the pegboard. I take cash or endorse the check to myself.			•
Patient pays \$50 cash. I write receipt for \$50, but write it by hand on the pegboard for \$40, or I white out the \$50 on the pegboard and write in \$40. I take the \$10 and go buy lunch with it.			•
I take some of the cash box money and spend it, and put receipted patient cash in the cash box so it balances. I then log this patient cash on pegboard the next day, replacing it with more patient cash so that the cash box balances.			•
I balance the cash box daily and state that the box is in balance. I also take money from cash box and spend it.			•
I am a cash poster			
I pick up the cash and checks from the cashiers. I pocket some of the cash or endorse some of the checks, and run a new tape, entering and depositing the smaller amount.			•
I prepare the deposit and post the batches. I take \$20 cash for myself.			•
I post the batch and take \$20. Deposit is made the next day. However, I take \$20 from the next day’s patient cash so the deposit balances.			•
I prepare and post batches and make the deposit for another cash poster and myself because the other cash poster is sick. I take \$20 from the other poster’s cash, run a tape, enter, and prepare deposit on smaller amount.			•
I receive a refund from a vendor. I endorse the check to myself and do not include it in the deposit.			•

consideration. This cash balancing tool was approved for distribution to the over 300 facilities served! Facility management was delighted that, although a lot of work was required, their first review resulted in identification of something that could be shared with others.

Summary and Conclusion

It is not hard to develop an audit program to address risks and controls in a financial process. To perform this audit

at a facility that has no experience with internal audit, and to get it completed in five weeks, may provide challenges not usually encountered in an audit. It requires that we scope the audit very carefully, provide education at the facilities on how internal audit benefits the facility, and show them the unmitigated risks that need to be addressed. This project was effective because it combined the risk assessment with education, involved individuals at all levels—from senior management to the

individuals actually performing the steps in the process, and shared best practices. The CFO recommended that this type of project be performed at any new facility that CHW acquires in the future. ■

Renee Jaenicke serves as a Senior Audit Manager for CHAN Healthcare Auditors. Based in Camarillo, California, she works with a team of audit managers at 11 facilities owned by Catholic Healthcare West in southern California. She also performs financial, compliance, and operational audits for two acute-care facilities.

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Surgery Charge Capture: An Audit Approach to Stop the Bleeding

By Angelique Hemstreet and Jill Linden

Hospitals are losing millions of dollars in revenue due to unbilled surgical services and supplies. The culprit is poor charging controls. A solution, used extensively by the Catholic Healthcare Audit Network (CHAN), is operational auditors combined with clinical coding and computer-assisted audit techniques (CAAT) resources.

Using this approach, CHAN discovered control weaknesses in the surgery departments of many of its 300-plus hospital IT audits. Hospital management is usually surprised to hear that they are losing up to hundreds of thousands of dollars annually due to:

- Information systems that interface improperly.
- Incomplete charge entry screens or charge tickets.
- Charge masters that are not updated properly.
- Inadequately trained staff.
- Poor communication among hospital departments.

These audit issues can be solved, and the financial “bleeding” stopped, through an audit approach requiring an operational auditor’s close interplay with experts in CAAT and clinical coding.

CAAT Shows Trends

CAAT is effective because it allows the testing of 100 percent of surgery accounts within a particular time. Other sampling methods test only a small subset of accounts, which may fail to show trends altogether or take longer to identify them, and don’t determine the root causes of errors. There are many CAAT tools commercially available that could be used to perform this analysis, such as ACL, IDEA, etc.

Pairings Help Reveal Missing Charges

To facilitate testing of surgery charges, CHAN Healthcare Auditors, developed many one-to-one relationships, or pairings,

between International Classification of Diseases, Ninth Revision (ICD9) codes, Current Procedural Terminology (CPT) codes, Diagnostic Related Group (DRG) assignments or individual service and charge codes with other charges that should be present on the patient account given the surgical procedure being performed.

Example: If a patient underwent a total hip replacement, an ICD9 procedure code of 81.51 would be coded to the patient account by Health Information Management (HIM). Based on the presence of this ICD9 code and the charging practices of the hospital, the charges posted to the account would be tested for the presence of an implant charge, a surgery procedure charge, a recovery room charge,

and an anesthesia charge. Using this simple approach, missed implant charges alone amounted to nearly \$350,000 of annual lost net revenue at one hospital.

Our audit analysis begins by establishing universal surgery charge “pairings” to apply against actual charge data. The general criteria for a code to be included in the surgery pairings is that in 95% of all cases, the surgical procedure described by the code will require anesthesia and recovery services. For implant procedures, an ICD9 or CPT code will only be considered if the procedure described by the code indicates the use of a device that will stay in the body and must be surgically removed in 95% of all cases. Clinical coding specialists are

engaged in the analysis to assess each ICD9, CPT, and DRG code within the surgical ranges and provide a list of codes meeting the established criteria. The lists are then 'built-in' to CAAT procedures as standard testing that can be performed at any hospital.

In addition to the standard pairings, there are often opportunities to develop hospital-specific pairings. These should be evaluated on a case-by-case basis and may vary depending upon how a hospital charges for procedures, OR time, supplies, etc. As the pairings are identified, the operational auditor works with the CAAT specialist to build a CAAT analysis to test applicable surgery accounts for these hospital-specific charging patterns.

Identifying which charges are posted for each surgery procedure, recovery room, anesthesia, and implant depends largely on the charging practices within each hospital. The operational auditor, CAAT specialist, and clinical coding auditor must work closely to define these charges and provide accurate test results. Charges may be defined by the use of specific service and charge codes, revenue code assignments, CPT code assignments, or a combination of department code and revenue code assignments. The variety in the charging methodology makes this the most challenging portion of the testing.

Planning Ensures Right Data Is Obtained

One of the most critical audit development steps is ensuring the right data is extracted for analysis. During the planning phase of a surgery charge capture audit, a data request should be submitted to the hospital's Information Technology (IT) department specifying all of the data fields required for the review. The need for CPT codes originating from both the charge description master and HIM coding should be emphasized in the request as this data element often resides in a separate HIM abstract file as well as the patient accounting database. A download of the hospital's complete charge master should be requested, and copies of surgery department charge sheets should be obtained.

Once received, data files should be tested for integrity by the CAAT specialist. One easy way to do this is to reconcile revenue totals to financial statements to ensure the completeness and accuracy of the data provided.

HINT:

It is helpful to request all patient accounts for a given test period. If the hospital IT department extracts only "surgery" accounts, they may inadvertently filter out accounts with missing surgery codes and/or incorrect patient types. Requesting all accounts for the test period ensures the testing will identify these instances, and how often they occur, so that appropriate follow-up can be performed.

Questionnaire Shows Hospital's Charging Practices

Prior to the data analysis, it is also helpful for the operational auditor to work with surgery department staff to complete a questionnaire. The purpose of the questionnaire is to determine the charging practices at the hospital and refine the scope of the surgery charge capture audit. For example, the questionnaire reveals whether separate Cardiac Catheterization, Gastroenterology, Interventional Radiology and Special Procedures, or Eye Procedures departments exist within the hospital, and, if so, whether these departments are included within the scope of the surgery audit. Generally, these departments perform surgical procedures that require anesthesia administration and recovery time. If, however, they are not included in the scope of the audit, related patient accounts will need to be removed from the population for testing. If departments outside of the main operating room area of surgery are within the scope of the review, the operational auditor will need to ensure that the charging practices in these departments, if different from the main operating room, are detailed in the questionnaire. Otherwise, false exceptions may appear on CAAT exception reports.

Specific charging practices for recovery room and anesthesia should also be addressed in the questionnaire. If there are circumstances or a set of surgical procedures that should be built into the total surgical procedure charge,

rather than being separately charged to recovery room services or anesthesia, this information will be available to the CAAT specialist for consideration.

Report Verification Eliminates False Exceptions

Once initial CAAT exception reports are produced, the CAAT specialist should review a sample of exceptions to ensure that charging procedures outlined in the CAAT questionnaire were properly handled during the CAAT testing (to minimize the number of false exceptions). In reviewing this sample, the CAAT specialist often discovers commonalities in the exception reports that require further investigation by the operational auditor. The CAAT specialist should then review all reports in detail with the operational auditor to ensure there is an understanding of how the testing was performed and how the reports should be interpreted, and to discuss any observations noted by the CAAT specialist during the analysis.

NOTE:

To review and validate CAAT exception reports, some degree of familiarity with clinical practices and procedures is needed. An auditor lacking the background to do this analysis independently could work with a clinical resource to ensure that exceptions are properly understood and evaluated.

Following this discussion, the operational auditor can begin analyzing and verifying the exception reports. This step ensures that false exceptions are eliminated before quantifying the extent of missed charges. The auditor may find it necessary to engage other resources to perform this analysis, including clinical coding auditors, subject matter experts, or hospital clinical staff.

The following are typical approaches to validating exception reports:

Surgery Charge, continued on page 25

Governance: An Inoculation for Corporate Fever

By Stacey Hamaker

Governance and enterprise best practices are hot topics these days. No one understands how the recent corporate fiascos could have reached such enormous proportions. Who is accountable? Where were the directors, the auditors, the accountants, and the other executives?

Theories and remedies abound. In response to the bevy of corporate scandals, Congress passed the Sarbanes-Oxley Act (SOX) of 2002 to address some of the most pressing issues of corporate responsibility and governance. The SOX provisions addressed such topics as executive responsibility for financial statements, conflicts of interests on behalf of auditors, securities analysts and attorneys, audit committee independence and whistleblower protection. Numerous additional safeguards have since been proposed or enacted worldwide by governments, regulatory agencies, stock exchanges, securities firms and investment watchdog groups.

But are they missing the mark? Perhaps there is a more subtle source of corporate affliction. Perhaps there is a new strain of fever that thrives in upscale environments where growth, profits and conspicuous consumption are highly valued, a contagion that incubates in executive offices with ample light and expansive views. Let's call it... Executivitis: a condition wherein afflicted executives have become caught up in too much of a good thing.

Hypothetically speaking then, Executivitis would be most commonly found in aggressive, innovative, risk-takers with a history of successful accomplishments. Symptoms begin with an awe-inspiring achievement, followed with renewed confidence and a yen for further high-profile success. Particularly

hard hit are executives whose resistance has been worn down by years of hard work, sacrifice and recognition. Also susceptible: leaders of public companies with intensely profit-driven investors.

Inoculate against Executivitis... "a contagion that incubates in executive offices..."



Like most viruses, there can be a variety of strains, such as:

- Financialitis: Characterized by over-use of financial instruments including extended credit, derivatives, or off-balance sheet transactions.
- Growthitis: Obsession with growth whether it makes sense or not. Companies are "going national" or "going global." Franchisers may boast of opening 300 new locations per year.
- Merger, Acquisition and IPO-itis: Characterized by wheeler-dealer

executives who are too caught up in financial statements to notice or sufficiently address growing operational problems.

- Brainstormitis: Found in executives who rush projects in order to establish a reputation as "industry leader" without providing sufficient resources to ensure success.
- TechnoMania: Similar to Brainstormitis. These executives are enthralled with the sex appeal of technology, but do not dedicate the time or resources to understand and manage the ramifications.
- Divinitis: Another variant of Brainstormitis in which the leader is completely enamored with his/her brilliant and intellectually-superior vision. No one else could possibly comprehend it. Therefore, discussing it or attempting to gain consensus on the direction would not be feasible.
- Grandiositis: Inability to focus or prioritize objectives for the over-worked staff. Executives "want it all" and consider themselves over-achievers.
- Competitivitis: Total absorption with beating the competition "at all costs" leading to internal implosion.
- Operationalitis: Such pre-occupation with the operational details of running the business that management fails to *adequately* address strategic issues. They mistakenly believe that a cursory attempt at strategic planning has "x-ed the block".
- Elititis: Belief that the organization cannot be touched because it is the unequivocal leader in its industry.

- **Controlfreakitis:** An unhealthy obsession with running the show and making sure everyone knows who is in charge. Making firm decisions regardless of any supporting analysis. (“My way or the highway.”)
- **Paralysisitis:** Characterized by the inability to make decisions or produce a meaningful strategy, even if there has been abundant analysis or consultant assistance.
- **Swingeritis:** Found in executives more interested in a lavish lifestyle than running a sustainable business.

Like Gingivitis, Executivitis begins in a small, inconspicuous, but sticky spot. Lighter cases may cause headaches, acid indigestion or sleeplessness. A couple of aspirin, an antacid and a dose of creative accounting will usually take care of it. But with the more severe cases, drastic measures such as board interventions, bankruptcies or federal investigations are often necessary to eradicate the infection.

The largest outbreaks of Executivitis are observed in those who “don’t see the value” in establishing and enforcing good enterprise governance practices. However, executives with clearly defined strategies guided by strong business ethics (the vast majority of business leaders today) are rarely afflicted.

What are the precautions to avoid Executivitis? Establish strong, well thought-out and aggressively monitored enterprise governance practices that provide the checks and balances necessary to break virulent Executivitis fevers, and restore cool heads and clear thinking.

Over and above corporate governance, strong enterprise governance includes:

- An atmosphere of emotional maturity which encourages open communications among all levels of personnel and which does not punish, stifle or discourage honest and legitimate objections or challenges.
- A formal, active, involved, and informed oversight committee e.g. Board of Directors or Trustees with well-defined roles and relationships to the organization’s management.
- A well-defined sense of purpose or mission with respect to the organization’s market and customers.

- A clear understanding of the organization’s core competencies as it relates to its market.
- A culture of accountability, transparency, integrity, honesty, and compliance with laws, policies, processes and procedures – at all levels.
- Well-defined short/long-term goals relating to sales, operations, and finance.
- Clear tactical plans for achieving goals.
- Proactive and responsible management of risk.
- An appropriate, stable, and public organizational hierarchy.
- Operations and processes that are reasonably updated, efficient, and effective.
- Frequent and public comparisons of performance to plan to determine whether goals should be revised or corrective action taken.
- An emphasis on measurement and disclosure of key health indicators in an accurate, timely, consistent, and public way.
- Well-documented and widely understood policies, procedures, and practices.

Entrepreneurial inspiration and innovation are vital to economic growth. The challenge comes in balancing agility, time to market pressures, as well as short and long-term objectives with a reasonable level of checks and balances.

Good enterprise governance practices do not guarantee protection from corporate malfeasance—but like most good vaccines, they provide significant protection from this deadly contagion... hypothetically speaking, that is. ■

Stacey Hamaker is Managing Principal of Shamrock Technologies, a consulting firm that specializes in governance and strategic information management, including Sarbanes-Oxley IT compliance. For more information, access www.shamrock-technologies.com.

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Chair, continued from page 3

strengthen AHIA membership in Canada. The goals and objectives related to the Canadian initiative include:

- Promote the healthcare internal auditing profession in Canada.
- Unite the healthcare internal auditing professionals in Canada.
- Provide a platform for technical interchange addressing the uniqueness of the Canadian healthcare system.
- Share information on Canadian healthcare systems and audit issues with other members of AHIA.

AHIA Board members involved in the Canadian initiatives are Karen Young, Debi Weatherford, and Mark Ruppert. The Canadian contingent is composed of:

- Dave Rubel, Director, Internal Audit, Winnipeg Regional Health Authority.
- Ruhil Popatia, Director, Internal Audit, Capital Health, Alberta.
- Terry Hrischuk, Director, Internal Audit, BC Health.
- Givonna Debruin, Manager, Internal Audit, Interior Health Authority.

We are excited by the opportunities to pioneer strategic efforts outside of the United States as we address the needs of our Canadian members. Stay tuned for developments from these efforts.

As you can see from these key initiatives and associated activities there are many opportunities to support AHIA through volunteer efforts. I encourage you to get involved! ■

Debi Weatherford, CIA, is Chairman of the AHIA Board of Directors. She is Vice President, Compliance and Audit Services, Revenue Cycle Solutions, in Marietta, GA. She can be reached at dweatherford@ahia.org.

Survey Results on the Design and Implementation of Hospital Compliance Programs

By David B. Pariser, Ph.D., CPA, CFE and Anthony J. Amoruso, Ph.D., CPA

A major component of the Office of Inspector General's (OIG) outreach activities in preventing fraud and abuse in federal healthcare programs is the publication of a series of voluntary compliance program guidelines encouraging healthcare organizations to design and implement effective compliance programs. The OIG believes that healthcare providers participating in federal healthcare programs have a legal and ethical duty to ensure the integrity of their transactions with these programs. This duty, according to the OIG, includes implementing a compliance program to detect and prevent the occurrence of fraudulent, abusive, and wasteful activities.

The OIG's compliance guidelines not only identify the major components of effective compliance programs, but also offer recommendations on the kinds of internal controls and other compliance measures that healthcare organizations should consider when developing and implementing new compliance programs or evaluating existing programs. To date, the OIG has issued Compliance Program Guidelines for hospitals and ten other segments of the healthcare industry. The compliance guidelines are available on the OIG's website at <http://oig.hhs.gov> in the "Fraud Prevention & Detection" section.

This article presents the results of a survey on the design and implementation of hospital compliance programs. It focuses on six compliance program components: (1) development and distribution of written codes of ethical conduct; (2) designation and reporting lines of compliance officers and compliance committees; (3) auditing and monitoring compliance programs; (4) using compliance as a factor in evaluating performance; (5) systems for responding to and resolving allegations of improper/illegal conduct; and (6) non-

employment of sanctioned individuals and training of employees and agents. These six components are included in the OIG's compliance program guidelines for hospitals published in the *Federal Register* on February 23, 1998 (Vol. 63, No. 35, pp. 8987-8998). The OIG published "Supplemental Compliance Guidelines for Hospitals" in the *Federal Register* on January 31, 2005 (Vol. 70, No. 19, pp. 4858-4876). The survey findings and analysis should help hospital CEOs, compliance officers, and managers to benchmark the characteristics of their compliance programs with others in the hospital industry.

Survey Methodology and Data

The survey was designed to determine the frequency of hospital compliance programs that include specific components that the OIG recommends in its compliance guidelines for hospitals, and how the frequency varies by hospital size. Hospital size is taken into account because Section §8B2.1 of the 2004 *Federal Sentencing Guidelines Manual* (http://www.ussc.gov/2004guid/tabcon04_1.htm) indicates that size of an organization is a relevant factor affecting the design and implementation of compliance programs, and because classifying hospitals into size categories is an industry tradition.

The data for this article were collected through an anonymous survey questionnaire on hospital compliance programs mailed to the Chief Executive Officers (CEO) of 1,200 hospitals. The cover letter requested the CEO or the compliance officer to complete and return the questionnaire. Respondents were asked to classify their hospitals into one of five size categories based on number of beds: 0-149 beds, 150-250 beds, 251-350 beds, 351-450 beds, and greater than 450 beds. The survey questionnaire instrument

does not identify the organizations or the individuals completing the questionnaire. A total of 250 surveys were returned. Eight incomplete questionnaires were excluded, leaving 242 usable survey instruments, a response rate of 20 percent. Table 1 shows the distribution of the 242 respondents across the five hospital size categories.

Table 1: Distribution of Respondents by Size

Size Classification	# of Hospitals	%
0 – 149 beds	22	9%
150-250 beds	76	31%
251-350 beds	44	18%
351-450 beds	39	16%
>450 beds	61	25%

Survey Findings and Analysis

Development and Distribution of Written Codes of Conduct

The OIG recommends that hospitals develop a written code of conduct and distribute it to all employees and other agents. Table 2 shows that 99 percent of all respondents have developed and distributed written standards of conduct. The results are uniform across the sample with a high degree of compliance in all size categories.

Designation and Reporting Lines of Compliance Officer and Compliance Committees

The OIG's compliance program guidelines recommend that hospitals hire or appoint a compliance officer. The compliance officer is responsible for developing and implementing compliance

Table 2: Development and Distribution of Codes of Ethical Conduct, By Hospital Size

	Compliance Program Element: Development and distribution of written standards of conduct, policies and procedures that promote compliance with high-risk areas identified by OIG
All Respondents N=242	99.2%**
0-150 Beds N=22	100.00%**
151-250 Beds N=76	98.7%**
251-350 Beds N=44	97.7%**
351-450 Beds N=39	100.00%**
>450 Beds N=61	100.00%**

** Significant at the 0.01 level

policies, procedures, and practices that will ensure compliance with federal healthcare program requirements. As shown in Table 3, 84 percent of all respondents employ a full-time compliance officer and slightly more than 15 percent have a part-time compliance officer. The employment status of compliance officers varies across the five size categories, and the percentage of full-time compliance officers increases with hospital size. With regard to the reporting lines of compliance officers, 84 percent of all respondents' compliance officers either report directly to the CEO (42 percent) or report to both the CEO and governing body (42 percent). The remaining 15.6 percent of the respondents' compliance officers have different reporting lines. Table 3 also shows that nearly 90 percent of the respondents' compliance committees report directly to the CEO and the governing body, and this percentage is relatively uniform across the five hospital size categories.

Auditing and Monitoring Compliance Programs

The OIG recommends that hospitals maintain an internal audit function that is responsible for auditing and monitoring operations for compliance with federal healthcare regulations. Table 4 summarizes the survey findings relating to the auditing and monitoring of com-

pliance programs. Nearly 26 percent of all respondents indicate that their internal auditors perform compliance audits, and the percentage varies across the five hospital size categories, ranging from a low of 16 percent to a high of 40.5 percent. About 71 percent of all respondents indicate that compliance audits are performed by a combination of internal auditors and outside contractors, and this percentage is relatively uniform across all size categories.

Nearly 67 percent of all respondents indicate that the compliance officer is responsible for the compliance auditing and reporting function, with the percentage ranging from 54.5 to 76.7 percent across the five hospital size categories. Nearly three-quarters of all respondents distribute audit compliance reports to senior managers and to compliance committee members. Reports are also distributed to the governing body of the organization by 58 percent of the respondents. Only 23 percent of the sample hospitals distribute compliance reports to employees of the unit being audited.

Using Compliance as a Factor in Evaluating Performance

In evaluating employee performance, OIG recommends that adherence to the elements of a hospital's compliance

Table 3: Designation and Reporting Lines of Compliance Officer and Committee, By Hospital Size

Compliance Program Element	All Respondents N=242	0-150 Beds N=22	151-250 Beds N=76	251-350 Beds N=44	351-450 Beds N=39	>Than 450 Beds N=61
<i>Employment status of compliance officer:</i>						
- full-time	84.4%**	68.2%**	82.9%**	81.0%**	89.2%**	91.7%**
- part-time	15.6%**	31.8%**	17.1%**	19.0%**	10.8%*	8.3%*
<i>Compliance officer reports directly to:</i>						
- CEO	42.4%	59.1%**	43.4%**	46.5%**	43.2%**	31.7%**
- the governing body	7.6%	0	14.5%**	4.7%	5.4%	5.0%
- both the CEO and governing body	42.0%	27.3%*	35.5%**	44.2%**	40.5%**	55.0%**
- director of internal audit	0.8%	0	1.3%	0	0	1.7%
- other	9.2%	18.2%*	7.9%*	7.0%	13.5%*	6.7%*
<i>Designation of compliance committee that reports directly to CEO and governing body</i>	89.6%**	81.8%**	85.5%**	97.7%**	87.2%**	93.3%**

* Significant at the 0.05 level
 ** Significant at the 0.01 level

Table 4: Auditing Program Compliance, By Hospital Size

Compliance Program Element	All Respondents N=242	0-150 Beds N=22	151-250 Beds N=76	251-350 Beds N=44	351-450 Beds N=39	>Than 450 Beds N=61
<i>Compliance audits are performed by:</i>						
- internal auditors	25.6%	27.3%*	19.7%**	16.3%**	40.5%**	30.0%**
- external auditors on a case-by-case basis	7.6%	13.6%	7.9%*	9.3%*	13.5%*	0
- outside contractors who perform all compliance audits	2.5%	0	5.3%*	2.3%	2.7%	0
- a combination of internal auditors and outside contractors	71.4%	59.1%**	75.0%**	79.1%**	62.2%**	71.7%**
<i>Compliance auditing and reporting function is the responsibility of:</i>						
- the compliance officer	66.8%**	54.5%**	63.2%**	76.7%**	67.6%**	68.3%**
- the head of internal audit	13.4%	22.7%*	10.5%**	4.7%	18.9%**	16.7%**
- the audit committee of the governing body	2.9%	0	6.6%*	0	2.7%	1.7%
- the heads of operating departments	12.2%	9.1%	17.1%**	16.3%**	5.4%	8.3%*
- other	11.8%	22.7%*	11.8%**	7.0%	10.8%*	11.7%**
<i>Compliance audit reports are distributed to:</i>						
- senior management	73.0%	77.3%**	76.3%**	69.0%**	64.9%**	75.0%**
- all employees of the unit subject to audit	23.1%	27.3%*	18.4%**	20.9%**	24.3%**	28.3%**
- compliance committee members	73.1%	77.3%**	69.7%**	83.7%**	78.4%**	65.0%**
- governing body of the organization	58.4%	81.8%**	51.3%**	60.5%**	62.2%**	55.0%**

* Significant at the 0.05 level

** Significant at the 0.01 level

program should be a factor in evaluating the performance of managers and supervisors. Table 5 (page 23) summarizes re-sponses regarding the use of compliance performance measures. Nearly 70 percent of hospitals report using compliance measures when evaluating performance, from a high of 82 percent among the smallest hospitals to a low of 65 percent among the largest hospitals.

In addition to their greater use of compliance measures in evaluating performance, 81 percent of the smallest hospitals prepare compliance measures at the department or operating unit level and report the results to management and the governing body. This compares to 61 percent for all respondents and only 47 percent for the largest hospitals in the sample. Other uses of compliance measures are relatively

low for all hospitals, regardless of size category. Only 15 percent of hospitals report integrating compliance measures into a Balanced Scorecard approach to performance evaluation. Regarding managerial compensation, 13 percent of the sample hospitals link compliance to compensation for senior managers, compared to only 9 percent that link the compensation of mid-level managers to compliance performance measures.

Systems for Responding To and Resolving Allegations of Improper and Illegal Conduct

The OIG encourages hospitals to use hotlines, e-mail, written memoranda, newsletters, and other forms of information exchange to maintain open lines of communication. OIG also recommends that a hospital’s chief compliance officer or other management officials should

promptly investigate allegations of illegal conduct and determine whether material violations have occurred.

Hospitals report using a variety of hotline services to receive complaints, as shown in Table 6 (page 23). The most common hotline services are 800 numbers, written memoranda, and e-mails, which are used by 72 percent, 33 percent, and 32 percent, respectively, of all hospitals. The greatest difference between large and small hospitals is in the use of 800 numbers to receive complaints. While the use of all other hotline services is fairly similar across size categories, 85 percent of the largest hospitals use 800 numbers, compared to only 36 percent of the smallest hospitals. Despite this disparity, the outsourcing of hotline services is similar across size categories. On average, 54 percent of hospitals use employees

Table 5: Using Compliance as a Factor in Evaluating Performance, By Hospital Size

Compliance Program Element	All Respondents N=242	0-150 Beds N=22	151-250 Beds N=76	251-350 Beds N=44	351-450 Beds N=39	>Than 450 Beds N=61
<i>Compliance performance measures are:</i>						
- used as performance measures	69.5%**	81.8%**	76.3%**	59.1%**	67.6%**	65.0%**
- prepared at the department and operating unit level and reported to management and the governing body	60.9%**	81.0%**	68.9%**	58.1%**	59.5%**	46.7%**
- integrated into a Balanced Scorecard approach to measuring and evaluating operating unit performance	15.3%	14.3%	18.9%**	7.0%	18.9%**	15.0%**
- linked to senior manager compensation	13.2%**	9.5%	9.5%**	18.6%**	24.3%**	8.3%*
- linked to mid-level manager compensation	8.9%**	9.5%	4.1%	9.3%*	18.9%**	8.3%*

* Significant at the 0.05 level

** Significant at the 0.01 level

Table 6 Systems to Respond to and Resolve Allegations of Improper/Illegal Conduct, By Hospital Size

Compliance Program Element	All Respondents N=242	0-150 Beds N=22	151-250 Beds N=76	251-350 Beds N=44	351-450 Beds N=39	>Than 450 Beds N=61
<i>Types of hotline services used to receive complaints:</i>						
- an 800 telephone line service	72.3%	36.4%**	59.2%**	97.7%**	70.3%**	85.0%**
- e-mails	32.4%	31.8%**	34.2%**	32.6%**	24.3%**	35.0%**
- written memoranda	32.8%	40.9%**	32.9%**	37.2%**	27.0%**	30.0%**
- newsletters	16.0%	18.2%*	13.2%*	16.2%**	16.2%*	18.3%**
- suggestion boxes	16.8%	31.8%**	17.1%**	20.9%**	13.5%*	10.0%*
- other	27.7%	27.3%*	32.9%**	27.9%**	24.3%**	23.3%**
<i>Hotlines to receive complaints are operated by:</i>						
- employees	54.2%	66.7%**	57.9%**	55.8%**	44.7%**	50.0%**
- outside contractors	39.9%	28.6%*	38.2%**	34.9%**	47.4%**	45.0%**
- employees with assistance from outside contractors	4.6%	0	5.3%*	9.3%*	2.6%	3.3%
<i>Procedures to protect anonymity of complaints and whistleblowers</i>	99.6%**	100%**	100%**	100%**	100%**	98.3%**
<i>Standards for resolution and disclosure of inappropriate activity</i>	92.5%**	86.4%**	94.7%**	90.9%**	92.1%**	93.3%**
<i>System to respond to allegations of improper and illegal activities</i>	98.8%**	100%**	98.7%**	97.7%**	100%**	98.3%**

* Significant at the 0.05 level

** Significant at the 0.01 level

exclusively to receive complaints, while 40 percent exclusively use outside contractors. Hospitals of all sizes report a high level of compliance regarding the development of procedures to protect the anonymity of whistleblowers, standards for the resolution and disclosure of inappropriate activity, and systems to respond to allegations of improper or illegal activities.

Non-employment of Sanctioned Individuals and Training of Employees and Agents

Congress enacted several laws authorizing the OIG to exclude individuals and entities from participating in federal healthcare programs who have engaged in fraud and abuse. Consequently, no federal healthcare program payment may be made to excluded individuals or entities. In addition, the OIG recommends that hospitals develop and implement education and training programs for all affected employees and agents including vendors, contractors, and physicians. These education and training programs should emphasize the hospital's compliance program, federal and state fraud and abuse laws, as well as federal healthcare program billing and claim submission requirements.

As shown in Table 7, more than 91 percent of sample hospitals have policies addressing the non-employment of sanctioned individuals. The two largest size categories are both above the sample average, with compliance for smaller hospitals being as low as 82 percent for the smallest size category. Education and training programs are provided for affected employees by nearly every hospital in the sample. Training for physician providers is also relatively high across size categories, reflecting an average of 84 percent for all respondents. However, the largest hospitals in the sample are more likely than the smaller hospitals to provide education and training programs for vendors and contractors, with only 32 percent of the overall sample providing such programs.

Table 7 also shows that 54 percent of respondents use employees exclusively to conduct compliance training. The smallest hospitals are more likely to rely on employees for training, with a response rate of 68 percent compared to only 47 percent for the largest hospitals. Accordingly, 53 percent of the largest sample hospitals use a combination of both employees and outside contractors to provide compliance training, as opposed to 32 percent for the smallest hospitals.

Concluding Remarks

The survey findings reported above indicate a large majority of the sample hospitals have compliance programs containing the six program components the OIG recommends in its guidelines for hospital compliance programs. Four areas in which hospitals demonstrated nearly universal compliance with OIG recommendations were written codes of ethical conduct, procedures to protect the anonymity of whistleblowers, systems to respond to allegations of improper or illegal activities, and compliance training programs for all affected employees. Respondents used a variety of hotline services to receive complaints. The 800 number is the most common service, used by nearly three-quarters of all sample hospitals. The largest hospitals were more than twice as likely as the smallest hospitals to use 800 numbers. Sample hospitals in the largest size category were also more likely to provide education and compliance training for vendors and contractors.

The survey findings also indicate that nearly three-quarters of all sample hospitals use compliance measures when evaluating performance, from a high of 82 percent among the smallest hospitals to a low of 65 percent among the largest

Table 7: Program Components Relating to Non-Employment of Sanctioned Individuals and Training of Employees and Agents, By Hospital Size

Compliance Program Element	All Respondents N=242	0-150 Beds N=22	151-250 Beds N=76	251-350 Beds N=44	351-450 Beds N=39	>Than 450 Beds N=61
<i>Policies addressing the non-employment or retention of sanctioned individuals</i>	91.3%**	81.8%**	92.1%**	86.4%**	97.4%**	93.3%**
<i>Education and training programs provided for:</i>						
- all affected employees	99.8%**	100%**	98.7%**	97.7%**	100%**	98.4%**
- vendors and contractors	32.0%**	27.3%*	34.2%**	25.0%**	25.6%**	40.0%**
- physician providers	83.8%**	95.2%**	82.9%**	72.7%**	84.2%**	88.5%**
<i>Compliance education and training is conducted by:</i>						
- employees	54.2%**	68.2%**	50.0%**	67.4%**	51.4%**	46.7%**
- outside contractors	0.8%	0	0	2.3%	2.7%	0
- both employees and outside contractors	45.4%	31.8%**	47.4%**	30.2%**	54.1%**	53.3%**

* Significant at the 0.05 level

** Significant at the 0.01 level

hospitals. In addition, 81 percent of the smallest hospitals prepare compliance performance measures at the department or operating unit level, and report the results to management and the governing body. This compares to 61 percent for all respondents and only 47 percent for the largest hospitals in the sample. Other uses of compliance measures are relatively low for all hospitals, regardless of size category. With regard to managerial compensation, less than 15 percent of all sample hospitals link compliance performance measures to compensation of senior managers, and less than 10 percent link the compensation of mid-level managers to compliance performance measures.

In the area of education and training, nearly all of the sample hospitals offer education and training programs to all affected employees, while only 32 percent provide education and training for vendors and contractors. In addition, the largest hospitals were found to be more likely than the smaller hospitals to provide education and training programs for vendors and contractors. The smallest hospitals in the sample rely primarily on their employees to conduct training programs, while the largest hospitals are more likely to use a combination of their employees and outside contractors to conduct training. ■

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Surgery Charge, continued from page 17

- **Analyze exception reports** by CPT or ICD9 procedure code. This will group like exceptions and help identify whether a significant portion of the exceptions stem from a few procedures. This may indicate a systemic problem related to certain procedures or may point out the need to adjust CAAT procedures if there was an omission or incorrect answer in the initial questionnaire.
- **Sort the exception report** by hospital service or department to determine if a sizable number of exceptions originate from one or

two departments. This may indicate a significant control weakness in a given department, or that charging practices are not uniform between departments for the same services. For example, the cost of recovery room services may be bundled in the surgical procedure charge when services are performed in the GI Lab, but separately costed and charged when the procedure is performed in the operating suite.

- **Obtain medical records** for a sample of exceptions and enlist the assistance of a clinical coding expert to determine whether the medical documentation supports the need for a certain charge.

Another proven approach is to gather the operational auditor, the surgery department manager, an HIM coder, a charge master analyst, and billing personnel in a meeting to review a sample of the exceptions. The review would include the medical record documentation and the detailed charges posted for each account in the sample. This may increase the efficiency of the audit by having many of the primary stakeholder's present and developing conclusion and preliminary actions collaboratively.

Determining Root Causes of Missing Charges

The real value of these audits is that they identify the root cause of the missing charges. Once the CAAT exception reports have been reviewed and the auditor verifies the extent to which charges have been missed, the auditor can focus on identifying the cause(s) of the missing charges. For instance:

Communication issues are often at the top of the list. For example, often the surgery department is under the impression that the anesthesia group is billing globally for its services when in fact they are only billing for the professional component of the anesthesia services, resulting in unbilled technical component charges.

IT issues may be the cause of significant missed charges. For example, if the interface between the surgery subsystem and the patient billing system is not working properly, charges may be dropped between the two systems. If the interface is not monitored and associated exception reports are not continuously addressed by department

personnel, missing or lost charges may go undetected.

Charging for implants can be particularly vulnerable to errors and omissions depending on the level of manual processes involved. Because new items are regularly introduced, there may be a delay between when new devices are used and when the item is added to charge tickets, charge entry screens, and the charge master. Additionally, some hospitals build their charge masters to allow for manual price overrides for some implants, to compensate for fluctuations in purchase prices. This requires staff to manually input the actual charge; a process prone to error. Another common issue is the use of a miscellaneous charge code to bill for implants that could result in denials, and in statistics aberrations.

Inadequate training in hospital billing procedures also causes problems. Staff turnover combined with evolving hospital information systems and practices creates vulnerability around the charge entry process. This risk can be mitigated by regularly performing charge reconciliations, but such reconciliations are often not completed. One recent surgery audit identified roughly \$1.1 million in missing recovery, anesthesia, and surgery procedure charges due to inadequate charge reconciliation procedures. The result was a net revenue impact to the hospital of approximately \$652,000.

The Bottom Line and Beyond

Lost charges do not just reduce a hospital's net reimbursement. They also may affect the integrity of cost report calculations and the allocation of certain costs among departments, skew analyses in the hospital's cost accounting system, and lead to compliance issues.

In summary, auditing a hospital's surgery charging processes can identify numerous opportunities to strengthen internal controls and improve the integrity of the overall charge capture process. By combining the expertise of an operational auditor with CAAT and clinical coding resources, surgery charge capture audits can be performed more effectively and yield greater value for the hospital. ■

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The Quality and Compliance Nexus: Appreciating the Connection

By Alice G. Gosfield

The healthcare industry has now finally reached the stage where the risks of false claims liability for improper claim submission are now widely recognized. In what many view as an unrelated development, though, the Institute of Medicine published two studies dealing with quality of care: (1) "To Err is Human", focused attention on medical errors which generated an explosion of interest in patient safety; (2) "Crossing the Quality Chasm", announced principles which, if brought to bear widely throughout healthcare, could change the quality of care delivered. Taken together, they galvanized attention to the failure of the American healthcare system to deliver those levels of quality which most people would consider acceptable and many lay people simply assume is present. Many of the initiatives, which followed, including those around pay for performance and the Leapfrog Group, are direct responses to these studies. What is less well understood is the growing connection between statutory and regulatory controls for quality and increasing fraud and abuse enforcement regarding the quality of care delivered.

To the extent that compliance has been seen primarily as risk management of the billing function, quality issues must now also be taken into account for a meaningful and comprehensive compliance program. This article (1) explains the connection between quality and compliance; (2) identifies under-appreciated controls over quality which already present enforcement liabilities; and then (3) presents some practical steps to link quality concerns with compliance activities.

Quality in Compliance Guidance's

The initial impetus for compliance plans was the federal sentencing guidelines, enacted by Congress to curb the discretion

of a federal judiciary seen as too liberal. The sentencing guidelines are formulaic and prescriptive. They establish the range of prison time for a criminal penalty and then they indicate what will be considered mitigating and aggravating factors that determine the extent of prison time. One of the mitigating factors is whether the enterprise has in place a compliance program which generally tries to prevent violating behavior. Compliance plans and programs are voluntary. The motivation to put one in place comes from the risk aversion of the potential criminal.

All of the Office of the Inspector General's (OIG) Model Compliance Guidance's refers to quality as a government concern generally and state that one of the potential benefits of a voluntary compliance program is improved healthcare quality. The home health agency (HHA) guidance refers to a clinical review to be sure the beneficiaries are getting medically necessary and appropriate numbers of visits. The durable medical equipment guidance refers to the quality of the item for which the claim is submitted as meeting appropriate standards. The hospice guidance explicitly addresses the need for a quality assurance program as required in the entity's conditions of participation, but also refers to the timeliness of referral to hospice as a quality issue since late referrals can undermine the value of the hospice benefit. So proper hospice utilization is a compliance issue in terms of how hospices relate to their referral sources, and in particular hospitals.

The strongest statements linking quality and compliance can be found in the Medicare+Choice Guidance and the one for skilled nursing facilities (SNF). The Medicare+Choice Guidance puts strong emphasis on underutilization and quality of care issues to be taken into account in the

compliance program. Quality assessment, insufficient numbers of providers, provider licensure, and review of quality data are all included in the specifically enumerated risk areas. Similarly, quality of care is a significant component of the Compliance Guidance for SNF.

In the physician guidance, the relationship between anti-kickback violations and quality is addressed with the observation that remuneration for referrals can undermine quality. This guidance also notes that medical record documentation serves both a quality function and a billing function. In the pharmaceutical industry guidance the interrelationship between remuneration arrangements on one hand and patient safety and quality on the other are also considered in the risk areas, which include formulary development. The explicit reference to quality concerns in every Model Compliance Guidance makes it clear that the government expects providers to be integrating some quality functions into their compliance activities. The OIG is not the only locus of quality based law enforcement.

Quality in DOJ Settlements

The Justice Department's first sortie into the quality realm took off, as many of its creative enforcement techniques have, out of the US Attorney's Office in the Eastern District of Pennsylvania. Faced with a SNFs failures of care as demonstrated in aggravated and serious bed sores, the US attorneys went after the home in a novel way. Having learned that one of the contributing factors to bad bedsores is malnutrition, they fashioned an argument that every day of care paid for by Medicare where the patients had bedsores was a false claim since the obligation to provide the nutrition was implicit in the payment to the SNF. The failure to provide

adequate nutrition made every such claim false. In *US v. GMS Management-Tucker Inc.* (ED Pa 1996), the facility paid \$535,000 dollars in settlement and agreed as part of its Corporate Integrity Agreement to apply the clinical practice guidelines for treatment of decubiti which the government's Agency for Healthcare Policy and Research had published a few years earlier. This theory was further applied throughout the country in some 40 or so additional settlements, often as instigated by whistleblowers. In 2003, in *US v. United Memorial Medical Center*, a hospital in Michigan pleaded guilty and paid a \$1.05 million fine where a very prolific anesthesiologist on staff performed unnecessary procedures for which the hospital was paid the associated facility fees. The patients suffered significant complications. The physician himself was criminally prosecuted and convicted.

Quality-Relevant Federal Regulation

There are a number of sources of quality-relevant enforcement regulations that implicate compliance issues. Some of these involve basic federal regulation of quality as in conditions of participation that hospitals, SNF, dialysis centers, HHA and the like must meet to be eligible for payment. Any well-organized compliance program will pay some attention to maintenance of compliance with those conditions. In the Medicare+Choice program now transferred to Medicare Advantage plans as well, there are defined quality mechanisms that plans must provide as part of their continuing compliance with their rules for participation.

Perhaps the most significant compliance-relevant quality regulation in the Social Security Act has been the PRO program where the operating entities are now referred to as Quality Improvement Organizations (QIO). These physician-based organizations have the responsibility by statute to review the cost and quality of care rendered to Medicare patients to assure it was medically necessary, met professionally recognized standards of care, and in the case of inpatient care was provided in the most economical location to meet the patient's needs. This program focuses on specified measures of quality and how to produce them. It targets nursing homes, HHAs, hospitals, and physicians within each QIO's jurisdiction. For all of its quality improvement orientation, though, the program has always had the authority

to recommend exclusions and fines where there are either substantial failures in a substantial number of cases to provide appropriate care or in any instance of a single gross and flagrant violation of professional standards.

The Emergency Medical Treatment and Active Labor Act (EMTALA) also present a quality-relevant compliance issue because of the requirement for appropriate medical screening, timely response in person by an on-call specialist and the interrelationship of these provisions with the demands of managed care organizations. Here, again, liabilities run separately to both hospitals and physicians to meet the applicable obligations. Addressing these concerns in a compliance program would seem important since there are \$50,000 civil money penalties available for violations and they do get imposed.

All of these major programmatic initiatives are known in healthcare delivery circles but frequently are ignored in compliance program development. Even lesser known are a number of specific exclusion and civil money penalty authorities that directly implicate quality.

Exclusions and CMPs Related to Quality

A provider, whether a hospital, supplier or physician, can be excluded from the federal programs for providing items or services to patients (whether or not eligible for benefits under Medicare or Medicaid) which are substantially in excess of the patient's needs or of a quality which fails to meet professionally recognized standards of healthcare. (42 USC 1320a-7(b) (6) (B)). This catchall provision does not specify a body of standards to be referenced to make this judgment. Where a QIO has norms, criteria and standards on a point, they would certainly be relevant. After that, national clinical practice guidelines or even expert witness testimony might be looked at to make this kind of case.

Civil money penalties (CMP) are the punishment of choice for a range of other problems. Where claims demonstrate a pattern of medical items or services that a person knows or should know are not medically necessary (42 USC 1320a-7a (a) (1) (E)), up to \$10,000 CMP is available to the government. Again, no standards are referenced. A different type of problem is at issue where a civil money penalty of \$25,000 may be imposed on anyone who

provides false or misleading information that could be expected to lead to premature discharge of a hospital inpatient (42 USC 1320a-7a(a)(3)).

Finally, in a recognition of the changed financial environment for hospitals, physicians and managed care plans, a \$2,000 civil money penalty may be assessed in each instance where a hospital makes payments to physicians to reduce or limit services (42 USC 1320a-7-a(b)) even if they are reduced from a baseline of over utilization! Here a penalty may be imposed on the hospital for making the payment and another penalty may be imposed on the physician for accepting it. This provision formed the basis for the OIG's rejection of most "gainsharing" programs. Similarly in a provision which is applicable under the statute on a stand alone basis as well as under the Stark law (42 USC §1395) (e) (3) (B), penalties can be assessed for physician incentive plans that put physicians at substantial financial risk and do not adhere to the regulatory protections there which are primarily reporting to the government and disclosure to the beneficiaries. (42 CFR §417.479 and 42 CFR §1003.100 et. seq.)

Programmatic Integration

The scope of quality concerns, which are tied to fraud and abuse penalties, has expanded. Eager prosecutors are hatching new theories of liability. Yet, compliance often is an activity which operates apart from the core mission of most healthcare organizations, even those which adopt compliance programs. Compliance is often conceived of exclusively as a billing-related function. Regardless of the type of healthcare enterprise, some quality based fraud and abuse penalties lurk. In addition, medical necessity is a mandated predicate for every claim submitted for payment. Claims for services which are not medically necessary not only can be denied, they can lead to false claims liability as well after they are paid.

To apply techniques which anticipate all of these concerns, address them in an organized way without adding undue administrative burden, in a setting that furthers appropriate evidence-based care ought to be the shared goals of compliance and the basic healthcare mission. The true integration of compliance into the fundamental strategic plans of the organization would strengthen both activities. Since the delivery of high quality care is the essential purpose of

all healthcare businesses, the linkage of the quality mandate into compliance and audit activities will be increasingly important.

Confronting the Challenges

From documentation requirements to substantiate both the services rendered and their medical necessity, to quality assurance demands as part of conditions of participation, to basic risk management and the impact of public reporting of performance, there are a myriad of disparate forces which can lead to managerial and operational paralysis if confronted as if they are disconnected. One of the most important techniques to adopt to alleviate many of these concerns from an audit, finance, and compliance perspective would be increased standardization of care processes and documentation of care delivery. The wide and deep use of clinical practice guidelines throughout the healthcare enterprise to organize how care is delivered and documented would significantly advance the reimbursability, defensibility against malpractice claims, and quality of care provided and would create a far better audit trail to demonstrate as much.

To reorient compliance away from administrative minutiae (e.g., one level discrepancies on documentation of evaluation and management codes), and toward basic themes of healthcare delivery, of which quality care is the most significant, would improve both compliance and quality. To make compliance programs more seamless components of the business and avoid the "gotcha" syndrome that makes the personnel from whom compliance is sought dread the vision of the compliance officer's arrival in their office, it is important to shift the view and role of compliance. The dual goals of improved quality and compliance are not only complementary, they can reinforce each other. Some practical steps are worth considering:

1. Review the enforcement challenges identified here (EMTALA, conditions of participation, PRO/QIO measures, premature discharge, etc.) and incorporate them explicitly into your compliance program.

2. Begin to work within the organization to standardize care delivery and documentation of it in accordance with good national clinical practice guidelines, many of which are available at the government's National Guidelines Clearinghouse (www.ngc.gov).
3. Think about how measuring performance within the organization in accordance with CPGs can point out lurking compliance problems.
4. Read *Doing Well By Doing Good: Improving the Business Case for Quality* and the related publications available at www.uft-a.com which deal with how broader applications of CPGs make a real business case for quality.

Conclusion

The rise of quality as a fraud and abuse issue can no longer be ignored as a fundamental compliance challenge. There is a far better way to look at this issue, however, than merely from the perspective of prosecutorial and enforcement scare tactics. To connect compliance with the fundamental care delivery process in a way which enhances clinical performance while it lowers false claims risk while improving efficiency, would seem so seductive as to command attention throughout the healthcare system. Many healthcare organizations today are staggering under the weight of decreased reimbursement, increased expenses, and a crushing administrative burden. Most also view compliance as a particularly odious and onerous undertaking that adds to their workload without adding any real value. It is time to change that view. The quality and compliance nexus offers a real opportunity to reorient those functions with others to fundamentally improve the healthcare work environment while truly improving healthcare quality. ■

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Confirmation Approach risks identifying exceptions without providing adequate insight as to their actual origin. Most auditors are more likely to find their audit environments on the weak half of the Internal Control Spectrum. However, general control assumptions can be associated with industries. For example, the banking environment will tend to be well controlled, while healthcare will tend to be poorly controlled.

Conclusion

Tailoring each operational audit to its unique control environment creates the best opportunity to add value to management, and meet IIA Performance Standards in an efficient way. Spending more time on planning the operational audit and evaluating the risk/control will focus the audit on identifying the most important issues at the level management is best prepared to address. In conclusion, the unlocked potential of efficient value-adding operational audit can not only fill the control assurance gap illustrated by Sarbanes Oxley; but also can firmly stamp the standard of excellence and value the internal audit profession provides to a dynamic and changing accounting environment. ■

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Compliance Education and Awareness Tools and Techniques

By Kathy Thomas

A focus group of Health Care Compliance Association (HCCA) and Association of Healthcare Internal Auditors (AHIA) members has been meeting throughout the past twelve months to explore opportunities to better define and explain auditing and monitoring, clarify the roles of compliance and internal audit functions as they address issues within their healthcare organizations, and develop guidance and reference materials on key aspects of health care auditing and monitoring processes. The *Seven Component Framework* developed by the HCCA/AHIA focus group for compliance auditing and monitoring is comprised of the following activities:

1. Perform a risk assessment and determine the level of risk.
2. Understand laws and regulations.
3. Obtain or establish policies for specific issues and areas.
4. Educate on the policies and procedures and communicate awareness.
5. Monitor compliance with laws, regulations, and policies.
6. Audit the highest risk areas.
7. Re-educate staff on regulations and issues identified in the audit.

This article provides guidance on compliance training and awareness tools and techniques. This is the seventh and final article in the series of articles prepared by the HCCA/AHIA auditing and monitoring focus group.

A key goal of an effective compliance program is a culture that encourages open lines of communication. For such a culture to exist, the organization must provide an on-going program of compliance education and awareness activities that promotes understanding of the regulatory requirements of the organization and the policies and procedures the organization has implemented to meet such requirements. The educational program should strive to ensure that all employees comprehend their role in the compliance process.

The Compliance Office will want to work with Management to develop a detailed compliance education and

awareness plan that is designed to address compliance issues faced by all departments within the organization, with specific emphasis on those areas at greatest risk for non-compliance. In addition, the compliance education and awareness program should be proactive and flexible so that education can be delivered as needed to rapidly address risk areas as deemed appropriate.

An effective compliance education and awareness program should be a multi-tiered system that addresses varying levels of employee learning abilities, available technology, and personal preferences. The program should provide education to these different audiences through multiple

channels, while relaying a consistent message.

Know Your Audience

Compliance training must recognize that diverse audiences require both different levels of detail as well as various approaches to education. These different audiences include new employees, existing workforce members, and employees that are in positions that require compliance with specific regulations. Volunteers, vendors, and other non-employed agents of the organization may also need compliance education or awareness training.

1. Compliance education at orientation is important for new employees as they join your organization and for the initial training of staff during the rollout of the compliance program. The compliance orientation should:
 - a. Provide an overview of the compliance program.
 - b. Outline the significant legal and regulatory requirements the organization must follow.
 - c. Clarify the duty of employees to report any possible non-compliance.
 - d. Publicize compliance hot-line information.
 - e. Provide contact information for key compliance staff members.
2. At a minimum, existing employees should receive education/awareness about the compliance program annually. This annual activity will facilitate employees' continued understanding of how to recognize potential compliance issues, reemphasize the different means available to address such concerns and will reinforce the organization's commitment to compliance.
3. For employees in positions that require compliance with specific regulations, specialized education on the policies and procedures that have been implemented in their areas to deal with regulations specifically affecting their job functions should be provided to those employees. Examples of staff that may require specialized education include employees involved in billing, coding, admissions, and physician relations. The Compliance Office should work with department management to be sure that appropriate education is provided for those areas within the organization that are deemed to be high risk.
4. Contractors, volunteers and other non-employee agents doing business with the organization should be provided information about the organization's compliance program and relevant policies and procedures in order to understand how their actions directly impact compliance.

Delivery

Much has been written on the effectiveness of various delivery methods for education and awareness communications. When developing a specific educational program it is often helpful to conduct a learning needs assessment that includes both specific topics or questions the audience would like covered as well as their preferred learning method. This may help to ensure good attendance and understanding of the material presented.

Current compliance educational methods include: classroom sessions, computer or web-based training, self-study materials, videos, "lunch and learns", presentations at staff meetings, newsletters, e-mail alerts and promotional items. Each of these methods has a role in the effective delivery of compliance training.

1. *Classroom sessions* allow direct interaction between the Compliance Office training staff and the workforce. Attendees can associate a name and face with the compliance program. Face-to-face training is a good choice for orientation training of new employees. The disadvantage to classroom training is that it may be difficult to provide the training in a timely manner to a large number of individuals and monitor the level of comprehension of the material.
2. *Computer or web-based training, self-study training and videos* offer more convenience, allowing employees to complete the training at their own pace. With computer and web-based training, employees test their knowledge of the materials learned through quizzes and receive immediate feedback on their level of comprehension and completion of the educational course can be automatically recorded.
3. *Sponsored training during lunchtime*, a.k.a. "lunch and learns", as well as presentations at department staff meetings provides the opportunity for the Compliance Office to deliver specialized training on critical regulatory issues in a timely manner to staff. In addition, this training allows staff to place a face and name to the compliance program.

4. *Newsletters, e-mail alerts, and promotional items* provide the Compliance Office with the opportunity to reemphasize the importance of specific compliance concepts with the workforce and address key issues.

Content

In addition to the delivery, compliance education and awareness activities should provide content that is timely and important to the audience. Educational objectives should be clearly stated and measurable. Make sure that the material presented includes something that the audience can relate to in their jobs. The material should demonstrate how their actions could impact the organization. For instance, present relevant and entertaining case studies. Or provide for trainee interaction through games like "Jeopardy" or quizzes. Strive to make the training enjoyable, relevant, and memorable.

Feedback

Whatever form or method the Compliance education takes there should be some form of feedback to verify that the educational objectives have been achieved. Staff should have the opportunity to assess whether the educational content was understandable. Did it keep the audience's interest? Compliance Office personnel can use the information obtained through feedback to validate that the information on compliance is getting across to the audience and that the audience understands how their actions can affect the organization and their own future.

Certain elements of compliance education should be mandatory to ensure that all members of the workforce receive an understanding of the key regulatory requirements faced by the organization and how the organization's compliance program operates. Senior management should set the proper tone by mandating attendance and participation. This can be done using either the carrot or the stick approach. Scheduling compliance education during regular staff meetings is one effective way to emphasize the importance of the education and assure attendance. To encourage staff to

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Audit Technology: An Essential Ingredient for Conducting Historical Bad Debt Analysis

By Doug Burton

Under mounting pressure from regulators and other external bodies, senior auditors and financial management in healthcare organizations today are taking extra steps to ensure the accuracy of their financial statements. Recently, large discrepancies and adjustments in the valuation of accounts receivables have both highlighted the importance of review and promoted awareness of the high level of risk associated with making these valuations.

Recently, a historical bad debt analysis of a large healthcare organization with close to \$125 million in accounts receivables and \$36 million in reserves revealed that the organization's reserves were understated by about \$10 million. Results such as this are not atypical. Clearly, inaccurate estimates can impede effective business decisions.

Healthcare organizations are recognizing that they need to maintain vigilance to ensure that accounts are appropriately reserved. But determining accurate reserve requirements for bad debt, charity, and other adjustments involves making numerous estimates, which can lead to increased risk and serious shortages in reserve accounts.

This proposition becomes riskier with the reality of a constantly changing healthcare environment. Recent trends include changes in the payor mix, with more self-insured, underinsured, or uninsured patients. Alongside these changes are the ongoing adjustments in the aging of accounts receivables. These factors can result in significant changes to the overall snapshot of an organization's accounts receivables.

Acknowledging this change in payor mix and concomitant changes to the

aging of accounts receivables, the Spring 2004 issue of PricewaterhouseCoopers *Internal Audit Newsletter* cited valuation of accounts receivables by hospitals among its top ten list of issues facing healthcare organizations. And, it recommended that "Internal Audit should evaluate a comprehensive retrospective review of receivables valuation methodology and related processes."

Three Essentials for Accurate Results

There are many ways to conduct a valuation of bad debt and charity reserves but three elements are essential to making it accurate: audit technology, reliable data, and communication.

Essential 1: Audit Technology

Many healthcare organizations review historic reserve percentages to determine current reserve requirements. Unfortunately, they often rely on analysis from decision support systems that provide high-level indicators and that can only analyze data from a sample of the patient population. Organizations seeking greater confidence in their accounts receivable valuation have turned to sophisticated audit technology. With computer-assisted audit techniques, organizations can produce a detailed hindsight analysis that compares actual adjustments, charity, and bad-debt experience to the reserves that were booked to offset these same write-offs.

Audit technology allows an auditor to evaluate the activity that has transpired on every single patient account over a period of time, capturing and categorizing each payment, adjustment, and write-off, and determining the status of any remaining

balance. This data can be analyzed in many ways. One effective approach is to calculate past payment and write-off trends by financial class and aging category for both inpatient and outpatient accounts. From these results, a detailed matrix can be developed that provides corresponding estimated allowance percentages for current doubtful accounts and charity based on the financial class and aging of each receivable. These historical percentages can be applied against current accounts receivables to predict future write-offs based on past experiences.

The Fringe Benefits

Some organizations have found that conducting bad debt analysis using audit technology provides fringe benefits, especially if the organization has previously relied on information from decision support systems. Analytics may reveal areas where processes could be enhanced or internal controls could be improved. For example, the analytics may demonstrate that there is a specific class or group of accounts that are showing bad debt write-offs that should not be occurring. They could also reveal that the organization had a higher number of denials during this period than they were aware of.

Essential 2: Verification and Re-verification

When performing a retrospective review of accounts receivable valuation, it's critical to base the analysis on complete and accurate data so that erroneous conclusions are not drawn. Key to the review process is ensuring that the accounts receivable data being analyzed is representative of "normal" accounts receivable activity. For example, the

quality and reliability of the audit results may decrease if system conversions and major process changes have occurred during or immediately preceding the test period.

Other recommendations for ensuring data accuracy and integrity:

1. Reconcile accounts receivable data to the general ledger to ensure completeness.
2. Create a roll forward of all accounts to ensure that transactions are appropriately captured. Using the data obtained for the review, every account should be able to be re-created to agree with the ending period balance.
3. Differentiate bad-debt write-offs and charity write-offs from other types of adjustments.
4. Perform a second verification to test whether the write-offs agree with how your organization's internal controls identify bad debt. This may be especially important if your organization has more than one source of revenue.

Essential 3: Communication

A valuation's accuracy depends heavily on open communication and feedback between the auditor and healthcare facility management. At the start of the project, all parties should meet to discuss the time period to be analyzed. This is an opportunity to bring to the surface any information — such as changes in collection activities or the accounting process — that could affect the results of the review. As preliminary results are generated, management should be involved to validate any assumptions made in the analysis. The ensuing discussions may reveal that some changes should be made.

In addition, management needs to be aware of the limitations of any historical analysis. Significant price increases, unusual large dollar balances, and/or changes in payor mix may impact the ability to use historical information as a predictor of future accounts receivable collections.

The results of a hindsight review should be reported not only to management, but also to the appropriate committee of the Board of Directors. This communication helps the committee

understand the high degree of judgment required in the accounts and financial reporting process. It also contributes to a strong system of internal controls.

Conclusion

Shortages in reserve accounts are becoming more prevalent. A healthcare organization can eliminate such shortages and minimize risk by undergoing a hindsight review of its accounts receivables. But not all reviews are created equal. The best ones employ the latest audit technology, a thorough verification process, and continual communication. ■

Doug Burton is Account Manager, Healthcare Education, for ACL Services, LTD, in Vancouver, Canada.

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complete compliance education, some organizations offer continuing education credit. Some organizations track completion of mandatory compliance education as part of the annual employee performance evaluation. Some facilities have fined physicians and other healthcare providers who do not fulfill their training requirements and others have implemented disciplinary measures against employees who did not complete training.

Documentation

As in all things related to compliance, compliance education and awareness activities must be documented. Documentation should include agendas, educational materials and sign-in sheets or other proof of who attended. Records should be retained in accordance with your organization's record retention policies.

Summary Comments

Have fun with your compliance education. Look for experts in education of adult learners within your organization such as nursing educators, or educators within your Human Resources department to assist in the development of a compliance education and awareness program that recognizes your employees' learning abilities and makes the best use of available technology. "One size" will not fit all organizations so try different methods to determine what works best for your organization. ■

About the HCCA/AHIA Auditing and Monitoring Focus Group

The HCCA/AHIA auditing and monitoring focus group completed a series of seven articles regarding the seven components to expand on the roles of compliance and internal audit functions, provide detailed "how to steps", and discuss the essential coordination links between compliance, internal audit, legal, and management that are necessary for each component.

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AHIA/HCPPro affiliation provides reduced subscription opportunity to HCPPro monthly newsletter - *Health Care Auditing Strategies*. Available to AHIA member's at a 25% discount - \$224 annually. *Health Care Auditing Strategies* is the only newsletter that focuses on healthcare internal auditing techniques.

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Research Compliance: Preventing, Identifying and Addressing Misconduct in Human Subject Research

By Lauren Sullivan

In 1999, 18-year old Jesse Gelsinger died after receiving a gene therapy agent in a clinical trial at the University of Pennsylvania Institute for Gene Therapy. The ensuing investigation revealed, among other things, that Jesse was not notified that the principal investigator was also founder of the company that held rights to the product being studied.

In 2001, healthy 24-year old Ellen Roche, a laboratory technician at Johns Hopkins University's Asthma and Allergy Center, agreed to take part in a federally funded asthma study. A month after inhaling the hexamethonium intended to induce asthmatic symptoms, she was dead. In the aftermath, Ellen's parents sued Johns Hopkins, and the federal government suspended Johns Hopkins's research funding while they reviewed Johns Hopkins's human subject protection and research policies and procedures.

The deaths of these two research subjects led to numerous calls for reform in the conduct of human clinical research, and for enforcement of existing laws. However, even prior to these high profile deaths, federal agencies with regulatory enforcement authority over human subject research had begun to question the current state of human research subject protections. A year before Jesse Gelsinger's death, the Office of Inspector General (OIG) had issued a report called *Institutional Review Boards: Time for Change* (June 1998). The report was highly critical, and concluded that the effectiveness of Institutional Review Boards (IRB) was in jeopardy.

The OIG and other governmental authorities have begun to focus even greater time and energy on research compliance. In its 2005 Work Plan, the OIG identified a variety of investigative

initiatives concerning human subject research, including investigations into the nature of financial interests disclosed by clinical investigators in Federal Drug Administration (FDA) regulated studies, the extent to which adverse event reports to IRBs are used effectively to protect human subjects, whether IRB's have adequate procedures in place to allow appropriate consideration of adverse event reports in the clinical trial review process and compliance with privacy requirements in clinical trials funded by the National Institutes of Health (NIH) and other research. The OIG will also continue to focus on compliance with time and effort reporting requirements and will continue to pursue False Claims Act cases against institutions receiving federal grant funds.

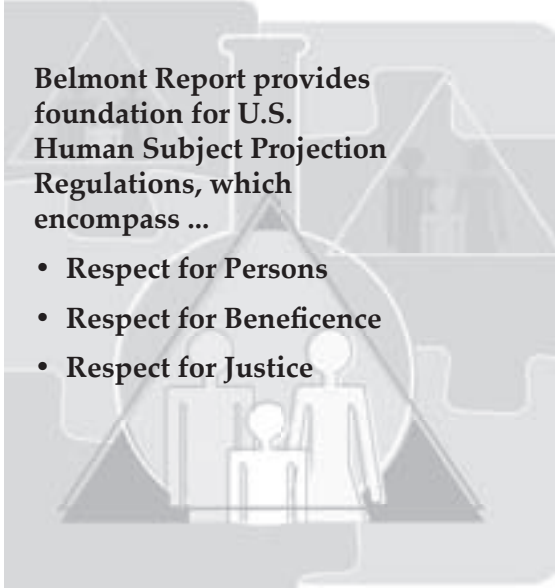
This article discusses existing laws and regulations directing the conduct of human subject research, and provides examples of how research institutions and healthcare providers conducting human subject research can tailor their compliance programs to comply with the myriad regulations directing the conduct of clinical research.

Regulatory Landscape

Federally funded research and privately sponsored drug trials are subject to separate, but similar and sometimes overlapping rules. These rules, whether regulating federally funded research or research directed at obtaining FDA approval for a new drug, are aimed at protecting human subjects in research and ensuring the integrity of the data that comes from such research.

The rules and regulations governing the conduct of human subject research are largely the result of instances of

serious research misconduct, particularly the Public Health Service (PHS) study of untreated syphilis in African American men from 1932 to 1970. During this study, despite available treatment, the research subjects' syphilis was left untreated, and the subjects were not warned of the risk of continuing sexual activity, leading to numerous cases of death and disability. The public outcry following disclosure of the study conduct resulted in the formation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in June 1974, and led to the first codification of human subject protection regulations. The Commission drafted the Belmont Report, which sets forth three main principles: respect for persons, beneficence, and justice. These principles form the ethical foundation of human subject research, and are the basis of human subject protection regulations in the United States.



Belmont Report provides foundation for U.S. Human Subject Protection Regulations, which encompass ...

- **Respect for Persons**
- **Respect for Beneficence**
- **Respect for Justice**

Federally Sponsored Research

The Common Rule

Both the Department of Health and Human Services (DHHS) and the FDA issued regulations based on the Belmont Report. DHHS codified the protection of human subjects in 45 CFR Part 46 Subpart A, the provisions of which are also known as the "Common Rule." The FDA codified its version of the Common Rule, at 21 CFR Parts 50 (Human Subjects) and 56 (IRB). The Common Rule applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency, including the NIH. The Common Rule regulates such things as IRB membership, functions and operations, informed consent requirements, basic rules for the approval and conduct of research, and additional protections for vulnerable populations.

Research Misconduct

Most federal research funds for clinical research are granted through the NIH and therefore are subject to PHS regulation. All recipients of federal research funds, as part of their grant award, certify to the truth and accuracy of the claims they make to receive federal funding of their research. Further, all PHS grant recipients are required to have their own administrative procedures for identifying and addressing scientific misconduct. Each grantee must certify to PHS, as a condition of the grant, that it will comply with both PHS and its own administrative procedures.

Pursuant to federal regulations at 42 CFR Part 50, Subpart A, the Office of Research Integrity (ORI) handles allegations of misconduct that involve research supported by PHS and that fit within the definition of "misconduct" or "misconduct in science." "Misconduct" or "misconduct in science" means the fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. Allegations of scientific misconduct involving NIH-specific grants may be referred to NIH's Office of Management Assessment, which is authorized to investigate misuse of NIH grant and contract funds, as well as NIH grantee and contractor conflicts of interest. If the researcher is found to have committed scientific misconduct, pursuant to 42 CFR Part 50, PHS may impose sanctions,

including debarment from receiving federal research funding for some period of time or the case may be referred to the OIG and the United States Attorney's Office for prosecution under the False Claims Act or other federal law. The Office for Human Research Protections (OHRP) is responsible for responding to allegations of misuse of humans in research supported by PHS.

Recently, OHRP cited the University of Washington for significant problems in the oversight of human subject research. In its letter to the University dated April 1, 2005, OHRP cited the University IRB for frequently approving research contingent upon substantive modifications or clarifications, such as the receipt of additional information or changes to the informed consent form, without requiring additional review by the convened IRB. Studies were approved on a contingent basis, with substantive questions concerning the risk/benefit determination still outstanding. OHRP noted that IRB meetings failed to sufficiently detail actions taken by the IRB, the basis for requiring changes or disapproving research and a summary of discussions concerning controverted issues. OHRP also found numerous instances where the IRB failed to conduct continuing review of research at least once per year. As a result of OHRP's findings, the University is implementing changes to improve its human research subject protection programs, but any changes come too late for subjects who were not adequately protected in the past, and don't forestall any private causes of action.

As mentioned above, alternatively, or in addition to sanctions imposed by PHS and ORI, allegations of scientific misconduct may be addressed through the federal False Claims Act. The False Claims Act prohibits knowingly submitting or causing to be submitted a false or fraudulent claim for payment to the federal government, including filing false or fraudulent data in support of grant applications. Violations of the False Claims Act are subject to treble damages, plus penalties of \$5,500 to \$11,000 per claim. Both the institution and its researchers are potentially liable under the False Claims Act for the integrity of research conducted under a grant funded by PHS.

Some examples of recent False Claims Act actions based on research misconduct are:

- In a case against Thomas Jefferson University, the government alleged research fraud relating to NIH and National Cancer Institute grants, including submission of false research data to obtain grant funds, and using false or fabricated research data in several publications that were then used to obtain grant monies. The DOJ settled the case for \$2.6 million in an unpublished settlement.
- In a case against the University of Alabama at Birmingham, a court ordered the University to pay nearly \$2 million to the federal government and to a former graduate student who had conducted research at the University, because the University violated the federal False Claims Act by failing to credit the graduate student with the work and failing to accurately report her work in grant applications to the NIH.
- In a qui tam action against the University of California and the University of Utah, a researcher at the institutions was found to have fabricated and falsified data on a burn trauma research report in grant applications, leading to a \$1,575,000 settlement.

FDA Regulations and Guidance

Human subject research involving the testing of drugs, biologics, and medical devices is subject to oversight by the FDA. Regulations promulgated under the Federal Food, Drug and Cosmetic Act direct the conduct of IRBs (21 CFR Part 50), informed consent (21 CFR Part 56) and the research itself (21 CFR Part 312).

While the ultimate responsibility for the Investigational New Drug Application (IND) under Part 312 is the responsibility of the sponsoring organization, much of the responsibility for the conduct of the research is placed on the clinical investigators. Each clinical investigator must sign an "investigator statement" also known as FDA form 1572, under which the investigator agrees to:

- Conduct the study in accordance with the relevant, current protocol(s) and only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.
- Personally conduct or supervise the investigation.

- Inform any patients or any persons used as controls, that the drugs are being used for investigational purposes and ensure that the requirements relating to informed consent and IRB review and approval are met.
- Report to the sponsor adverse experiences that occur in the course of the investigation.
- Ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed of their obligations in meeting the above commitments.
- Maintain accurate records and to make those records available for inspection.
- Ensure that an IRB that complies with 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the study, report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others, and not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

FDA Bioresearch Monitoring Program

Under the FDA's Bioresearch Monitoring Program, the FDA monitors and audits clinical research records of clinical investigators, institutions, and IRBs involved in the conduct of human subject research for drugs, biologics, and medical devices. The FDA conducts two kinds of audits. The first, "study-oriented inspections," are conducted by the FDA on studies that are important to the evaluation of the efficacy and safety of a product under review. The second kind of audit, a "for cause" audit, is directed at the behavior of a particular investigator or institution, and may be triggered by a number of factors, including a report by the study's sponsor, data that is inconsistent with other investigative sites or unusual enrollment patterns.

The FDA frequently identifies scientific misconduct during these inspections. If the violations are more than de minimis, the FDA may seek to have the investigator or IRB debarred from conducting FDA regulated research in the future, or pursue criminal charges

for violations of the Food, Drug, and Cosmetic Act. Instances of research misconduct by clinical investigators identified through these audits are too numerous and too varied to point out one exemplary case. Common findings include the failure of research subjects to meet inclusion or exclusion criteria, inadequate or no informed consent, inadequate informed consent process, no IRB approval or approval of a different version of the protocol, failure to obtain continuing review, inadequate adverse event reporting, inadequate, incorrect or falsified data, poor record keeping including undocumented changes to records, failure to follow the protocol and failure to store the investigational drug as directed. Frequently, an investigator is cited with most or all of the above violations, in addition to some more creative kinds of misconduct. What is noteworthy is the level of scrutiny required to ferret out many of the above violations, and that FDA directs that level of scrutiny to these inspections. Accordingly, for a research institution to avoid being cited by the FDA for research misconduct, its compliance program must direct the same level of scrutiny to its ongoing clinical research programs.

Addressing Research Misconduct

While covering all of the pitfalls that clinical researchers and research institutions are subject to is beyond the scope of this article, we discuss below methods to resolve research misconduct and ensure data integrity.

Institutions receiving PHS funding are required to have a research misconduct policy. The policy should include, as appropriate to the institution, procedures on: reporting allegations of scientific misconduct; pursuing the allegations; maintaining confidentiality; conflicts of interest; expertise of committee members conducting investigations of allegations; rights of respondents; how inquiry committee members are appointed; conduct of the inquiry; inquiry reports; sanctions; appeals; and the role of whistleblowers.

Once discrepant data is identified, through whatever means, the matter must be reported to the appropriate official responsible for research misconduct (all recipients of PHS funds are required to have such an official). The official determines whether further inquiry is required, and should consider whether the

discrepancies are the result of honest error or carelessness or intentional fraud. If further inquiry is required, the institution may be required to notify the PHS or study sponsor.

There are numerous tools available from the NIH and FDA on their websites, (<http://grants.nih.gov/grants/policy/policy.htm#guidance> and www.fda.gov) including audit checklists and guidance documents on how the FDA conducts an inspection, to assist with conducting an inquiry into research misconduct. An institution's report on the results of its inquiry should state how the original discrepancies were identified, the allegations of research misconduct found in the inquiry, the process of the inquiry, including who was interviewed, and the findings of the inquiry. For additional assistance, PHS provides instructions and examples for preparing inquiry and investigation reports, in the *ORI Model Procedures for Responding to Allegations of Scientific Misconduct*, available on ORI's website (<http://ori.dhhs.gov/>).

Conclusion

Clinical research is highly regulated and is subject to a complex and broad array of governing statutes, regulations, guidance, and other rules making compliance especially challenging. The federal laws and regulations addressing research misconduct affect the risk of severe civil, and in some cases criminal, penalties for research misconduct. It is important for individual investigators, research sites and institutions, as well as the entities that sponsor them, to be aware of the how to prevent, identify and address research misconduct. ■

Disclaimer: Nothing in this article constitutes legal advice, which can only be obtained as a result of personal consultation with an attorney. The information included in this article is believed to be accurate at the time of publication but is subject to change and does not purport to be a complete statement of all relevant factors.

Lauren Sullivan is a member of Wiggin and Dana's Business Practice Department and Biotechnology and Life Science Practice Group. She concentrates her practice on the biotechnology and pharmaceutical industries, with an emphasis on the acquisition, licensing, and joint venturing of intellectual property rights relating to pharmaceutical products and on FDA compliance, IRB and privacy issues in connection with clinical drug development.

Value of Internal Auditing Applauded

By Trish Harris

Internal auditors are an indispensable cornerstone of effective corporate governance, a critical component to effective and efficient operations, and an invaluable contributor to an organization's system of internal control. This summarizes much of the discussion that took place at the U.S. Securities and Exchange Commission's (SEC's) April 13, 2005, roundtable on the implementation of reporting requirements of Section 404 of the U.S. Sarbanes-Oxley Act of 2002 (SOX). The message sent by many participating CEOs, CFOs, and board and audit committee members was loud and clear: Internal auditing is an internal resource that responsible companies simply cannot do without.

Prior to the roundtable, the National Association of Corporate Directors (NACD) issued an insightful and somewhat prophetic treatise on SOX. The March 23, 2005, *DM Extra* pointed to the guidelines provided by *NACD Blue Ribbon Commission Report on Audit Committees* eight years ago. "The real point is that if internal controls are reasonable, there should be no 'liability' to share," wrote NACD CEO and President Roger W. Raber. Having worked on the NACD Blue Ribbon Commission, The Institute of Internal Auditors (IIA) agrees wholeheartedly. The NACD also advocates for audit committee discretion in setting the scope of the internal control program and assessment, and opposes any standard that would exacerbate the litigious climate directors already face.

Savvy board and audit committee members have long understood the importance of an organization's system of internal control, as well as internal auditing's role in ensuring controls are adequate to mitigate the risks. As is evidenced by the rash of devastating corporate frauds that prompted new legislation, however, not all companies

behaved as they should have, in spite of the proliferation of blue-ribbon guidance. Today, as a result, listed companies in the United States are footing the bill of SOX compliance.

What's a board to do? The NACD suggests starting with these steps:

- **Talk to your internal auditors.** These are the people doing the most important work without any direct financial gain (unlike external auditors who can bill by the hour). How are they holding up under the strain? Do they need more employees on their team? What are they learning? What do they need to learn? How is training and development proceeding for them? Now is not the time to stint on internal audit staffing and training.

IIA NOTE: As organizations move toward their next annual audit planning cycle, it is critical that executive management and the audit committee have in-depth discussions with the chief audit executive (CAE) regarding all risks facing the organization. Many of the risks that could result in substantial losses to an organization are within operational areas. The CAE can ensure that the agreed upon audit plan includes those areas and is well balanced and effective. The IIA advocates for an enterprise risk management (ERM) process that takes into account all aspects of an organization, rather than one that focuses only on the financial issues.

- **Talk to the PCAOB to get a sense of what they expect of audit committees.** The PCAOB is widely regarded as taking a sensible approach to this topic. Some complain that the advice is too little or too late, but to our

knowledge, no one has accused it of being flawed.

- **Connect the Code of Ethics and Internal Control charter.** The same concepts should permeate them, and they should reference each other.
- **Consider rotation.** This applies not only to external auditors, but everyone else involved in assessing risk, including internal audit staff, board risk management advisors, and board audit committees.
- **Be available to read and comment on management's report on internal controls.** Directors can add valuable perspectives to reports on internal controls. Since the definition of a material weakness is not written in stone, directors can help determine what is and is not significant. For guidance, directors can turn to Auditing Standards No. 2, which includes "Illustrative Reports on Internal Control over Financial Reporting." For those who prefer concrete examples to theoretical descriptions (and many directors do), this document provides valuable guidance for section 404 compliance.
- **Encourage and support continuing director education.** Every director can benefit from learning about the workings of audit committees, one of the modules in our new Corporate Directors Institute and a regular subject for customized in-boardroom education. Another hot topic is board-CFO relations. NACD has teamed up with the Financial Executives Institute to offer this course in a public seminar

Value, continued on page

The Question They Dare Not Ask: Why Bother? Challenging Conventional Views of Compliance

Part Two of a Three Part Article

By Neil Caesar and Richard M. Tuten

In the Spring 2005 issue of *New Perspectives* we challenged the conventional view of regulatory compliance programs. First, we explored the premise that any healthcare organization without a working, effective regulatory compliance program has, in effect, decided that there is no need to bother with compliance initiatives. This phenomenon is certainly not limited to any particular segment of healthcare. Medical groups, ancillary service providers, homecare companies, long term care organizations as well as hospitals continue to operate without any compliance programs in place. Others offer half-hearted attempts that fail the "effectiveness" test. (To be effective, a healthcare organization's Compliance Program must have clear policies that address how it actually operates from the perspectives of billing, medical records, contracting activity, marketing, and all the other areas that implicate regulatory compliance.)

Second, we acknowledged that a decision to treat compliance as a second-class goal is rarely voiced explicitly. Rather, it manifests when billing managers suggest that imprecise billing is not a concern, because the payer won't fix it if it's wrong; or when Administration wants to appease heavy referrers with all sorts of perks and financial incentives. Often, it manifests when an auditor's or compliance officer's recommendations are rejected because of concerns about cost or because of potential negative impact on revenues, or because the problem was caused by a cardiac surgeon who brings in \$1 million a year.

Third, we proposed that one answer to *The Question They Dare Not Ask* ("Why Bother?") is to educate about and advocate for the many benefits which effective compliance programs offer to healthcare

providers. Everyone talks about how a compliance program can prevent trouble, in a variety of ways. But in addition an effective compliance program can improve bottom line reimbursement, and can enhance relationships with personnel and with outside partners as well.

In fact, we propose that there are at least twenty different ways in which an effective compliance program can produce ongoing benefits for a healthcare organization's profitable growth! So, when you perceive that officers within your organization are asking *The Question They Dare Not Ask* (whether in words or by actions or omissions), you may find it helpful to help them appreciate *all* of these benefits.

To explain this assertion, our previous column focused on six reasons within the overall framework of "staying out of trouble with the government." While these reasons certainly are important, too often they are the only issues considered by healthcare organizations.

In fact, however, there are at least fourteen additional benefits from an effective compliance program, and these have nothing to do with the federal (or state) fraud and abuse rules, Medicare and Medicaid programs, etc.

So, let's explore our next eight benefits of an effective compliance program. These benefits focus on the ways in which compliance programs may improve the success of a healthcare organization's relationship with business colleagues, financiers and customers.

Improved Interaction with Business Colleagues, Financiers and Customers

In addition to compliance benefits that focus on legal safety and improving internal communications and employee morale, eight more benefits of an effective compliance system focus on a healthcare organization's business colleagues, financiers and customers.

6 REASONS TO "STAY OUT OF TROUBLE WITH THE GOVERNMENT"...

- 1. Reduces likelihood that organization will violate reimbursement and fraud rules.**
- 2. Reduces likelihood of penalties under federal law**
- 3. Reduce likelihood of whistle-blowing.**
- 4. Helps organization obey disclosure obligations.**
- 5. Increases perception that organization has its act together.**
- 6. Reduces likelihood of government imposed management program**

7. An effective compliance program provides reassurance to important third parties

A compliance program demonstrates that the healthcare organization is committed to effective policing of its internal and external activities. More generally, a compliance program demonstrates an organization's ability to create and operate an effective system for ongoing problem-solving. Compliance programs thus can be used to assure many different outside parties that the healthcare organization is unlikely to have substantial fraud or reimbursement problems. In addition, if an organization's compliance program satisfies the requirement of the federal guidelines, this gives further assurance to third parties that the healthcare organization has minimized the potential sanctions for inadvertent violations of fraud or reimbursement rules.

What third parties care about a healthcare organization's compliance program? Here are five examples: First, the organization's board of directors and owners should take comfort from its compliance program, because it suggests that the board and owners can delegate significant discretion to the management team. This is particularly important for outside directors and passive owners. It is essential for those organizations which must comply with Sarbanes-Oxley.

Second, many healthcare organizations participate in contracting networks and other provider alliances to offer services to health plans, to outside businesses and to other purchasers (and users) of health care. A healthcare organization with an effective compliance program will be a more desirable partner in any such alliance. Why? The presence of the compliance program should suggest to the alliance partners that the healthcare organization will probably not contribute to reimbursement or other fraud problems which could lead to heightened scrutiny for the alliance. (Conversely, if another alliance partner's fraud problems result in heightened scrutiny for the alliance, the supplier's compliance program will minimize the scrutiny likely to befall the company.) Point this out if they don't realize it!

Also, one key to success in any contracting network or other provider alliance is to choose partners who "have their act together" and who can demonstrate superior value to the users and

purchasers of health care. A healthcare organization's ongoing compliance program can be "marketed" by the provider alliance to purchasers and patients as evidence of the organization's (and, by implication, the alliance's) progressive, forward-thinking attitude, and its commitment to the highest standards when providing patient care.

Third, a healthcare organization should also "market" its compliance program to private third party payers. Although many of the federal and state laws which expose healthcare organizations to sanctions for non-compliance relate only to Medicare, Medicaid and other federally-reimbursed programs, healthcare fraud is a substantial problem for third party payers and managed care organizations in general. Also, most states have laws which affect reimbursement and healthcare relationships. These laws generally affect all patients, regardless of coverage. An effective compliance program will address these rules as well.

If these payers learn that a healthcare organization has implemented a comprehensive compliance program, this suggests the organization's willingness and ability to comply with the payers' reimbursement rules as well. This may lead to relaxed scrutiny by the payers, creating a presumption of legitimacy with ongoing billing activities. At a minimum, it demonstrates a healthcare organization's willingness to improve constantly, which makes it an attractive candidate for contracts, risk arrangements, etc. Be sure to point this out!

Fourth, the presence of an effective compliance program may be of value to the investment community. Banking institutions, venture capital funds and the like all seek assurance that a healthcare organization is not in trouble with the government, and are unlikely to invite trouble in the future. An effective compliance program is obvious evidence of that safety cushion.

Fifth and finally, a healthcare organization's ability to create and implement a successful compliance program demonstrates both a commitment to ethical performance and a demonstrated ability to set up internal systems for self-assessment. This ability is of value to many potential business allies, even parties with minimal interest in compliance issues. A healthcare organization's ability to assess itself, to utilize its strengths and minimize

its weaknesses, is directly related to its ability to take advantage of business opportunities in general, and to position itself for success.

8. An effective compliance program helps healthcare organizations achieve accreditation status

A healthcare organization's ability to demonstrate compliance knowledge now weighs heavily in accreditation efforts. Compliance is no longer viewed as just a governmental concern. It is now considered important by JCAHO and by other accrediting agencies outside of the hospital context. HIPAA compliance, fraud compliance, reimbursement compliance and accreditation compliance all fit together in an integrated system. Benefits are synergistic. Because there are substantial overlaps among the compliance efforts, substantial efficiencies and economies of scale are possible.

9. An effective compliance program is a valuable part of due diligence activities with acquisitions and mergers.

A healthcare organization which purchases or sells assets, or which merges with another organization, must undertake a due diligence process to assure the other parties that the supplier has the capacity to consummate the transaction, and that the transaction will not create any undisclosed or unexpected problems for the other parties. The presence of an effective compliance program demonstrates that the healthcare organization is less likely to have any lurking problems stemming from violations of fraud or reimbursement rules.

Further, because an effective compliance program demonstrates a healthcare organization's capacity for effective self-assessment and self-policing, this can give comfort to the other parties that the organization has the ability to carry out its promises in general, and may also have the ability to identify and resolve internal problems which do not involve compliance issues. This often results in a less burdensome due diligence process, thereby reducing the organization's costs (in both money and time).

10. An effective compliance program permits a healthcare organization to respond more quickly to problems in general

A key part of an effective compliance program is its procedure for identifying potential problems, investigating these problems, and resolving them. While the compliance program applies these procedures toward compliance with fraud and reimbursement rules, these internal systems can be expanded to allow a healthcare organization to respond quickly to problems in general.

11. A healthcare organization can use its compliance program to help focus on its objectives and to assist and enable growth, interaction with third parties, etc.

In order to create the specific standards, policies and protocols which constitute a compliance program, a healthcare organization must identify which issues are important to it and how it wishes to resolve them. Does a policy against conflicts of interest mean that the healthcare organization will not do business with other businesses owned by employees, owners or board members? Or, does it simply mean that such transactions must be approved by disinterested parties? Does it apply to all transactions, or only those above a certain dollar amount?

There are no "correct" answers to these sorts of questions. How a healthcare organization decides them should reflect its philosophy, vision and mission, as well as its corporate culture. Conversely, the process of creating and using the documents that are part of a compliance program can help a healthcare organization identify where its values and corporate culture truly lie, so that it can strive for consistency of vision in day-to-day operations.

12. An effective compliance program facilitates expansion into new services or new markets by identifying many of those topics which must be addressed for profitability.

When a healthcare organization wishes to expand into new markets or to offer new services, the organization's existing compliance protocols can help identify many topics which must be addressed for legal safety and profitability of the expansion. When a hospital, for example, seeks to expand into the homecare field, it can look to general topics applicable in the hospital context to identify what issues must be researched and addressed for the

expansion. What are the rules for patient or referral marketing? When are financial incentives allowed? What are the billing rules? What record keeping requirements are required? What resources did it use to learn these answers in the hospital context, and are there similar resources for the homecare context?

Similarly, when a healthcare organization seeks to expand into new markets, such geographic growth raises service, communication and marketing questions. Its existing compliance protocols suggest the topics to be addressed for expansion, and how to find answers to expansion questions.

13. An effective compliance program establishes approved ways to deal with problems and opportunities, and this facilitates growth

No organization wants to re-invent solutions each time problems arise. Successful healthcare organizations find it valuable to have established procedures to govern appropriate business conduct, both internally and with outside parties. Within its niche of reimbursement and fraud compliance, an effective regulatory compliance program establishes such procedures.

Because a compliance program should be compatible with a healthcare organization's business philosophy in general, the compliance program should establish Standards of Conduct which, although focused on fraud and reimbursement issues, nonetheless define the appropriate parameters in general for conduct within the company. Consistent standards, policies and protocols also can improve employee morale and effectiveness.

14. Proactive, preventative compliance programs are tax-deductible

When a healthcare organization creates and operates a proactive compliance program to prevent problems and maintain smooth communications, the costs of creating and running the program have been consistently treated as deductible business expenses for federal and state tax purposes. This includes legal fees, consulting costs, hotline services, etc.

However, when a healthcare organization becomes subject to an investigation or government enforcement action, the punitive measures imposed by the government are

generally disallowed as tax deductible expenses. This includes compliance initiatives, corporate integrity agreements, and other programs agreed to by the organization when negotiating a settlement with the government. Further, the legal and consulting costs incurred in fighting or settling with the government may not be tax deductible. ■

The next installment of "Legal Insight from the Health Law Center" will wrap up our discussion of the many benefits of an effective Compliance Program, answering *The Question They Dare Not Ask*. We will focus on six ways an effective Compliance Program can improve efficiency and employee morale within a company, so that healthcare organizations may nurture a more loyal, efficient and savvy workforce. We will also draw some insights from this rather iconoclastic approach toward compliance.

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for both directors and CFOs. Encourage directors to learn about internal controls from subject experts. The IIA, an NACD Associate Member, is an excellent source of authoritative guidance (www.theiia.org).

- *Express your views now to the SEC, while there is still time to reshape section 404 rules.* The link for filing electronically: http://www.sec.gov/cgi-bin/ruling-comments?ruling=4497&rule_path=/news/press/4-497&file_num=4-497&action=Show_Form For instructions on paper filing: <http://www.sec.gov/news/press/2005-20.htm>. Reference File No. 4-497. ■

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SOX Snippets and Audit the Auditors

By John Landreth, CPA

It's springtime in the Midwest. The flowers are blooming, baseball and soccer seasons are well underway and soon the summer will be here. It's also the time for my college freshman son to come home. He'd said on the phone that he was worried about finding a summer job, his mother and I assured him that he shouldn't have these concerns. As he walked up the driveway this morning with a bright blue Mohawk haircut - we now had a deeper understanding of his concerns...which leads us into a deeper understanding of our concerns for our first topic...Sarbanes-Oxley (SOX).

Your LTA editorial staff has been on the road in recent months attending a variety of conference and seminars, many of which have had sessions on this historical legislation.

In the same way that my son found a new way to introduce himself, I will use a different device than our standard "letter from some reader" format. These are short comments, thoughts and perspectives that I have heard that you might find interesting. We'll just call them "Sarbane's Snippets."

Snippet #1: Will it Float?

In much the same way that David Letterman asks whether an object will float or sink in a tub of water, I've been in search of this answer. Will the Sarbanes-Oxley legislation work? Will it be successful in giving the common investor the confidence to jump back into the market? Will it prevent an Enron, WorldCom or Healthsouth from happening?

I raised this question at the Chief Audit Executives (CAE) roundtable in Chicago. These CAE's come from major Fortune 500 companies who all had to comply with these new regulations. I've attended these

meetings regularly over the last two years and listened to their frustration, angst, and bewilderment, with a smirk of gratitude that it was not me.

At the last meeting as their efforts for Sarbanes are winding down, I asked them: "Will it Float?" They were slightly taken aback. In essence, I was asking them if all their effort and toil would have the desired result, would it be worth it. Their eloquent reply was "it won't prevent it, if it does happen, the fraud won't be as widespread and pervasive". These frauds will be detected earlier because the awareness is there. Employees feel empowered now to report and do the right thing.

At a local public accounting firm symposium for internal audit directors, I asked the same question of Chuck Bowsher, the former chairman of the Public Company Accounting Oversight Board. He was one of the conceptual founders of Sarbanes. He said the same thing. It won't prevent them, or eliminate them. As long as there are greedy, egotistical and unethical business leaders, they will find a way. But, it won't be as broad and deep. It will be caught earlier.

Finally, at the April 2005 Institute of Internal Auditors annual seminar in Chicago. Cynthia Cooper, the Internal Audit Director for WorldCom, who was responsible for bringing that fraud to the public eye had some interesting comments. She told close to 650 internal auditors in attendance, that she believed it would be effective, but had concerns about the "pendulum" effect. How far will the "return swing" of the pendulum, the reverse momentum set us back? The risk ahead will be how management's expectations are "managed" to understand that this is not a "one time" event; it's forever.

Snippet #2: Frequent Deficiencies Found in SOX Work this Year

(Hint: Look for these in your external auditor's plans and future management letters)

- Information Technology (IT) program change control.
- IT system access controls.
- IT segregation of duties.
- Manual intervention in Legacy IT systems.
- IT user controls at service providers.
- Review and approval of Manual Journal Entries.
- Timely completion of account reconciliations.
- Timely reconciliation of suspense accounts.
- Financial statement closing.
- Tax related matters.

Snippet #3: Lessons learned for Future SOX Projects

"Don't implement a new system in the fourth quarter of your fiscal year." Why? There won't be enough time to fix it and prove that the fix is effective to prevent a deficiency finding"

"Don't implement a new system in the first quarter of the new fiscal year" Why? "You'll be too busy to test it with the year-end activities

Comment: There is never a good time to implement a system, is there? I am sure that over time IT organizations will adapt by insuring that they have more bullet-proof systems.

Snippet #4: Anecdotal Comment Political Underpinnings SOX and HIPAA Privacy legislation

"So the Democrats brought us HIPAA and the Republicans brought us Sarbanes-Oxley?"

Snippet #5: Best Prediction as to Whether SOX will be Required for Not-For-Profits

"If there's a big scandal for the not-for-profits, it will be a slam dunk for Congress to require compliance with Sarbanes."

Snippet #6: Statement Overheard At IIA Seminar

"Internal Auditors are no longer the Rodney Dangerfield of business...now we get respect!"

Snippet #7: Best Mitigating Control Idea Heard So Far.... (And SOX missed it.)

Audit directors are always performing a "balancing act" of professional independence, objectivity and keeping the kids fed and the mortgage paid. We are expected to be the independent "conscience" of our organization, yet we are supposed to "be unafraid" of the potential loss of our jobs and security of families for "doing the right thing" for the good of the public (and the Board of Directors D&O coverage.)

At another roundtable, an audit director (non-healthcare) told how he addressed this when he was hired. He insisted on having a severance package agreed to "upfront" that was the same as that of the executive team. If they could have the same financial assurance and security in their jobs, then he should too. He got it!

Comment: Maybe this Monday I'll ask for that same severance package to maintain my independence and domestic security. How about you?

Okay, time to remove the Mohawk and get back to our standard *Letters to the Auditor* format. Our letter this week comes from an audit director who's heard about the IIA's Quality Assurance Review requirements....

Dear LTA,

I have been reading and hearing a lot about the new IIA standards that require each internal audit department to have an audit of their department. I have been aware of this concept for a number of

years, but never really felt ready for it.

My team is currently too busy helping other people get their department operations and controls in shape. In addition, we have a very busy schedule in the year ahead and would never have time for the disruption of an audit. Maybe I can buy some time until I get through the next few plan years before my Audit Committee chairman or CEO bring it up.

Although I'm not ready for a review immediately, I'm thinking about what I can do to make sure that I am prepared when the time comes. What are some of the ways in which I can gradually get prepared for a quality assurance review of my department?

Signed,

Querulous about QAR's in the Quad-Cities

Dear Querulous,

It never ceases to amaze me that requests come from our readers about topics where I have had recent experience. What a coincidence! Let's address the facts before we deal with preparation.

According to the IIA's International Standards for the Professional Practice of Internal Auditing, Attribute Standards Section 1300,

"The chief audit executive should develop and maintain a quality assurance and improvement program that covers all aspects of the internal audit activity and continuously monitors its effectiveness. This program includes periodic internal and external quality assessments and ongoing internal monitoring."

Section 1312 states: "External assessments, such as quality assurance reviews, should be conducted at least once every five years by a qualified, independent reviewer or review team outside the organization."

This means that every internal audit department needs to have a quality assessment review completed by January 1, 2007. That means that for your department to be compliant with our professional standards, you will need to have this completed in about one and a half years.

As Judy Collins sang, "I've looked at cloud from both sides now". Over the last few months I have been on both sides of a Quality Assurance Review- both a giver

and a receiver. Both experiences have been very positive and worth the effort.

Getting Ready Emotionally

Although your procrastination style may be get it done *later* or *much much later*, I'd encourage you to get your department's QAR preparations started as soon as possible. You should decide to take the initiative. Make it look like your idea; at least appear to be proactive.

It's just a matter of time before your Audit Committee chairman, CFO or CEO will read some "best practices in governance" article, or your external auditor will be in search of additional consulting revenue and will raise it as a management letter comment.

*IIA Standards,
Section 1312
calls for QAR of
ALL aspects of
internal audit by
1/1/2007.*

If you take charge of the project, it will be less likely that one of them will take the lead. You can keep the project on task and not let it get out of control. Take my advice; just stick to the standards.

Any resistance you appear to put forward will make you look like you are the organization's biggest hypocrite - they will say that you can dish it out, but you can't take it. You can see your credibility going down the drain. Set a good example for the rest of the organization. It's better than running out of the audit committee meeting shouting "Never! Never! Over my dead body!" It's just more professional.

We all know the many reasons why an audit can't be done, we've heard them all: "This is a busy time." "We just got through a busy time." or "A busy time is coming up."

Think of it this way, you've been successful at deferring this review for

this many years, its time to take your lumps like everyone else. Your clients have been tolerating your audits for a long time. Be prepared to walk a mile in their shoes. Although we try very hard to be sensitive to our clients concerns and think we understand them, there is nothing like being the subject of an audit to know really know it feels.

Here are some thoughts that went through my mind when my department went through our QAR. You might:

- Feel a little nervous when the QAR team asks a sensitive question you did not expect, or where you know things aren't perfect. You might ask yourself, "Do I tell them now, or will I let them find it".
- Have an unhappy client who always gripes about your long reports, when the QAR team asks a question about report length, you might feel yourself internally seething.
- Be busy and you might not have time to get the QAR team everything they want. You might find yourself annoyed by their reminders and deadlines.
- Be commenting on the draft report and discussing the use of certain words and phrases; hear the "voices of auditees past" saying the same things.

Preparing for a QAR

Your preparation for a QAR will be somewhat guided by the QAR you select to do. QAR's can take several forms and can be done in a number of ways. They can be performed by external consultants, by the IIA, or even by your peers under certain circumstances. Generally, the IIA QAR's are much less expensive and are completed in a faster time frame – usually within two weeks. You can even do an internal review on your own and have it verified by an external reviewer. There are several "pro's" and "con's" to each of these. I would suggest talking to the IIA, fellow audit directors, or give me a call.

You asked about how to prepare for the review. Here are some suggestions:

- Order a copy of the IIA's professional standards (a.k.a. "The Little Red Book), *The Professional Practices Framework* (Mar. 2004). You probably

already have it. (You'll just need to find another book of the same size to keep your conference table propped and balanced.) This will give you a ready reference for the actual standards.

- Self-review materials. My recommendation is the IIA's *Quality Assessment Review, Fourth Edition*. This manual is used by the IIA reviewers in conducting QAR's; it walks you through each standard, has template workpapers, and shows you step-by-step how the reviewer determines compliance.
- If you find that a more interactive approach would be more helpful, there are also some excellent local chapter and national IIA seminars.

However, personally, in my opinion the *best* way to prepare for your QAR is to participate in one and experience the entire process for yourself. It is an extraordinary educational experience.

The IIA QAR process involves volunteers from Internal audit department management. You submit your name and experience and they will notify you of scheduled QAR's and the company's name and industry. (Most engagements last two weeks and this can be a challenge for your schedule.) You are reimbursed for all expenses for the QAR engagement, but you are not compensated for your time. You received CPE credit for your participation and receive credit for a free IIA seminar. In addition, you are provided and retain the IIA standards book, and the QAR manual. Please refer to the IIA website for more details. By far, the experience is the greatest value you will receive.

First, it is true hands-on experience. It is one thing to review the standards and examples in textbook or classroom experience. Application of these standards to real life examples is much more interesting. It's similar to a consulting experience. You have the opportunity to examine another audit department's processes, procedures, work papers, reports, etc. You can see what that audit department does well and does not do so well. You can share your experiences and practices with them, too. In like manner, you get to see how other audit shops do things and can bring those ideas back to your department.

Interviews are an important part of any QAR. These are conducted with the audit department's clients: the audit committee chairman, CEO, CFO, and department heads, as well as each member of the internal audit department. These usually involve 15-20 people. The QAR team talks to your customers about how your department serves their needs. These interviews can provide very frank and honest comments and feedback. I must compliment the IIA for this rigorous aspect of the QAR process. I cannot think of any profession that exposes itself to such an invasive examination process.

I know that we all value our relationships with our internal customers and work to keep these relationships strong. But, when you listen to the positives and negatives in these interviews, you cannot help but ask yourself "What would my customers say?" This experience in itself can provide you with motivation to work even harder on these relationships when you get back home to your department.

Another great benefit in participating with the IIA QAR team is the opportunity to work with the IIA team leader. These individuals are experts in the IIA standards. They can be your "audit Yoda". They are retired CAE's and have a bounty of knowledge, practical solutions, and excellent audit stories. My QAR leader and I had many discussions about the standards and their application to the QAR client.

I learned more about the IIA standards during my QAR experience than I have ever learned in any classroom setting. There were times that I thought I should be paying for this experience- it's that good. I think that volunteering members of your audit staff for a QAR would also be a great opportunity, too. They could get out of the office, make a contribution to their profession, and further learn about the IA standards. (In addition, they get CPE credit and you can save on your training budget with the free course.)

Well that's it for this issue. You can send your questions to *Letters to the Auditor* via mail to: *Letters to the Auditor*, c/o John Landreth, 1810 W. Birch Lane, Park Ridge, Illinois 60068, or via email to: prflag2004@aol.com or via phone 847-525-6529. ■

Learn the Terms

Healthcare is replete with poly-syllabic clinical terminology and unfamiliar acronyms. Learn the Terms is a quick guide for non-clinical personnel to what these terms mean. You can reference these terms below and others in the AHIA Electronic Audit Library – Terms and Acronyms section. Thanks to Theresa Crothers, RN, CMAS for her contribution. Theresa is a nurse auditor for United Audit Systems, Inc., and is 2005 President, American Association of Medical Audit Specialists.

Endoscopic

EGD: Esophagogastroduodenoscopy is a test that allows the lining of the esophagus, stomach, and upper duodenum to be visualized by the use of a flexible fiber-optic or video endoscope. This test is done to diagnose inflammation, tumors, ulcers, and any other injury to the esophagus and duodenum. Conscious Sedation is used.

ERCP: Endoscopic Retrograde Cholangio-Pancreatography allows for the visualization of the pancreas, liver, and gallbladder, by using a flexible lighted scope. A contrast medium is injected prior to the exam. Conscious Sedation is used.

Radiologic

CXR: Chest X-Ray

PA/Lat: Determines the position of the body in relation to the beam of x-ray. PA is a Posterior/Anterior view of the chest, and Lat (lateral) is a side view.

CT Scan: Computed Tomography provides a series of pictures representing a cross section of the particular organ that is scanned. The pictures are translated by a computer and displayed on a monitor. They are often performed with a contrast medium, which can be given intravenously, or orally.

MRI: Magnetic Resonance Imaging is a radiologic exam that provides highly detailed and multi-plane cross-sectional images of a particular organ. The biggest advantage is that MRI can “see through” bone, so is often used for intracranial and spinal, and thoracic imaging.

PET Scan: Positron Emission Tomography

SPECT: Single-Photon Emission Computed Tomography

These scans provide images through sophisticated computer reconstructed algorithms, and use elements of CT scanning, and conventional radionuclide imaging.

UGI: Upper Gastro-Intestinal x-ray of the esophagus, stomach, and small intestine. Barium is used as a contrast medium, and the use of fluoroscopy allows the visualization of the barium as it travels through the GI tract.

Radiologic (continued)

BE: Barium Enema, also known as a Lower GI, examines the lower intestine after the installation of Barium.

KUB: Kidney-Ureter-Bladder is an x-ray that shows the organs related to the kidney. Each kidney has a ureter that connects to the bladder.

Fluoroscopy: A continuous beam of x-ray to follow movement in the body.

IVP: Intravenous Pyelogram is an x-ray that shows the structures of the urinary tract using an IV contrast. It is done to evaluate size and location of kidney stones, cause of urinary tract infections, and tumor diagnosis.

BMD: Bone Mineral Density is a test that measures the amount of calcium in a specific region of the bones. It is used to determine bone strength, and in the diagnosis of osteoporosis.

BMD-DEXA: DEXA is Dual Energy X-Ray Absorptiometry. It uses two different x-ray beams, and is the most accurate method for measuring BMD. It uses low doses of radiation.

BMD P-DEXA: P-DEXA is Peripheral Dual Energy X-Ray Absorptiometry measures BMD in outlying (peripheral) areas of the body. P-DEXA machines are portable, use low doses of radiation with quicker results.

Arthrography: An Arthrogram is an x-ray done using a contrast material that is injected into an affected joint. It allows better visualize of problems with tendons, ligaments, muscle and cartilage.

IR: Interventional Radiology is the use of x-ray and other medical images to guide small instruments (catheters, scopes) through blood vessels or other pathways to treat disease percutaneously (through the skin). This method of diagnosis/treatment is much less costly and less invasive than conventional surgery.

Needle Biopsy: A small needle guided by x-ray is inserted into the abnormal area (often used for breast biopsy). A sample of the tissue is removed and sent for review by pathology.



Get In Tune!

By Joyce L. Lang, CPA, CIA

Are you ready to add some songs to your repertoire? How about getting some new healthcare internal auditing techniques? Either way, AHIA's 2005 Conference in Nashville, the *Music City*, is the place to be in October.

The conference is packed with opportunities to *Get in Tune*; to build professional knowledge, skills, and a network of your peers. Highlights include:

- **Four pre-conference optional sessions.** In half-day sessions take a comprehensive, in-depth look at internal audit's role in information system implementations, the revenue cycle, using internal control frameworks, and compliance auditing and monitoring.
- **Nationally-recognized speakers at two general sessions.** Barry Maher will motivate us to increase productivity and job satisfaction, and healthcare futurist Joe Flower will help us manage the changes in our industry's future.



Barry Maher



Joe Flower

- Five workshop tracks: Emerging Issues, Revenue Cycle, Compliance, Clinical, and the Healthcare Auditor's Toolkit. Build skills in your area of expertise or cross-over to appreciate the breadth of healthcare compliance and internal auditing.
- Forty workshops. Experienced auditors and experts share their knowledge and tools on topics that are relevant to new, intermediate and advanced healthcare professionals.
- Two networking events. Build your resource network as you renew acquaintances and meet new peers.
- Exhibits and demonstrations. See the latest products and services to support your audit and compliance activities.
- Nashville. Experience the music, food, dancing, shopping, history and sights of this exciting city.

Mark your calendar. Optional sessions are October 9 and the conference runs October 10 through 12. Look for more information and registration at www.ahia.org or watch the mail for your conference brochure. Whether you register on-line or by mail, do it before August 29 and save \$100!

Personally, I'm going to have trouble completing my registration form; there are too many exceptional sessions to choose from. Looks like I'm going to have to bring my co-workers so we can cover all the topics. This will be great! See you in Nashville! ■

Joyce L. Lang, CPA, CIA, is the Chair of the 2005 AHIA Annual Conference Committee. She is Director of Management Audit Services at Legacy Health System in Portland, Oregon.



Nashville Riverfront




Ryman Auditorium



Parthenon

AHIA is pleased to have the following vendors participate as exhibitors or sponsors at the 2005 conference.

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Conference schedule and registration form available on pages 46 and 47.

Visit www.ahia.org for full conference brochure and on-line registration form.

...
Nashville, TN

Get in Tune!

AHIA 2005 Annual Conference
October 8-12, 2005
Loews Vanderbilt Hotel

2005 CONFERENCE-AT-A-GLANCE

www.ahia.org or 1-888-ASK-AHIA

		Monday, 10/10	Tuesday, 10/11	Wednesday, 10/12
<p>Optional and General Sessions</p> <p>Saturday, 10/8 8 a.m. - 5 p.m. CIA Exam Review Part I: Internal Audit Activity's Role in Governance, Risk and Control</p> <p>Part II: Conducting the Internal Audit Engagement</p> <p>Sunday, 10/9 8 a.m. - Noon CIA Exam Review Part III: Business Analysis and IT Optional #1: Internal Audit's Role in IS Implementations Optional #2: Compliance Auditing & Monitoring</p> <p>Sunday, 10/9 1-5 p.m. CIA Exam Review Part IV: Business Management Skills Optional Session #3: Revenue Cycle 101 Optional Session #4: Using Internal Control Frameworks</p> <p>Monday, 10/4 8:30 - 10 a.m. General Session #1: Filling the Glass: Increasing Productivity and Job Satisfaction</p> <p>Tuesday, 10/11 8:30 - 10 a.m. General Session #2: Building the Next Healthcare Where You Work</p>	Compliance	<p>10:20 a.m. - Noon JCAHO: Compliance Implications for Auditors (A) 1:20 - 3 p.m. Clinical Trials: The Risks and How to Audit (F) 3:20 - 5 p.m. The Obligation to Make Refunds and Do Retrospective Reviews (K)</p>	<p>10:20 a.m. - Noon How to Manage Vendor Conflicts of Interest (F) 1:20 - 3 p.m. Legal Insight: What to Do When the Government Comes Calling (U) 3:20 - 5 p.m. Hospital/Physician Compliance Initiatives (Z)</p>	<p>8 - 9:40 a.m. Charge Master Maintenance Software: Payoffs & Pitfalls (EE) 10 - 11:40 a.m. Quality of Care (JJ)</p>
		Clinical	<p>10:20 a.m. - Noon Auditing Surgical Claims (B) 1:20 - 3 p.m. Keeping Narcotics Safe (G) 3:20 - 5 p.m. Tuning In to Medical Auditor Challenges (L)</p>	<p>10:20 a.m. - Noon The Complexities of Producing "Clean Claims" (Q) 1:20 - 3 p.m. Coding Cardiac Cath & Interventional Radiology (V) 3:20 - 5 p.m. Advanced Beneficiary Notice & Medical Necessity (AA)</p>
	Revenue Cycle		<p>10:20 a.m. - Noon Internal Audit & Compliance Working Together to Audit the Revenue Cycle (C) 1:20 - 3 p.m. Documenting Revenue Cycle Processes for Optimization and Section 404 Compliance (H) 3:20 - 5 p.m. Outpatient Revenue Opportunities Using CAATS (M)</p>	<p>10:20 a.m. - Noon Non-Acute Revenue Cycle for Dummies (R) 1:20 - 3 p.m. Denials Management & Auditing Managed Care Denials (W) 3:20 - 5 p.m. Charge Master Management Department Operational Reviews (BB)</p>
		Healthcare Toolbox	<p>10:20 a.m. - Noon Building the Foundation of Your Internal Audit Practice (D) 1:20 - 3 p.m. Effective Communications (I) 3:20 - 5 p.m. Coding 101: Basics for Coding in the Physician Setting (N)</p>	<p>10:20 a.m. - Noon Building an Effective Compliance Program on a Shoe-String Budget (S) 1:20 - 3 p.m. Chart Auditing 101 (X) 3:20 - 5 p.m. Internal Audit: Ahead of the Curve (CC)</p>
	Emerging Issues		<p>10:20 a.m. - Noon Trends in Healthcare Internal Audit (E) 1:20 - 3 p.m. OIG Work Plan Review (J) 3:20 - 5 p.m. Meeting the Needs of Governance (O)</p>	<p>10:20 a.m. - Noon Hot Topics in Foreign Outsourcing: How Can My Healthcare Organization Avoid Getting Burned? (T) 1:20 - 3 p.m. Tools for Managing Healthcare Change (Y) 3:20 - 5 p.m. Integrating IT Into the Audit Shop (DD)</p>

AHIA 2005 ANNUAL CONFERENCE REGISTRATION FORM

October 8-12, 2005, Loews Vanderbilt Hotel, Nashville, TN

REGISTER BY

AUGUST 29th

SAVE \$100

Name _____ Title _____
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Circle all that apply: AHIA Member? Yes No First Time Attendee? Yes No T-Shirt Size: S M L
 # AHIA Annual Conferences previously attended: _____ XL XXL

REGISTRATION FEES:

✓ Check all that apply	<i>Before 8/29</i>	<i>After 8/29</i>
AHIA Member Rate	_____ \$750	_____ \$850
Join and Register		
(Includes 1 year membership)	_____ \$930	_____ \$1,030
Quantity Discount*		
Member Discount (2nd registration)	_____ \$650	_____ \$750
Non-member		
(Includes 1 year membership)	_____ \$830	_____ \$930

OPTIONAL SESSIONS:

(All sessions include break)

CIA Exam Review (Part I, II, III, IV)	_____ \$75 Per Part	
Optional Session #1	_____ \$75	_____ \$95
Optional Session #2	_____ \$75	_____ \$95
Optional Session #3	_____ \$75	_____ \$95
Optional Session #4	_____ \$75	_____ \$95

Subtotal: Registration Fees (A) \$ _____

Meal Tickets (Paid registrants receive meals for all scheduled meal functions; required for guests)

Monday Luncheon	_____ \$30
Monday Welcome Reception	_____ \$35
Tuesday Luncheon	_____ \$30

Subtotal: (B) \$ _____

TOTAL AMOUNT ENCLOSED (A + B) = \$ _____

PAYMENT INFORMATION: (Check appropriate box)

NOTE: Payable in US Funds only.

Check (payable to AHIA)
 Credit Card: AmExp MasterCard Visa

Credit Card #: _____

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Name on Card (print): _____

Signature: _____

Please do not allow my name to be used by other organizations
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*\$100 discount for individuals from same organization at same mailing address. Applies to those who register after the 1st registrant. Check group rate on the registration form; forms must be submitted together in order for discount rate. See page 21 for specific group policy.

Yes - sign me up for the **free** Loews Cooking Demonstration. Note: limited to first 25 registrations. All others will be put on a wait-list.

SESSION CHOICES

(Check or circle one in each applicable time frame)

CIA Exam Review:

Saturday, 10/8

Part I (a.m.) Part II (p.m.)

Sunday, 10/9

Part III (a.m.) Part IV (p.m.)

Optional Sessions: Sunday, 10/9

- Optional Session #1 (8 am-Noon)
- Optional Session #2 (8 am-Noon)
- Optional Session #3 (1-5 p.m.)
- Optional Session #4 (1-5 p.m.)

Workshops: (Circle one for each time frame)

Monday, 10/10

10:20 a.m.-Noon	A	B	C	D	E
1:20 - 3 p.m.	F	G	H	I	J
3:20-5 p.m.	K	L	M	N	O

Tuesday, 10/11

10:20 a.m. - Noon	P	Q	R	S	T
1:20 - 3 p.m.	U	V	W	X	Y
3:20 - 5 p.m.	Z	AA	BB	CC	DD

Wednesday, 10/12

8 - 9:40 a.m.	EE	FF	GG	HH	II
10 - 11:40 a.m.	JJ	KK	LL	MM	NN

Mail completed registration form and payment to:

Association of Healthcare Internal Auditors
 PO Box 10
 Adrian, MI 49221-0010

Or Fax to: 517-467-6104 (secured fax line)

Or Register Online: www.ahia.org

Call 1-888-ASK-AHIA
 if there are questions.

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Association of Healthcare Internal Auditors, Inc.

2005 Membership Application

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Membership Fees: (U.S. funds only)

- \$180 - 1st member from organization
- \$150 - each additional member from same organization located at same address. Multiple member discounts are designed only for companies who have multiple memberships from the same address. They are not approved for members from different branches with different addresses.
- \$75 - Faculty membership (you must be an active faculty member or professor - adjunct or full - at a junior college, college or university).

- \$40 - Student membership (you must be a full time undergraduate student in a junior college, college or university, carrying at least 12 hours/semester, trimester, or quarter. Proof of your undergraduate status (e.g., registration form) must accompany your membership application).

Membership dues are not deductible as a charitable contribution. Membership dues may be deductible as an ordinary and necessary business expense. Consult your tax adviser for information.

Make checks payable to the Association of Healthcare Internal Auditors, Inc.

Your payment by check saves the organization substantial credit card fees. Send completed application and fee to AHIA, PO Box 10, Adrian, MI 49221-0010. Applications can also be faxed in at (517) 467-6104 (secured line).

Call 1-888-275-2442 if there are questions. Thank you for your interest in AHIA!

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