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HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

November 2014

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WWW.HCCA-INFO.ORG

Donald A. Sinko
Chief Integrity Officer, Cleveland Clinic

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Vice Chairman for Clinical Operations & Quality, Cleveland Clinic Imaging Institute; and Chairman, Corporate Compliance Committee

Quality improvement, patient safety, and the zeal to comply:

What a CPA and a radiologist bring to Compliance leadership

an interview with Don Sinko and Mark Sands

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Start planning now for

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Managed Care Compliance Conference
February 15–18 • Las Vegas, NV

Audit & Compliance Committee Conference
February 23–24 • Scottsdale, AZ

19th Annual Compliance Institute
April 19–22 • Lake Buena Vista, FL

Research Compliance Conference
May 31–June 3 • Austin, TX

Clinical Practice Compliance Conference
October 11–13 • Philadelphia, PA

Healthcare Regulatory Institute
October 25–28 • Washington DC NEW

Regional Compliance Conferences

January 23 • Atlanta, GA
February 6 • Orlando, FL
February 13 • Portland, OR
February 20 • Dallas, TX
February 26–27 • Anchorage, AK
March 6 • St Louis, MO
March 13 • Washington DC
March 20 • Charleston, SC NEW
April 30–May 1 • San Juan, PR
May 8 • Columbus, OH
May 15 • New York, NY
June 5 • Philadelphia, PA
June 12 • Seattle, WA
June 19 • Santa Ana, CA
September 11 • Boston, MA
September 18 • Minneapolis, MN
September 25 • Overland Park, KS
October 2 • Indianapolis, IN
October 9 • Pittsburgh, PA
October 15–16 • Honolulu, HI
October 23 • Denver, CO
November 6 • Louisville, KY
November 13 • Scottsdale, AZ
November 20 • Nashville, TN
December 4 • San Francisco, CA
December 11 • Houston, TX

Basic Compliance Academies

January 19–22 • New York, NY
January 26–29 • San Juan, Puerto Rico
February 9–12 • San Francisco, CA
March 9–12 • Las Vegas, NV
April 27–30 • Orlando, FL
June 8–11 • Scottsdale, AZ
August 10–13 • New York, NY
September 14–17 • Chicago, IL
October 19–22 • Las Vegas, NV
October 26–29 • Nashville, TN NEW
November 16–19 • Orlando, FL
Nov 30–Dec 3 • San Diego, CA

Healthcare Privacy Basic Compliance Academies

March 2–5 • San Diego, CA
June 15–18 • Location TBA
November 2–5 • Orlando, FL

Research Basic Compliance Academies

March 2–5 • San Diego, CA
November 2–5 • Orlando, FL

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Web Conferences

Explore hot topics in healthcare compliance with instant and up-to-date education from the convenience of your office. HCCA announces new conferences regularly, and prior sessions are available for purchase. Visit www.hcca-info.org to learn more.

Conference dates and locations are subject to change.

by Roy Snell, CHC, CCEP-F

Business crisis? Proceed as quickly as you must …but as slowly as you can

Please don't hesitate to call me about anything any time.
612-709-6012 Cell • 952-933-8009 Direct
roy.snell@corporatecompliance.org
@RoySnellSCCE *in/roysnell*

A business crisis occurs and everyone wants to spring into action. They want meetings held, people called, emails sent, and the problem fixed immediately. You may want to do all of that eventually, but there is a period of time, whatever you can afford, in which you just want people to stop and think. There are two moments in everyone's life where their ability to think is severely hampered—during their first kiss and when they have their first business crisis. In either case, people should take a moment and really consider their next move carefully.


Snell

Let me give you an example. I just received an email from a software vendor. They are a competitor of the software company we use to manage all our data. We, like their clients, have tens of thousands of records in our database and the database is used by many employees every day. This competitor had installed an update and accidentally deleted a lot of their client's data. They sent three emails. The first two went to their clients. The third went to me. I could see the three email string describing the problem differently in each subsequent email.

The first mistake they made was trying to explain to their clients the problem they had caused, before they fully understood the problem. The second mistake they made was that they sent the third email to the wrong list. I am not, and never have been, a client of this company; but I am probably on their marketing list. Someone was in such a hurry to fix a crisis that they caused a bigger problem by announcing to their potential clients that they lost their current clients' data.

> The first mistake… was trying to explain… the problem they had caused, before they fully understood the problem.

Had I been their CEO, instead of getting mad and trying to find someone to blame, I would have told everyone, "Stop, calm down, and have someone check all your work/decisions. This stuff happens and we need to fix it, but we are all a little stressed right now and we need to proceed as quickly as we must…but as slowly as we can." People often create the false notion that all-out speed is necessary. In compliance this happens regularly. A problem occurs and many people, including those above you, need to be asked to slow down. It's one thing to make a mistake, it's inevitable. What really frustrates me is people who rush to fix one problem and create another.

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Compliance Today is printed with 100% soy-based, water-soluable inks on recycled paper, which includes 10% post-consumer waste. The remaining fiber comes from responsibly managed forests. The energy used to produce the paper is Green-e® certified renewable energy. Certifications for the paper include Forest Stewardship Council (FSC), Sustainable Forestry Initiative (SFI), and Programme for the Endorsement of Forest Certification (PEFC).

> Knowing that current regulations are going to have to change, but not knowing when and how, adds stress to being able to do the right thing.

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ARTICLES

Compliance TODAY

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VOLUME 16, ISSUE 11

GAO releases its report on Duplicate Postpayment Claims Reviews

A report—*Program Integrity: Increased Oversight and Guidance Could Improve Effectiveness and Efficiency of Postpayment Claims Reviews*—recently released by the Government Accountability Office (GAO) recommends that the Centers for Medicare & Medicaid Services (CMS) "take actions to improve the efficiency and effectiveness of contractors' postpayment review efforts, which include providing additional oversight and guidance regarding data, duplicative reviews, and contractor correspondence. In its comments, the Department of Health and Human Services concurred with the recommendations and noted plans to improve CMS oversight and guidance."

According to the GAO report, "CMS implemented a database to track Recovery Auditor (RA) activities, designed in part to prevent RAs, which conducted most of the postpayment reviews, from duplicating other contractors' reviews. However, the database was not designed to provide information on all possible duplication, and its data are not reliable because other postpayment contractors did not consistently enter information about their reviews. CMS has not provided sufficient oversight of these data or issued complete guidance to contractors on avoiding duplicative claims reviews."

The report also finds, "CMS has strategies to coordinate internally among relevant offices regarding requirements for contractors' claims review activities. The agency also has strategies to facilitate coordination among contractors, such as requiring joint operating agreements between contractors operating in the same geographic area. However, these strategies have not led to consistent requirements across contractor types or full coordination between Zone Program Integrity Contractor (ZPICs) and RAs. GAO previously recommended that CMS increase the consistency of its requirements, where appropriate, and the HHS Office of Inspector General has recommended steps to improve coordination between ZPICs and RAs.

"…[T]o improve… Medicare postpayment claims review efforts and simplify compliance for providers," the GAO report specifically recommends the following four actions:

- monitor the Recovery Audit Data Warehouse to ensure that all postpayment review contractors are submitting required data and that the data the database contains are accurate and complete;
- develop complete guidance to define contractors' responsibilities regarding duplicative claims reviews, including specifying whether and when Medicare Administrative Contractor (MACs) and ZPICs can duplicate other contractors' reviews;
- clarify the current requirements for the content of contractors' additional documentation requests (ADRs) and results letters, and standardize the requirements and contents as much as possible to ensure greater consistency among postpayment claims review contractors' correspondence; and
- assess regularly whether contractors are complying with CMS requirements for the content of correspondence sent to providers regarding claims reviews.

For the complete GAO report:
http://1.usa.gov/1BwyGcy

Read the latest news online ▶ www.hcca-info.org/news

Regulatory news

FY 2015 Policy and Payment Changes for Inpatient Stays in Acute Care and Long-Term Care Hospitals

According the fact sheet released by CMS on the Hospital IPPS for Acute Care Hospitals and the Long Term Care Hospital PPS and Fiscal Year 2015 Rate, "The final rule, which applies to approximately 3,400 acute care hospitals and approximately 435 LTCHs, will generally be effective for discharges occurring on or after October 1, 2014. Under the final rule, the operating payment rates for inpatient stays in general acute care hospitals paid under the IPPS that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users will be increased by 1.4 percent. (The market basket update is 2.9 percent (up from the projected 2.7 percent that was included in the proposed rule) for FY 2015, but is reduced as described in detail below.) Beginning with FY 2015, those hospitals that do not successfully participate in the Hospital IQR Program and do not submit the required quality data will be subject to a one-fourth reduction of the market basket update (previously these hospitals received a 2 percentage point reduction). Also, the law requires that the update for any hospital that is not a meaningful EHR user will be reduced by one-quarter of the market basket update in FY 2015, one-half of the market basket update in FY 2016, and three-fourths of the market basket update in FY 2017 and later years. Total IPPS payments are projected to decrease by $756 million. Medicare payments to LTCHs in FY 2015 are projected to increase by approximately 1.1 percent."

For Fact Sheet information: *http://go.cms.gov/1sLiZj0*

For the final rule: *http://go.cms.gov/1sLjh9r*

OEI Report on Nursing Facilities' Reporting Allegations of Abuse or Neglect

A report issued by the OIG Office of Evaluation and Inspection—*Nursing Facilities' Compliance with Federal Regulations for Reporting Allegations of Abuse or Neglect*—finds "that 85 percent of nursing facilities reported at least one allegation of abuse or neglect to OIG in 2012. Additionally, 76 percent of nursing facilities maintained policies that address Federal regulations for reporting both allegations of abuse or neglect and investigation results. Further, 61 percent of nursing facilities had documentation supporting the facilities' compliance with both Federal regulations under Section 1150B of the Social Security Act. Lastly, 53 percent of allegations of abuse or neglect and the subsequent investigation results were reported, as required."

The report recommends, "that CMS ensure that nursing facilities: (1) maintain policies related to reporting allegations of abuse or neglect; (2) notify covered individuals of their obligation to report reasonable suspicions of crimes; and (3) report allegations of abuse or neglect and investigation results in a timely manner and to the appropriate individuals, as required. CMS concurred with all three of our recommendations."

For more on this report: *http://1.usa.gov/1uWoec9*

For an OIG Podcast on this report: *http://1.usa.gov/YH8qiT*

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MANAGE YOUR COMPLIANCE PROGRAM WITH COMPLIANCE 360:

Claims audits and denials by payers, new policies and procedures to reflect ever-changing laws and regulations, scrutiny of physician relationships, Medicare compliance audits, and managing HIPAA privacy rules are just a few of the issues creating unprecedented compliance and financial risks that healthcare organizations must manage effectively. With so much complexity – and so much at stake - you need a comprehensive, unified solution that helps you identify and fix the gaps… before something falls through them.

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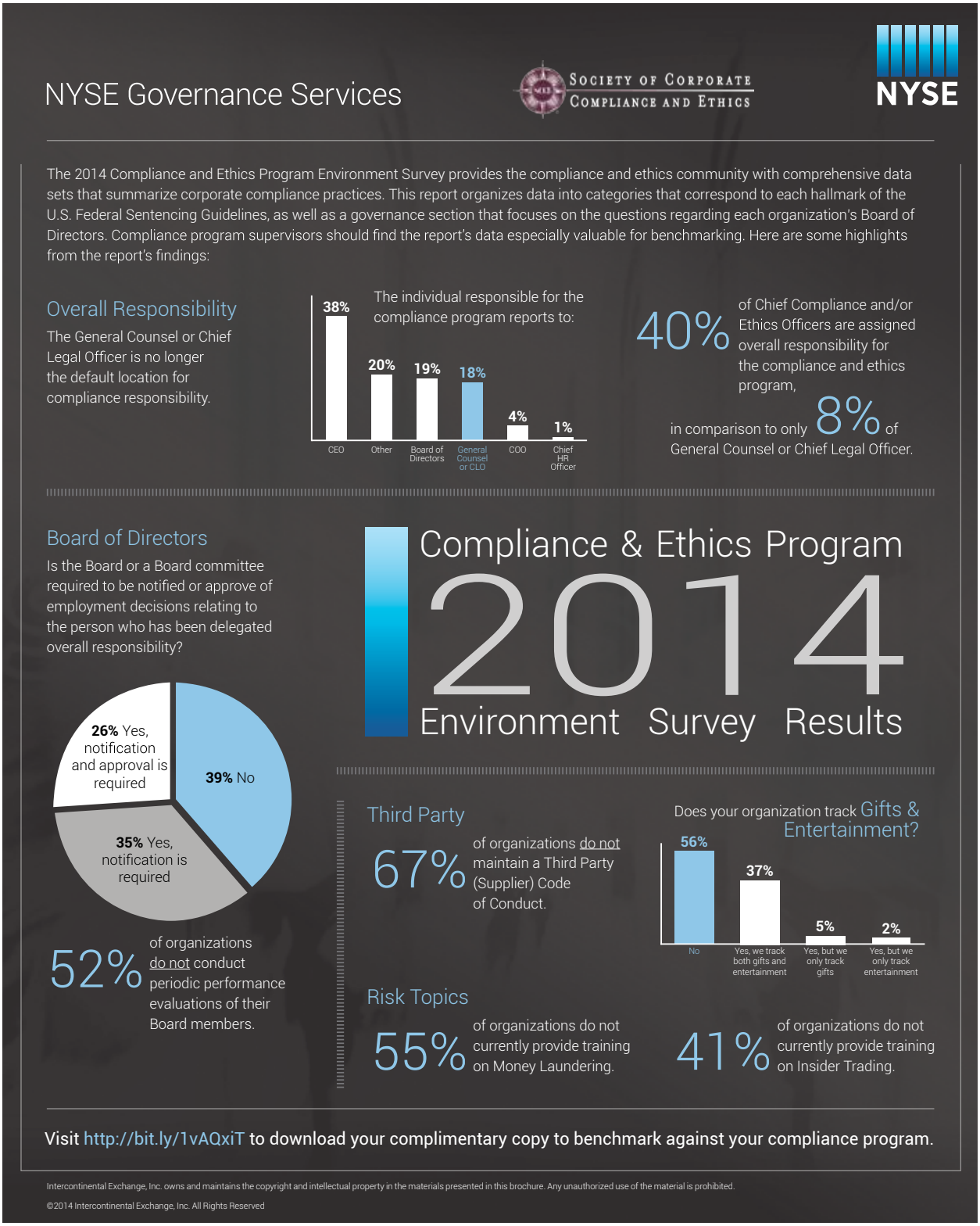
Infographic of the month



To see more compliance-related links: *www.pinterest.com/theHCCA*

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Plan now to join your peers for the primary networking and educational event for those involved with managing compliance at health plans.

AGENDA NOW ONLINE

Managed Care Compliance Conference

February 15–18, 2015 | Las Vegas, NV

Join your peers:

– Compliance professionals from a health plan *(all levels: officers to consultants)*
– In-house or external counsel for a health plan
– Internal auditors from a health plan
– Regulatory compliance personnel
– Managed care lawyers

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HCCA *conference news*

Managed Care Compliance Conference

February 15–18, 2015 | Las Vegas

www.hcca-info.org/managedcare

The Managed Care Compliance Conference is moving to a new location in 2015—join us in Las Vegas! The conference will be held at Caesars Palace from February 15–18, 2015. Plan to attend if you are a compliance professional from a health plan (all levels from officers to consultants), in-house or external counsel for a health plan, internal auditor from a health plan, regulatory compliance personnel, or managed care lawyer.

Hot Topics include:

- Regulatory Compliance Monitoring
- FDR Oversight—Turning theory into practice: A systemic, tool-laden approach to meeting CMS expectations
- Health Insurance Exchange Compliance
- And many more!

For the full agenda, visit:

www.hcca-info.org/managedcare

Speed Networking

New this year, the Managed Care Compliance Conference will offer a Speed Networking opportunity during the pre-conference on Sunday, February 15. This is a fun, fast-paced activity that allows you to meet a variety of colleagues in a friendly, no-commitment setting. Discussions that begin here often lead to conversations that extend beyond the conference. These one-on-one connections are the backbone of the compliance profession.

General session topics and speakers include:

- The Outer Limits: Understanding when a compliance matter becomes a legal matter, and what to do when it does
  - **Christopher Bennington**
    Principal and Senior Consultant, INCompliance Consulting
  - **Mark Chilson**
    EVP General Counsel, CareSource
  - **Jeffrey McFadden**
    Partner, Steptoe & Johnson
  - **Kurt Lenhart**
    Vice President and Corporate Compliance Officer, CareSource

- Getting Audit Ready—ACA Compliance
  - **Kelly Lange**
    Director, Blue Cross Blue Shield of Michigan
  - **Sharon Gipson**
    Director & Assistant General Auditor, Blue Cross Blue Shield of Michigan

- Making Decisions Ethically in Managed Care Delivery
  - **Bruce Anderson**
    Chief Ethics Officer, Health Net, Inc
  - **Sandy Tuttobene**
    Director Health Care Services, Health Net, Inc

Get certified at the meeting

The Certified in Healthcare Compliance (CHC)® Exam will be offered on Wednesday, February 18. You must be pre-registered to sit for the exam.

See you in Las Vegas!

Find the latest conference information online ▶ www.hcca-info.org/events

HCCA *website news*

Contact Tracey Page at 952-405-7936 or email her at tracey.page@corporatecompliance.org with any questions about HCCA's website.

Top pages last month

Home Page | Job Board | Events | My Account | Add CEUs

Number of website visits last month

46,170

Digital Edition

Have you checked out our digital edition of *Compliance Today* yet? With our digital edition, you get all of the design and formatting of our regular magazine, and it's available anywhere you have your devices. It also has features such as built-in links, a table of contents that takes you to each story, and the ability to share or print pages in the magazine.

To check out our digital edition, go to the *Compliance Today* page, under *Resources* on our website, *www.hcca-info.org*. Then click on a story title or on the *Digital Magazine* button.

Video of the month

What role does a compliance office play in a False Claims Act case?

http://bit.ly/votm-2014-11

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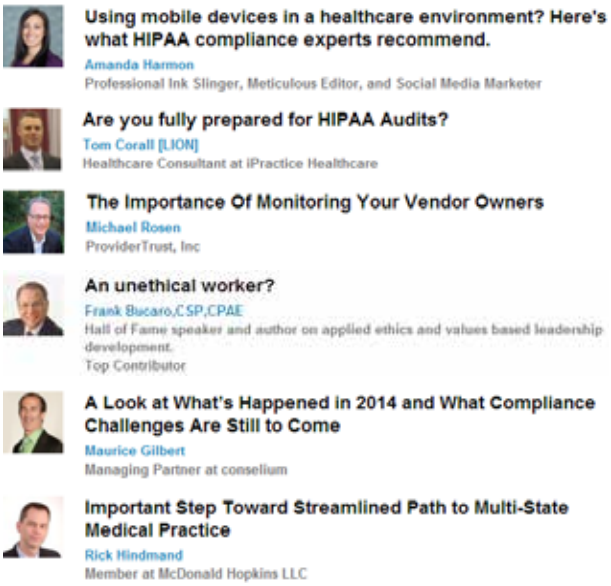
HCCA *social media news*

Contact Kortney Nordrum at 952-405-7928 or email her at kortney.nordrum@corporatecompliance.org with any questions about HCCA social media.

LinkedIn — *www.hcca-info.org/Linkedin*

Join us on LinkedIn—a business-oriented network with more than 240 million active users. With more than 18,000 members, our LinkedIn group fosters more than 75 new discussion posts every week. Some recent highlights:

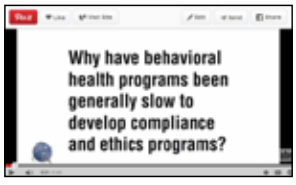


SlideShare — *www.slideshare.net/theHCCA*

We love sharing! Find informative and helpful presentations from every one of our conferences and presenters—free!

Pinterest — *www.pinterest.com/theHCCA*

We've recently joined Pinterest! Check out our boards for HIPAA, ICD-10, ACA, Compliance Videos, and using Technology & Social Media in healthcare. Our infographics of the month and much more can all be found on our boards.

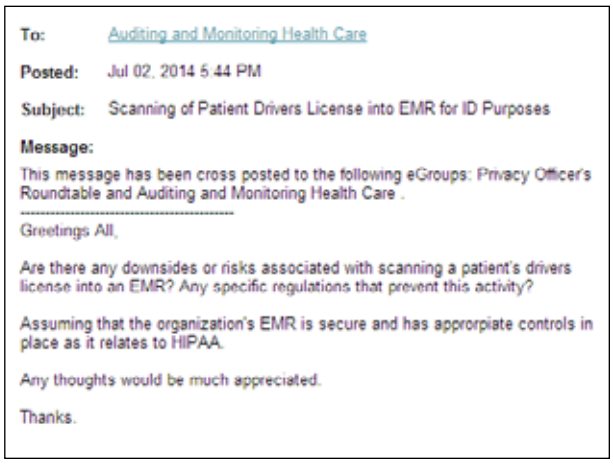


Twitter — *www.twitter.com/theHCCA*

Join 10,700 others and follow HCCA for breaking news and insights. Recent favorite tweets:

HCCA*net*® — *www.hcca-info.org/HCCAnet*

HCCA's own social network. Signing up is free and you'll be able to network, ask and answer questions, and collaborate with your healthcare compliance peers. One recent discussion:



To: Auditing and Monitoring Health Care

Posted: Jul 02, 2014 5:44 PM

Subject: Scanning of Patient Drivers License into EMR for ID Purposes

Message:

This message has been cross posted to the following eGroups: Privacy Officer's Roundtable and Auditing and Monitoring Health Care .

Greetings All,

Are there any downsides or risks associated with scanning a patient's drivers license into an EMR? Any specific regulations that prevent this activity?

Assuming that the organization's EMR is secure and has approrpiate controls in place as it relates to HIPAA.

Any thoughts would be much appreciated.

Thanks.

Find the latest HCCA*net*® updates online ▶ www.hcca-info.org/HCCAnet

PEOPLE *on the* MOVE

▶ AMAG Pharmaceuticals, Inc., based in Waltham, MA, has appointed **Robert Blood**, Esq. as Vice President of Legal Affairs and Chief Compliance Officer.

▶ **Nancy Merritt** has been named Chief Compliance Officer for Wellmont Health System in Kingsport, TN.

▶ Forest Park Medical Center in Dallas has appointed **Christy Naylor** to serve as its Chief Compliance Officer.

▶ **Tyler Granger** has been appointed Corporate Compliance Officer by Regency Post-Acute Healthcare System in Victoria, TX.

▶ **Colette Peterson**, JD, has appointed Assistant Compliance Officer at Miami Beach Community Health Center in Miami.

Received a promotion? New staff member in your department?

▶ If you've received a promotion or award, earned a degree or certification, accepted a new position, or added staff to your Compliance department, please let us know. It's a great way to keep the Compliance community up-to-date. Send your updates to: *margaret.dragon@corporatecompliance.org*

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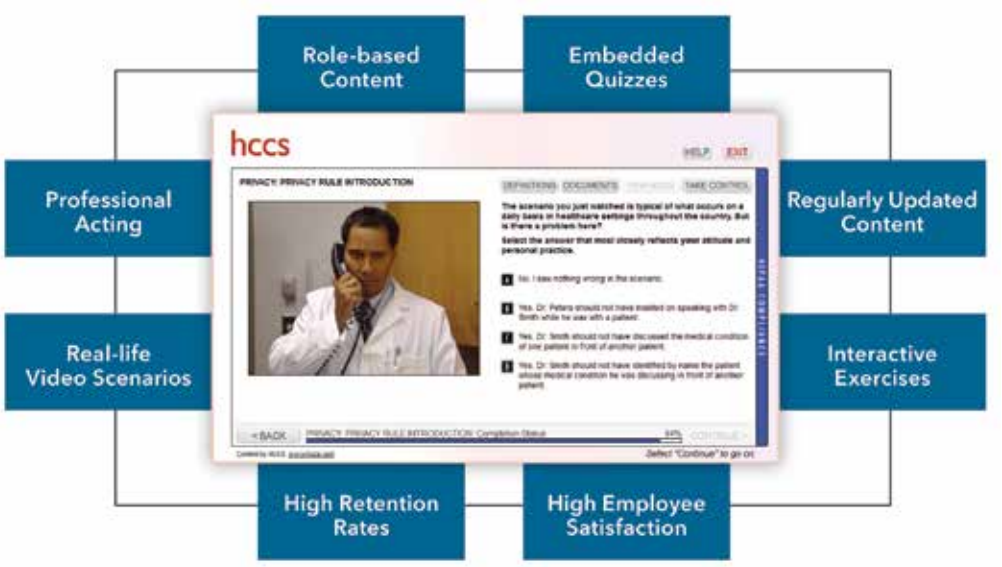
Corporate Compliance
HIPAA Compliance – Provider, Health Plan and Business Associate Versions
Deficit Reduction Act: False Claims and Employee Protections
Nursing Facility Compliance
Health Plan Compliance - ***New***
EMTALA - ***New***

Quality Improvement Suite

Patient Safety
Reducing Medication Errors
Documentation for Quality Care
Competency for Quality Care
Organizational Performance Improvement
Infection Control
Patient Rights
Patient Education
Bioterrorism and Disaster Preparation

The secret to success.



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Professional Relationships and Data Issues

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Preventing Conflicts of Interest
Responsible Use of Social Media in Healthcare - ***New***

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Cleveland Clinic Imaging Institute; and
Chairman, Corporate Compliance Committee

an interview by Jennifer O'Brien, JD, CHC, CHPC

Meet Don Sinko and Mark Sands

*This interview with **Donald A. Sinko** (SINKOD@ccf.org) and **Dr. Mark J. Sands** (sandsm@ccf.org) was conducted in August by SCCE/HCCA Board Member **Jennifer O'Brien** (Jennifer.obrien@uhc.com), Chief Compliance Officer with UnitedHealthcare in Minneapolis.*

JO: Please tell us a little bit about yourselves and the experience you bring to your roles as a physician and CPA, including your path to compliance leadership roles within the Cleveland Clinic.

MS: I am a practicing interventional radiologist who has assumed Quality Improvement and Patient Safety roles over the last decade. My initial motivations to venture into these areas were selfishly geared to preserving my ability practice in a world of accelerating regulatory requirements, where non-clinicians might have had difficulty understanding the resultant clinical dilemmas posed. I wanted to prevent a situation where a zeal to comply, without a nuanced understanding of the best process to employ, might have had a significant and unhelpful impact on patient care.

Having served as Section Head of the Interventional group since December 2000, I was, for instance, acutely aware that the suggestion of jettisoning point-of-care laboratory testing in a procedural area—for being too tedious to perform correctly—would have been a major impediment to work flow, patient

satisfaction, and quality of care. I became a part of the newly formed Cleveland Clinic Quality and Patient Safety Institute at its inception (2006) and soon after was asked to serve as the Imaging Institute (Radiology) Vice Chair for Clinical Operations and Quality. In this role, since 2007, I have worked collaboratively with the professional and ancillary staff of the Imaging Institute across nine Cleveland Clinic Health System hospitals to develop oversight and quality management structure as well as patient-level safety programs. It was from this setting that I came to Corporate Compliance.

The preceding Corporate Compliance Committee chair was seeking to add a radiologist to the committee with knowledge of imaging and testing billing matters—an area with which I had begun to become familiar as quality and reimbursement were just becoming linked by CMS dictate. After the first meeting, I was hooked. It was as if I had been handed the obscure (and as a physician, seemingly secret) rule book by which a complex healthcare delivery system was to be operated.

DS: I started my career at Ernst & Young Cleveland, where I was randomly put into the Healthcare Audit group. Because of E&Y's dominance in the healthcare market in Cleveland, I was able to work on many different hospital audits and gained significant experience. This was prior to the consolidation of individual hospitals into large health systems, so we were able to experience different styles and approaches to healthcare management and governance. I left E&Y as a Senior Manager to accept the Director of Internal Audit position at Eaton Corporation, a large international SEC-reporting company with businesses on six continents. It was there that I was able to gain significant board reporting and international experience. While I had no interest in ever working for a hospital, the Cleveland Clinic is a complex, international organization, like no other health system in the Midwest. I accepted the opportunity to become the Director of Internal Audit here 14 years ago. It was a few years later that the Audit Committee and senior management wanted to form the Integrity Office and put Internal Audit and Corporate Compliance under one umbrella in the C-suite. I think the many years of experience auditing healthcare operations and working with boards provided for a natural transition into Compliance. Compliance is more than understanding laws and regulations; it's about being able to implement them, which requires operating experience to be effective.

JO: Don, as the Chief Integrity Officer, please share with us your strategy in structuring your Integrity Office to leverage audit and compliance resources.

> In general, the missions and operations of Internal Audit and Corporate Compliance are very similar…

DS: In general, the missions and operations of Internal Audit and Corporate Compliance are very similar, and both reported directly to the Audit Committee of the Board of Directors. Our Internal Audit staff consists of specialists, whether they are CPAs or have backgrounds in revenue, IT, coding, or research. I structured Compliance the same way. We have staff with backgrounds in nursing, research, coding, billing, risk management, and law. Because compliance issues come in many forms and arise from many areas of the business, the diversity of our staff's experience allows us to have people working on compliance issues with

experience in those areas. They know the operations and speak the language. Having the two departments under one umbrella also allows for getting the right resources at the right place at the right time. We may have an audit that benefits from a compliance resource providing support, as well as an auditor helping with a particular compliance issue. Each staff learns from the other, and we don't have politics involved with the process. I do keep the two departments organizationally separate though, because many audit activities need to be independent, and compliance staff may be involved in operating activities and policy development.

JO: Dr. Sands, what motivated you to serve as the Chair of the Clinic Corporate Compliance Committee?

MS: After two years as one of three physicians on the Committee, I was asked to become chair. From my time on the Committee, I was most struck that although the "rules" may have always existed, how much we, as physicians, primarily relied on others to relate them to us. When combined with the Cleveland Clinic's pattern of leadership "dyad" (the coupling of a physician leader with an executive, non-physician content expert), the environment on the Committee to proactively advance beyond this level was compelling. Don's purview of internal controls as the Chief Integrity Officer steeped in years of experience in Internal Audit, teamed with my vantage of clinical practice across a wide array of care scenarios as a diagnostic radiologist and clinical proceduralist, provided a unique opportunity to merge adherence to rules with clinical operational process.

JO: Ensuring business operational accountability for compliance with the regulatory obligations that govern your business can be challenging. How are you able to achieve this within each of your roles at the Cleveland Clinic?

MS: In a word: education. Through my experiences in quality and patient safety, I have found that people are willing to change behaviors and even hard-learned habits, if they know why and if we are clear and consistent in our approach to these challenges. The Cleveland Clinic "eco-system" is large and complex. There are many moving parts. Regulations, particularly those not well understood, can be seen to threaten the overall operation. At Cleveland Clinic, I have never seen an operational issue go unresolved, once uncovered, digested, debated, and discussed with stakeholders. Often these are iterative processes, as success dictates that they cannot be built on the backs of the stakeholders.

DS: While Corporate Compliance has responsibility for the compliance programs and activities of the health system, the Corporate Compliance Committee's role is to support Corporate Compliance with its oversight role for the compliance programs of the individual operating institutes. The institutes have their own compliance committees and compliance programs, and perform their own monitoring activities. Corporate Compliance helps each operating institute with its individual compliance risk analysis used to develop its compliance program. The institutes annually report to the Corporate Compliance Committee the results of their compliance programs, along with the status of prior-year compliance issues and any new compliance issues. Since the Corporate Compliance Committee has physician leadership, along with representation from many other disciplines within the organization, evaluation of the institutes' compliance program results is more effective. The institutes do a great job of preparing and completing their compliance programs. They take them seriously. Not only do they want to do the right thing, I think the institutes are fairly competitive and none want to perform poorly in front of physician leadership.

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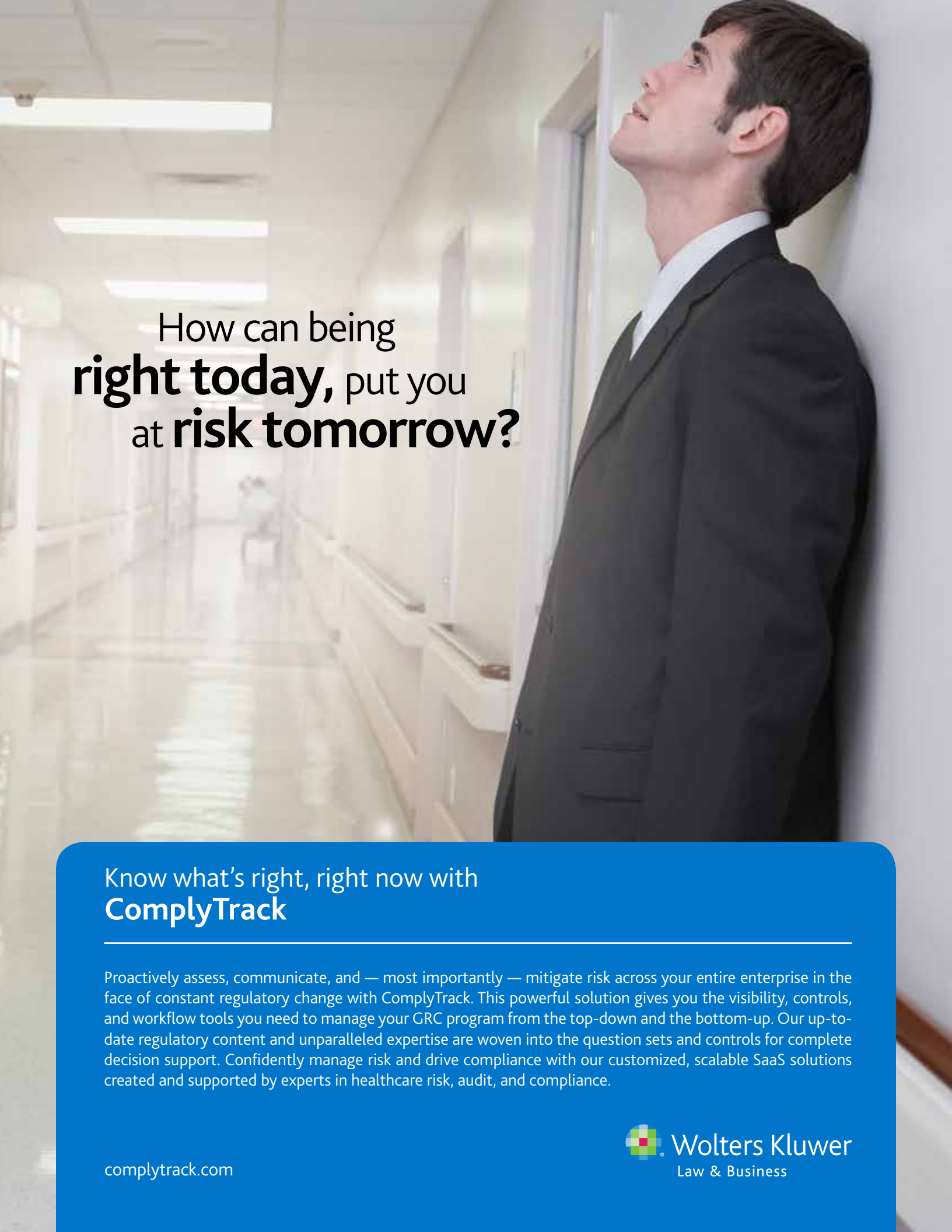

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JO: Getting physicians on board can at times be even more challenging with all the other competing priorities. Can you provide insight on how physician leadership has been leveraged to maximize compliance program effectiveness within your organization?

MS: There are clearly many priorities competing for care-giver attention in the current healthcare environment. Keeping them all in focus is a challenge for any practitioner. Cleveland Clinic affords several advantages: our physician-led employed staff model with clear lines of structure and accountability; our reputation and record of accomplishment; and innovative spirit.

Proactive adoption of the electronic medical record (EMR), a decade before Meaningful Use was mandated by law, is perhaps just one example that could only have occurred by marshaling them all. Leadership's vision, drawing collaboratively on both its physician and non-physician skills and expertise, has similarly helped frame and manage challenges before they amount to crises. To wit: attention to issues of staff communication led to the distribution of Clinic-owned smartphones (and apps) to physician and key non-physician staff, which have both facilitated patient-focused activities and provided protection of sensitive patient information. Extensive educational resources provided through on-line learning (COMET) and organizational forums are instrumental in getting the message(s) out to busy practitioners.

Additionally, the Clinic has done a terrific job in identifying physician champions for areas of concern, such as ICD-10 implementation, RAC audits, safety and quality improvement, clinical affairs such as E&M coding, IT implementation, and physician compliance. These supported champions are direct linkages of leadership back to their constituencies.

DS: Given that the medical institutes are physician-led and have their own compliance programs, the physicians themselves are accountable for their compliance activities and reporting the results of their compliance programs to senior physician management. Therefore, there is much greater buy-in and participation than if it was an "administrative" program. Once the physicians have buy-in, things get done. Our physician-leadership model really helps the effectiveness of our overall compliance program.

JO: Let's talk about compliance and quality. Dr. Sands brings a unique perspective to the table as a physician and with his role within Clinical Operations and Quality. How has this changed the dynamic and discussions within your compliance committee?

MS: Quality and compliance are really two sides of the same coin. We are asking healthcare providers to do the "right thing" in so many ways. Improving performance of patient safety indicators requires the same discipline as clearly elaborating the medical necessity for an admission or procedure. Sub-par documentation can undo clinical care just as easily as it can wreak havoc with billing and reimbursement. Both inevitably lead to poor outcomes.

> Quality and compliance are really two sides of the same coin.

Successful compliance programs, just as in the Quality arena, can only be formed through collaborative education efforts with "grass root" level attention to perceived issues.

DS: Our Quality Institute has an agenda that is similar to Corporate Compliance, with Quality having a narrower focus, and

Compliance encompassing quality. Having committee leadership with a physician's knowledge on quality is significant. As Mark noted, regulatory quality compliance issues have expanded beyond patient safety and his perspective, and those of the other physicians on the committee, are integral to our discussions. They can identify concerns others may not.

JO: As the regulatory environment continues to intensify, what can compliance officers and Compliance Committee chairs do to assist their organizations in demonstrating the effectiveness of their compliance program?

MS: Having a reasoned approach to compliance risk assessment is key. As challenges mount and far outstrip resources, compliance leadership must be able to articulate a cogent and ordered accounting of their outstanding issues. We have found that categorizing and managing "standard" clinical risks, which exist across most clinical departments, and developing structure to handle them similarly allows us to concentrate on those areas which exceed the "standard" compliance risk profile. In these instances (inordinate research burden, unusual pharmacy practices, etc.) extra effort is expended to clarify practices and elucidate process. Formal presentation of this assessment to the Board of Governors/Medical Executive Committee on an annual or semi-annual basis coupled with regular reporting to executive leadership has highlighted the activities and concerns of the Compliance Committee and it members.

As challenges mount and far outstrip resources, compliance leadership must be able to articulate a cogent and ordered accounting of their outstanding issues.

DS: Yes, I agree. Our biggest responsibilities are communications and education. The more preventative we are, the less reactionary we need to be. Working with the operations on their understanding of compliance risks and processes to mitigate them is critical. Different areas of the business have different compliance risks and we cannot cover or monitor all of them. Cascading compliance awareness down throughout the operations is key. We need to have tone and accountability at the middle, not just at the top. It's crucial to have employees at all levels who know what to do if something doesn't seem right. Effective compliance is more than just a checklist.

JO: What do you see on the horizon? What do you think are the most significant issues facing compliance teams today as they respond to increasing regulatory scrutiny?

MS: Upcoming challenges to healthcare compliance include the rearrangement of practice patterns from emphasizing episodic care to reflect the increasing impact of longitudinal quality and value metric-based reimbursement. Bundling of services, once previously made difficult by rules for fee-splitting and gain-sharing in the provision of services, is now front and center in the adoption of ACO and CMMI programs. These programs dictate unique compliance and reporting requirements, now as often as quarterly. Similarly, the granularity provided by the upcoming switch to ICD-10 will create many additional documentation requirements for healthcare providers.

The constitution of a diverse Corporate Compliance Committee, drawing from physicians, nursing, revenue cycle, internal audit, patient financial services, research, coding, and constituent Health System hospitals best equips us to face this changing environment.

DS: Information sharing, which is the future of healthcare, presents the conflict of keeping patient information private, yet making it available everywhere. Systems do not exist today that meet those conflicting requirements. Add cyber security to the mix and we have significant added cost and resource requirements during a period of reduced reimbursement. Knowing that current regulations are going to have to change, but not knowing when and how, adds stress to being able to do the right thing. I do think that the Cleveland Clinic physician-led business model has positioned us well for the future.

JO: On a more casual note, what do you like to do in your down time? What are your hobbies, interests, and activities outside the Cleveland Clinic?

MS: Non-work activities include: two teenagers, an attorney wife, and two dogs. Aside from these, having little time to generate new pursuits, I have re-embraced the activities of my youth: photography, tennis, sailing, and cycling. Cleveland is a great venue for all of the above.

DS: I have been very active as a member on non-profit boards, serving organizations involved in the arts, education, healthcare, and religion. While it is great to provide financial and compliance experience to these organizations, I have taken away more, learning about their operations and working with terrific people. When I can get away, it's usually on a golf course or boating on Lake Erie.

JO: Thank you, Dr. Sands and Don.

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Preparing people to lead extraordinary lives

by Shawn DeGroot, CHC-F, CCEP, CHRC, CHPC

Obstacles: Get on up

Shawn DeGroot *(shawn.degroot@navigant.com) is an Associate Director at Navigant Consulting in Denver. She is also the Immediate Past President of the HCCA Board of Directors.* bit.ly/in-ShawnDeGroot

Obstacles can be a nuisance that may temper your passion for the Compliance field. Maintaining persistence to deliver a tough message, when the last message may not have gone so well, is one example. If you need inspiration on addressing obstacles, see *Get on Up*, a movie about the life of James Brown. Yes, there were dark aspects to his behavior and life; however, he inspired many others and overcame countless obstacles with simple hard work and persistence. Although we cannot apply all of his tactics in healthcare, there is much to learn about his tenacity, even with repeated rejection.

DeGroot

Based on conversations with members, many have discussed obstacles within the C-suite, including budgetary constraints, lack of staff, and acquisitions. Although I cannot address all the obstacles professionals have shared, below are a few scenarios and responses that may be helpful.

1. **C-suite:** The CEO does not have time to meet in advance of a board meeting, you have a sensitive issue that may cause concern/questions from the board, and you do not want to blindside him/her.
   a. Provide a paper copy in a sealed confidential envelope, hand-deliver to his/her assistant with a succinct (brief) description of the issue, and ask him/her to talk to you in advance if there are any concerns; OR
   b. Do the above and copy legal counsel. Often legal and the CEO are both aware; OR
   c. Instead of the confidential envelope, highlight your time on the board agenda and the topic of concern with a question mark, and note, "We should talk."
2. **Budgetary constraints:** Reimbursement issues and government audits have created pressure wherein every organization is under time and cost constraints. First consider how you can consolidate and become more efficient with work practices. Identify opportunities to collaborate with another department, so you are not reviewing the same EMRs for similar reasons. Ask your staff—often they have the absolute *best* ideas with very creative solutions.
3. **Acquisitions:** This is the "reality" show in healthcare. Be as nimble as you can with a tool ready for due diligence. Create the expectation with your staff that this will be requested typically without considerable notice. Pre-identify the individual(s) and communicate so they understand the priority. Make a template for a final report in advance.

When James Brown was under physical or mental stress and strain, he turned to music. He tapped, danced, or sang his way out of indescribable situations. He continued to challenge himself with what people said couldn't be done. He beat the odds on many levels, which constantly changed the scene and improved his program. Brown overcame horrendous obstacles personally and professionally—so what can you do to jump/overcome your next obstacle?

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HEALTH CARE COMPLIANCE ASSOCIATION

by Cornelia M. Dorfschmid, PhD and Bernard McClellan, JD

OIG, EHR, and audit logs: Thinking ahead

» Turn EHR audit logs on to manage logs proactively and analyze logs routinely.
» Use audit logs as part of billing monitoring and anti-fraud detection.
» Require written policies and procedures on usage, storage, and configuration management of audit logs to ensure availability and integrity.
» Be prepared to respond to ADR requests for audit logs by contractors who are doing medical reviews.
» Use EHR audit logs to detect vulnerabilities before others do.

Cornelia M. Dorfschmid *(cdorfschmid@strategicm.com) is Executive Vice President and* ***Bernard McClellan*** *was a Summer Intern at Strategic Management Services in Alexandria, VA.*

Electronic health records systems (EHRs) replace traditional paper medical records with computerized record-keeping to document and store patient health information (e.g., patient demographics, progress notes, orders, medications, medical history, and clinical test results) from any healthcare encounter. Software vendors create EHR technology that includes a variety of applications and tools for collecting, managing, and sharing patient information electronically and for clinical decision-making.

One of the features of EHR systems includes functionalities that support audit control functions and requirements. Audit functions, such as audit logs that are files generated by usage of the system, track access and changes within a record chronologically by capturing data elements (e.g., date, time, and user stamps) for each update to an EHR. An audit log (a file generated automatically, if the audit function is enabled in the software) can be used to analyze historical patterns that can identify data inconsistencies.

EHR-certified systems that include these audit log capabilities are eligible for Meaningful Use criteria and incentive monies. Systems with these audit functions can also support investigative efforts related to fraud and abuse, but may also support claims auditing efforts. As the Office of the Inspector General (OIG) pointed out repeatedly, EHR systems are vulnerable to fraud and abuse due to inappropriate copy-and-pasting (i.e., cloning) and over-documentation (i.e., inserting false or irrelevant documentation to create the appearance of support for higher levels of billing).[1] In a recent OIG report of January 2014, OIG found that CMS contractors adopted few program integrity practices specific to EHRs to curb fraud and abuse that occurs when EHR vulnerabilities are exploited.[2]


Dorfschmid


McClellan

A particular OIG concern is how CMS contractors address fraud vulnerabilities directly related to Medicare health claims. OIG notes that audit logs can be used to analyze historical patterns that can identify data inconsistencies. To provide the most benefit in fraud protection, audit logs should always be operational, be stored as long as clinical records, and never be altered. OIG goes further in noting that few integrity contractors analyze audit logs as part of medical review

activities. This should give the healthcare industry pause. If CMS's audit contractors can be expected to request audit logs associated with electronic medical records in a medical review or audit, then healthcare organizations need not only prepare for responding to these record requests. They also need to make it their business to know what is going on in their own audit logs and the potential risk they harbor—before CMS contractors will. They harbor both documentation risk and audit risk. They also provide an opportunity to correct and detect risk internally and proactively. In other words, audit logs of EHR must be managed!

As OIG pointed out, "experts in health information technology caution that EHR technology can make it easier to commit fraud."

OIG on CMS contractors' integrity practices related to EHR

OIG's January 2014 study describes how CMS and its contractors implemented program integrity practices in light of widespread EHR adoption. The study produced two key findings: (1) CMS and its contractors adopted few program integrity practices specific to EHRs, and (2) CMS provided limited guidance to its contractors on fraud vulnerabilities in EHRs. To address these findings, OIG provided two recommendations to CMS.

First, OIG recommended that CMS provide guidance to its contractors on detecting fraud associated with EHRs. CMS has directed contractors to give special consideration to medical records within an EHR and to confirm authorship of medical records. However, contractors reported additional guidance is required for review of EHR-based claims. Specifically, CMS should provide more details on reviewing EHR documentation and electronic signatures in EHRs.

Second, OIG recommends that CMS direct its contractors to review providers' audit logs. As OIG pointed out, "experts in health information technology caution that EHR technology can make it easier to commit fraud." For instance, the copy-paste feature allows users to replicate information in one source and transfer the information to another source. Overuse or inappropriate use of copy-paste could produce inaccurate information and facilitate fraudulent claims. In addition, some EHRs provide templates that auto-populate fields by a single click, resulting in extensive documentation. As OIG notes, the use of audit logs may reveal such data inconsistencies and "provide the most benefit in fraud detection." Accordingly, "audit logs should always be operational and be stored as long as clinical records."

OIG found that few contractors have adjusted their practices for reviewing EHRs. Only three of 18 Medicare contractors reported the use of audit log data during their reviews or investigative processes. In addition, some contractors reported that they were unable to identify copied language or over-documentation in a medical record (see Table 1, page 31). OIG expressed concern over EHR documentation, because such practices are made easier in an electronic environment.

In response, CMS concurred with the recommendation to provide its contractors guidance on detecting fraud associated with EHRs. Specifically, CMS expressed an intention to "develop appropriate guidelines to ensure appropriate use of the copy-paste feature in EHRs." CMS partially concurred with

	Number of CMS contractors that reported conducting additional review procedures		Number of CMS contractors that reported being unable to identify copied language and over-documentation in EHRs	
Contractor	Conduct Additional Review	Use Audit Log Data	Copied Language	Over-documentation
MAC	2 out of 8	1 out of 8	4 out of 8	6 out of 8
ZPIC	0 out of 4	1 out of 4	3 out of 6	6 out of 6
RAC	2 out of 6	1 out of 6	2 out of 4	3 out of 4

Table 1: Contractors on use of audit logs, copy-pasting, and over-documentation

Source: OIG Report OEI-01-11-00570, p. 6,7

the recommendation to direct its contractors to use providers' audit logs. However, CMS did note that audit logs "should be part of a comprehensive approach to reviewing the authenticity of EHRs."

The industry should expect CMS contractors to adjust their program integrity practices specific to EHRs. Provider EHR documentation will be subjected to a higher standard of review. Accordingly, providers should start thinking ahead.

Making the most of your audit logs now

The OIG's report should be a warning shot. Providers should take proactive steps now to be ready for any audit log record requests by government entities. Providers should also advance their billing monitoring strategies by using the audit logs to detect vulnerabilities. These are steps we recommend to manage audit logs.

1. **Develop written procedures to ensure the generation, analysis, and storage for audit logs of EHRs and their availability and integrity.** Collaborate on this with IT, Reimbursement, Compliance, and the EHR vendor. Do you log what you want and need?
2. **Implement configuration management policies for the EHR that require:**
   - the use of an audit log function that specifies audit log operation and content for tracking EHR updates.
   - the method (i.e., copy-paste, direct entry, import) for any update to an EHR is documented and tracked.
   - the user ID of the original author is tracked when an EHR update is entered "on behalf" of another author (i.e., distinguish between entries made by an assistant and a provider).
   - EHR technology is able to record and indicate the method used to confirm patient identity (i.e., photo identification, prior relationship).
   - original EHR documents are retained after they are signed off and modifications are tracked as amendments.[3]
3. **Ensure that EHR audit logs remain as written (unaltered) and then are stored properly.** Backup and archive procedures are important to ensure availability and authenticity when they are needed. They should be kept at least 6 years to be consistent with HIPAA requirements for electronic PHI, if not longer. Many providers keep them longer, if not indefinitely.
4. **Use software analysis tools to regularly analyze audit logs.** Involve those who know analytics in your organization to help review them and extract potential patterns.
5. **Include results of audit logs analysis in periodic systems activity review meetings.**

The HIPAA security officer may want to inquire about these audit logs.

6. **Develop specific data analysis of patterns in audit logs to detect copy-paste and over-documentation risk.** Develop metrics or profiles that can be checked routinely to assess if a user or physician falls out of profile. For example, you may examine:
   - the ratio between average usage time per session and average record length of entries into a patient record (bit size increase or text length) to assess a physician profile. If very low, this may raise some questions.
   - the ratio of time online to size of a clinical record generated.
   - if copy-paste activity can be captured in the audit logs as an event, and study frequent users and claims where the function has been used.
   - the frequency of copy-pasting in a sample of high-level evaluation and management (E/M) or high-dollar claims and any activities/events captured in the audit logs of those records.
7. **Interview clinical users as to the ease of use or misuse of copy-paste and documentation features.** They may tell you about their likes/dislikes and along with those, risks inherent in the current configuration and usage.
8. **Turn on the audit logs and plan for backup, storage, and retrieval.**
9. **Consider audit logs sensitive information that is not handled or controlled by end-users, but is the responsibility of Information Security and Compliance.**
10. **Experiment.** It is data that can tell a story.

1. Office of the Inspector General: Not all recommended fraud safeguards have been implemented in hospital EHR technology (OEI-01-11-00570). December 2013. Available at http://1.usa.gov/1vrnkWx
2. OIG: CMS and its contractors have adopted few program integrity practices to address vulnerabilities in EHRS (OEI-01-11-00571). January 2014. Available at http://1.usa.gov/1fVwo24
3. See OEI-01-11-00570, Table 1 RTI recommendations, p. 4

by Melissa McCarthy, RHIT, CCS

Billing data: Tools to maximize data mining efforts

» Various resources are available to assist in data mining activities.

» Documentation review is key to support initial findings.

» Make sure you can see the whole picture before you react. If the data does not match up, pieces of the puzzle may be missing, and therefore, exhaust all avenues before you report on the findings.

» CMS data shows that a small percentage of providers account for large portion of Medicare costs.

» Verify that the available data matches your data.

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The volume of available data related to billed claims is staggering today. Learning how to navigate and use the data meaningfully can be challenging. The physician claims data newly released by the Centers for Medicare & Medicaid Services (CMS) opens the door for providers and consumers alike to calculate provider trends and financial gain from Medicare beneficiaries. Already existing resources, such as PEPPER data, allow organizations to compare the performance of their facilities for certain target areas to state and national trends. Keep in mind that the data collections mentioned in this article are just tools to help pinpoint potential problem areas.

McCarthy

CMS physician claims data

On April 9, 2014, the United States Department of Health and Human Services (HHS) and CMS, for the first time, released data related to payment for provider services and procedures provided to Medicare beneficiaries. The purpose behind this historic release is to provide more consumer transparency. The information was met with mixed reviews. Generally, it is believed that transparency is beneficial, but the use of the data should be within the proper context and with appropriate safeguards.

This information is a powerful tool for both Medicare beneficiaries and hospitals. For example, patients can determine how many times a provider has practiced a certain procedure and how much it may cost Medicare, even before patients make an appointment. Hospitals now have the ability to review this data about competing providers as well as reviewing physician billing trends before recruitment.

The CMS data is divided into three sections: Physician and Other Supplier, Inpatient, and Outpatient. In an attempt to maintain Medicare beneficiary privacy, the data from hospitals that have billed fewer than 11 patients per Medicare Severity Diagnosis Related Group (MS-DRG) and/or Ambulatory Payment Classification (APC), has been suppressed and is not searchable within the data.

The Physician and Other Supplier data contains 2012 information on utilization, payment, and submitted charges by individual National Provider Identification (NPI) number. The Inpatient data represents 2011 national hospital-specific charges for the top 100

most-frequently billed discharges to Medicare and is categorized by MS-DRG. The Outpatient data represents the 2011 estimated hospital-specific charges for 30 APCs paid by Medicare.

The New York Times published an article entitled "Sliver of Medicare Doctors Get Big Share of Payouts"[1] that included a link to a search function that concisely aggregated the data from CMS. The information is the same, just arranged differently and easier to navigate in comparison to the HHS Excel files. The *Wall Street Journal* also published an article on the same day, entitled "Small Slice of Doctors Account for Big Chunk of Medicare Costs."[2] Both of these articles explore the fact that a small percentage of providers account for large portion of Medicare costs.

The most common use of this Medicare billing data by healthcare consumers will likely be to view provider reimbursement and the number of times a provider has performed a procedure. The most likely beneficial use of the data for hospitals will be to benchmark provider utilization of services nationally as well as statewide (see Figure 1 below). This graph represents the comparison of established patient and new patient evaluation and management (E&M) levels across the United States and New York State for 2011.

Another way to approach this data would be to look at the same data, but add the element of the average Medicare reimbursed amount across the nation and in New York State (see Figure 2 below).

The addition of individual hospital or provider data on this graph would enable users to detect possible over/under utilization of codes as well as to detect areas to focus on for provider education efforts.

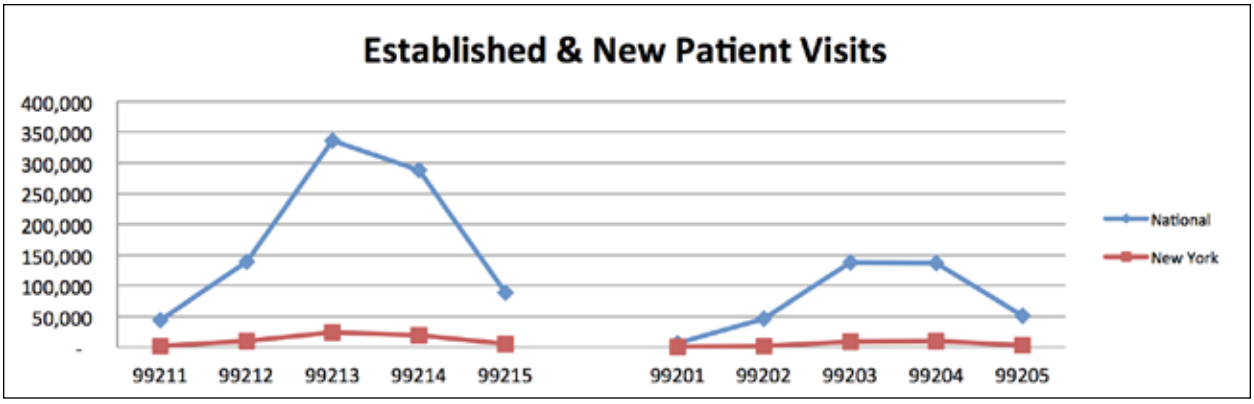

Figure 1: Comparison of national and New York state E&M data

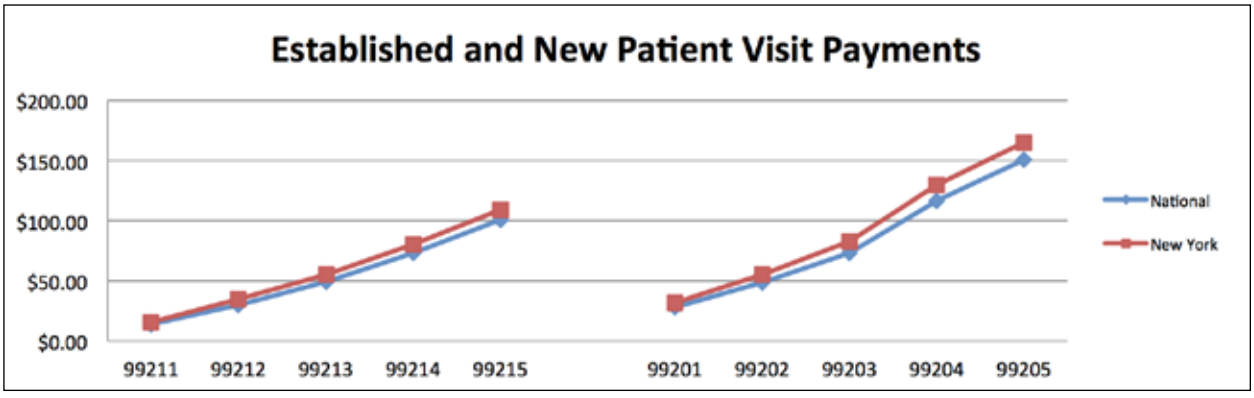

Figure 2: Average national and New York state Medicare reimbursement data

PEPPER data

Other data mining tools are available as well. The Program for Evaluating Payment Patterns Electronic Reports (PEPPER) is available from CMS, containing organization-specific data for target areas identified as high-risk payment areas. This data is available for inpatient hospital, inpatient psychiatric, inpatient rehabilitation facilities, skilled nursing facilities, hospice, and partial hospitalization services.

It is suggested that anything above the 80th percentile or below the 20th percentile, as compared to national, state, and jurisdiction (i.e., regional) benchmarks, should be reviewed. Even though a facility may be red (i.e., at or above 80th percentile for national, state, or jurisdiction) for a certain area, it does not mean the facility's coding is inappropriate. A facility could have a higher ranking because of demographic or other environmental reasons.

CMS dashboards

CMS also recently released a Chronic Conditions Warehouse and Geographic Variation dashboards. These resources give the public a deeper understanding of the chronic conditions among Medicare beneficiaries, disease prevalence, and the implications for our healthcare system. The Chronic Conditions Warehouse dashboard summarizes disease data to national, state, county, and hospital regions for 2008-2012, as well as looking at the differences within Medicare patient populations. The Geographic Variation dashboard is a tool that demonstrates the amount of money spent per capita, by type of service, by year. Users are able to compare and demonstrate trends by national, state, and/or county data.

Other data sources

External vendors can also be used to assist in data mining efforts. These vendors typically have algorithms based upon industry hot topics, such as those that are identified in the Office of Inspector General (OIG) Work Plans or by Recovery Audit Contractor (RAC) targets. Running an organization's billing data through these algorithms can be very helpful in identifying aberrancies in data; however, this is not necessarily indicative of definite issues. The aberrancy should be reviewed carefully, as well as the supporting documentation for the claim, in order to accurately identify whether a problem has been detected.

Organizations also have the ability to mine their own data, without the help of external vendors, through the review of their billing data. For example, an organization can review provider billing by providers' highest volume of charges. It is important to review the supporting documentation for these claims to verify that charges are accurate.

Data mining tips

CMS and your organization's billing provide the data, now what? Here are six suggestions on how to use the data effectively:

- Review the *Medicare Provider Utilization and Payment Data: Physician and Other Supplier* for your organization's providers. Verify that CMS data matches your data.
- Review the *Medicare Provider Utilization and Payment Data: Inpatient* to examine national and state data related to the diagnosis of Kwashiorkor. This topic appears in the 2014 OIG Work Plan. CMS data should be compared to your organization's data for this diagnosis. The review of this data may demonstrate that your organization is using incorrect International Classification Diagnosis – 9th Revision codes related to malnutrition documentation, which may lead to the reporting of a more severe diagnosis than the malnutrition that is common in the United States.
- Review the *Medicare Provider Utilization and Payment Data: Physician and Other Supplier* to trend facility place of service versus office place of service for your organization's providers. The exploration of this area may lead to the discovery that the incorrect place of service is billed for these encounters.

- Review PEPPER data reported for your organization across quarters to identify rising or falling trends related to PEPPER target areas. Target areas that are repeatedly reported higher than the 80th percentile or lower than the 20th percentile should undergo close scrutiny.
- Make sure you can see the whole picture before you react. If the data does not match up, pieces to the puzzle are oftentimes missing, and therefore, exhaust all avenues before you report on the findings. For example, CMS databases only include information on Medicare Fee For Service beneficiaries. A physician or provider's practice typically would include patients with other payment types or insurances. Conclusions about a provider's whole practice should not be drawn from CMS data alone.
- The CMS databases do not take into account incident-to or teaching physician rules. That is, some services may be rendered and documented by a physician extender or resident under the supervision of the billing provider and may not truly represent the volume of services that are rendered by the provider shown in the database. Always verify your findings through the review of medical record documentation.

Conclusion

Data mining is a compass that can guide you to the areas that require more investigation. Data mining can detect aberrancies in billing, but a deeper dive into the supporting documentation behind what was billed is always necessary and sometimes, the discrepancy is explainable.

The views in this article are the author's personal views and do not necessarily represent the views of her employer.

1. Reed Abelson and Sarah Cohen: "Sliver of Medicare Doctors Get Big Share of Payouts." *The New York Times*. April 9, 2014. Available at http://nyti.ms/1CBaOXL
2. Christopher Weaver, , Tom McGinty, and Louise Radnofsky: "Small Slice of Doctors Account for Big Chunk of Medicare Costs." *The Wall Street Journal*. April 9, 2014. Available at http://on.wsj.com/1vrnPjs

by Paul P. Jesep, JD, MPS, MA

Getting and keeping your board engaged

» As a best practice, strongly urge your volunteer board to do an annual, anonymous compliance survey and self-assessment (SSA) to measure knowledge and how well members think they and their colleagues perform fiduciary duties.

» SSAs should be crafted and strategic. It's acceptable to borrow from the many tools available, but the cookie cutter approach should not be used.

» Compile the results in an objective manner using graphs and charts. Use visuals if they enhance your ability to make a presentation and better position you to offer recommendations.

» Let the facts speak for themselves. If the survey and self-assessment questions are crafted strategically, what the board needs to act on should be self-evident.

» Enable board members to snail-mail the SSA in a stamped envelope addressed to you without anything that identifies the individual member.

Paul P. Jesep *(PJesep@gmail.com) is an ethics and compliance consultant and is employed part-time as the Compliance Officer for Hometown Health Centers in Schenectady, NY.*

An annual, anonymous compliance survey and board self-assessment (SSA) have several purposes. They educate, empower board directors with information, show a good faith effort at best practices, guide the compliance officer in determining focus areas, and obtain needed guidance from directors. They also may initiate a needed discussion that's not on anyone's radar screen due to meeting time constraints.

Jesep

Keep in mind that SSAs are distinct because both compliance knowledge and the board's overall effectiveness to run the organization is measured. They can be included as part one and part two of the same document, which may be more efficient, or handled separately at two meetings. Although they serve different purposes and should not be interchanged, they are complements. Each functions to survey and gather data.

Community leaders are pulled in multiple directions. Whether running a business or non-profit, members often serve on several boards. In doing so, time limitations sometimes make board attendance and active engagement challenging. SSAs help address this reality.

The SSA, done in the privacy of the home or office, lets board members focus on their individual and collective performance in providing quality oversight, leadership, and prudent stewardship of resources.

Good governance includes having the board self-critique its work, though devoting a half day to a facilitator in a group setting can be both time consuming and limit the discussion, because answers may not be as frank as when offered in an anonymous SSA.

Crafting SSAs

I use the word "craft," not "write" survey and self-assessment questions. It is smart to review question recommendations offered by the U.S. Department of Health and Human Services, the state Office of the Medicaid Inspect General,

and various trade associations. In doing so, however, remember the old saying, "Pick your battles." Theoretically, hundreds of questions could be asked.

If the SSA seems like homework, then you're less likely to get buy-in and a good return. SSAs should be informative and make the board member feel the questions are thoughtful, well-crafted, and respectful of their time.

Questions should be selected carefully and *strategically* tailored to your organization and its specific needs. Be careful when using boilerplate questions. They may not fit your organization's needs. In addition, your credibility for wanting the board's time could be compromised going forward.

Be careful when using boilerplate questions…. your credibility for wanting the board's time could be compromised going forward.

In addition, a volunteer board member may sincerely believe he/she understands corporate compliance and is well-informed. The difficulty in answering certain questions, however, may suggest otherwise, inferring the need for additional training by the compliance officer.

Self-assessment focuses on governance and asks questions regarding their individual engagement and overall board oversight. Are they asking enough questions? Are they getting the information needed to make informed decisions? What makes them an effective contributor as a director, and collectively, what makes the board govern with care and excellence?

Format

Several methods should be used to craft questions including, but not limited to, a numeric scale with: (1) Strongly Disagree, to (5) Strongly Agree. The board member also should have the option of Not Sure (NS). In certain cases, you may want to ask for a few sentences in a follow-up question as to why the board member ranked the previous question as he/she did.

Another option is a straightforward Yes, No, or Not Sure. ("Does the Fafner-Fasolt Health Clinic have the right tools to measure its quality performance?")

Again, have a select group of questions requiring short sentences. ("If you answered Yes in the previous question, list several tools you are aware of that help the Clinic pursue quality performance measurements.")

In addition, there should be some stand-alone questions that require short answers. ("In twelve words or less, describe the most important values of the organization." Or, "Are there resources—webinars, training, handouts, etc.—you would find helpful as a board member?")

SSA distribution

Ask for 15 minutes of board time at the next meeting to personally discuss and distribute the SSA. It underscores the importance you place on it and also that the CEO and board chair wanted it on the agenda. Emphasize, both in the document and verbally at its release in person, that the SSA is anonymous, which will empower users to offer honest and constructive feedback. Provide a stamped, self-addressed envelope without anything that identifies the sender.

Be clear about the goals. It merits repeating that the document is an information-gathering tool to assist them, meet a best practice of self-assessment, and give them an opportunity (hopefully an enjoyable one) to think about their contributions, the contributions of others,

and how, collectively, individual board members move the organization forward.

Set a deadline. If you ask for your SSAs to be mailed back in 30 days, for example, it's a good idea to email a reminder two weeks ahead of time, followed by another a week before the due date, and lastly, depending on the number of responses received, ask the CEO or board chair of your organization to send out a final reminder.

You may wish to attach a copy of the document in the reminder email, but underscore that they not identify themselves on the return envelope. Remember, you released the SSA in person and provided a stamped self-addressed envelope, which some may have mislaid.

Presenting the findings

Once you have received the SSAs back, carefully plan your upcoming board appearance regarding the summarized findings.

You do not want to occupy the entire meeting. Compile the findings in a single report and for PowerPoint purposes, use graphs and charts to highlight certain responses. In the slide presentation and in the comprehensive hardcopy distributed, make a provision under each response for "Recommendations."

Summary

Many clichés and metaphors have been used over the centuries to define time relating to the passing of each moment as it brings all of us to the inevitable. Time is more valuable than money, a great home, or even love. A fortune can be lost and made again. A home can burn, yet be re-built. A love may sour, but one can always fall in love again. It is impossible to create more time.

Hence, be sensitive to the busy lives and careers of volunteer directors. Maximize and leverage the opportunity to speak with them directly, and be appreciative of their time when provided. Your board has fiduciary duties, but also can be an invaluable resource. Be focused and organized. SSAs can help achieve these goals.

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by Wendy Wright, CHC, CHPC, CPC, CPMA, CEMC

Beyond the hospital walls: Compliance with provider-based clinics

» Compliance involvement in the planning stages of implementing a new provider-based clinic is imperative to future success.

» The Office of Inspector General has placed special emphasis on provider-based clinics due to the financial impact on the Medicare program.

» Provider-based clinic policies and procedures should mimic those of the main hospital provider and the clinic should stand out to the public as such.

» Provider-based clinics typically receive higher reimbursements than services provided in professional/physician-owned clinics.

» Compliance challenges with provider-based services can be mitigated through routine auditing and monitoring of these arrangements.

Wendy Wright *(wendy.wright@caromonthealth.org) is the Corporate Compliance Officer at CaroMont Health in Gastonia, NC.*

A lack of understanding of provider-based services rules and regulations has put many organizations at risk for non-compliance with Centers for Medicare & Medicaid (CMS) provider-based status requirements. An outpatient clinic where physicians provide services as though the clinic were a part of the hospital is considered a provider-based clinic. In order for a clinic to obtain provider-based status, CMS sets forth many requirements. A main requirement for provider-based status is that the provider-based clinic is owned by the hospital and operates under the same license as the hospital. Provider-based clinics can be located on the hospital campus or off campus. CMS defines "on campus" to mean within 250 yards of the main hospital building. Off-campus provider-based clinics are generally required to adhere to stricter guidelines than on-campus providers.[1] In provider-based clinics, patients receive two bills: one from the hospital facility and one for the physician's professional services, which typically results in higher reimbursements.

Wright

Regulation overview

CMS 42 C.F.R. §413.65 sets forth the appropriate steps in obtaining provider-based status.[2] Many carriers require facilities that are obtaining provider-based status to complete an attestation statement that indicates the facility has met the provider-based requirements outlined in the regulations. Documentation that the requirements have been met is required when submitting an attestation. A copy of the facility's state license, financial documents showing financial integration, policies of credentialing procedures, pictures of the exterior signage for the facility, and a detailed map of the facility's location are just a few of the requested documentation requirements when submitting the provider-based attestation.

Facilities that aren't affected by reimbursement, such as ambulatory surgical centers (ASCs), comprehensive outpatient rehabilitation facilities (CORFs), home health agencies, hospices, skilled nursing facilities (SNFs), inpatient

rehabilitation units, independent diagnostic testing facilities (IDTFs), ambulance providers, or facilities not seeking separate payment for services (e.g., laundry or medical records) are not characterized as provider-based.

One of the core requirements of obtaining provider-based status is that the facility is not only owned by the hospital, but must be under the same financial and administrative control of the hospital. This means that the facility seeking provider-based status must be 100% owned by the main provider, has the same governing body, has the same level of accountability as other departments of the main provider, and has common by-laws. Typically, provider-based facilities operate under the same license as the hospital, although some states require that the facility obtain a separate license for the facility seeking provider-based status.

> When billing patients and carriers, it is important to bill the correct site of service.

Another requirement when seeking provider-based status is that the clinical services are fully integrated. The steps taken to privilege medical staff should mimic those already in place at the main provider. Common privileges should be maintained for clinical staff at the provider-based facility and the main provider. Medical records are required to be integrated in a unified retrieval system of the hospital. Also, monitoring and oversight, such as in quality assurance, should be the same for the provider-based facility as in any other department of the hospital.

Financial integration of the provider-based facility is another area of consideration when obtaining provider-based status. The provider-based facility's income and expenses are incorporated in the main provider and reflected in the trial balance.

CMS regulations require that the location of the provider-based clinic be held out to the public and other payers as part of the main hospital provider. When patients enter the provider-based facility, they should be able to determine by signage and other means that the facility is a part of the main facility or hospital and that they will be billed accordingly.

Finally, facilities seeking provider-based status are required to comply with the Emergency Medical Treatment and Labor Act (EMTALA) and billing rules applicable to hospital outpatient departments. Regardless of whether the provider-based facility is on or off campus, compliance with the anti-dumping rules is required. When billing patients and carriers, it is important to bill the correct site of service. Provider-based facilities services are considered hospital outpatient services for billing purposes.

Increasing OIG scrutiny

Provider-based services have been heavily scrutinized by the Office of Inspector General (OIG). In 2000, the Office of Evaluation and Inspections (OEI) published a report indicating that many Medicare regions are not consistent with the regulations that affect provider-based status determinations; some hospitals were even claiming provider-based status without going through the appropriate steps to obtain the designation. As a result of the review, OIG recommended the elimination of provider-based status for hospital-owned entities.[3] OIG has continued their increased interest on the topic of provider-based clinics, because of the increase in the number of physician office visits being billed in provider-based clinics. In fact in 2013, OIG added a new review to its annual Work Plan. The review states that OIG will determine if practices that use the provider-based status meet CMS provider-based requirements.[4] In the 2014 annual Work Plan, OIG plans to compare payments made to provider-based clinics and

free-standing clinics for similar procedures provided in each of these facilities.[5]

Auditing and monitoring

Now is a great time for compliance officers to become familiar with the regulations involving provider-based status determinations. Because reimbursement is at risk, Compliance should be at the table for initial discussions that involve implementing a provider-based clinic. Important steps to implement controls include implementing policies and procedures that outline the CMS regulations for provider-based status clinics. To insure compliance effectiveness with the provider-based status regulations, training and education should be provided to physicians and staff regarding the requirements of provider-based status. Adding provider-based status auditing and monitoring to your annual compliance work plan will help to mitigate risks identified with provider-based clinics. When developing an auditing and monitoring plan, the best place to start is to inventory clinics that may be classified as provider-based. This inventory review is important to conduct annually, especially if the culture of reporting material changes in the organization has not been established. Following the clinic inventory review, use the attestation checklist found in 42 C.F.R §413.65 (d) to insure all the appropriate provider-based rules and regulations are being followed and properly reported. This may require an onsite visit to insure the clinic signage is appropriate.

Conclusion

CMS provider-based rules are very complex, but with the appropriate policies and procedures in place, hospital facilities can be successful in operating these facilities. It is important for Compliance to be involved in both the initial stages of planning a new provider-based facility and on an ongoing basis to monitor compliance with the CMS regulations related to provider-based status. Provider-based services impose residual risk to organizations, because of the recently increased level of scrutiny by the OIG. To mitigate the risk with provider-based services, it is important to routinely audit and monitor provider-based services.

1. U.S. Department of Health & Human Services (DHHS), Centers for Medicare & Medicaid Services: Program Memorandum Intermediaries: Provider-based Status On or After October 1, 2002, April 18, 2003. Available at http://go.cms.gov/1uWqC2s
2. 42 C.F.R. §413.65 Requirements for a determination that a facility or an organization has provider-based status.
3. DHHS, Office of the Inspector General, Office of Evaluation and Inspections: "HCFA Management of Provider-Based Reimbursement to Hospitals." Report OEI-04-97-00090, August 2000.
4. DHHS, Office of the Inspector General: Work Plan Fiscal Year 2013. Available at http://1.usa.gov/1fvteO6
5. DHHS, Office of the Inspector General: Work Plan Fiscal Year 2014. Available at http://1.usa.gov/1fuyPVZ

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by David Hoffman, Esq.

When regulators and providers disagree, validate the facts

David Hoffman *(dhoffman@DHoffmanAssoc.com) is President of David Hoffman & Associates, PC, a national healthcare consulting firm in Philadelphia.*

I have been monitoring multiple nursing homes throughout the country and have been stunned by how government regulators and healthcare providers see the world so differently. How can that be? There is no shortage of laws, regulations, and interpretive guidance governing the oversight of nursing homes, but there is at times little consistency in interpretation and application of these regulatory requirements. How is it possible that regulators in California and Florida see the world so differently and cite deficiencies accordingly, and what is a compliance officer to do?

Hoffman

The first task is to have a good relationship with government regulators before a dispute arises. I know what you are thinking… easier said than done. I can say for certain, however, that if the government believes that a healthcare provider entrusted to take care of patients/residents fails to do so, the trust factor has been compromised and can be difficult to rebuild. So, a good relationship with regulators and advocacy organizations related to the care of your patients/residents is always a good idea.

But what if there is a legitimate dispute between the provider and the government about whether care has, in fact, been compromised? Typically, this becomes a legal dispute and the attorneys take over. But I believe that this situation requires involvement by the compliance officer.

Initially, the compliance officer should be familiar with the specific allegations that led to the dispute with the government and be cognizant of the regulatory requirements involved in sustaining and/or overturning the deficiency at issue. For example, the Independent Informal Dispute Resolution (IIDR) process allows a nursing home to challenge a cited deficiency and imposition of a civil monetary penalty based on factual inaccuracies. The compliance officer must be involved in the investigation into the factual accuracy of the cited deficiency.

Next, the compliance officer must be able to show how the entity's compliance program focuses on care delivery issues and has overseen remedial efforts when there have been care breakdowns. These care delivery breakdowns should not have been identified solely through the regulatory system; rather a combination of monthly care audits, an effective quality assurance program, and a meaningful incident reporting system would provide evidence of a systemic approach to quality improvement activities. The argument may be that this internal system for care delivery oversight was not triggered, because the events underlying the deficiency were not correct.

I have recently seen what I believe to be unreasonable interpretations of regulatory requirements by both regulators and providers, and I wish there was more standardization in the application of the rules to the verified facts. A compliance officer must be able to sort through the arguments, apply the facts to the regulatory requirements, and competently evaluate the situation from a compliance perspective.

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by Jeannie O'Donnell, CIA, CISA, CHC

Unallowable costs related to a corporate integrity agreement

» In government, unallowable costs must be identified in the entity's accounting records and excluded from any submitted budget, cost reports, and requests for federal or state reimbursement.

» OIG negotiates corporate integrity agreements (CIA) as part of the settlement of federal healthcare program investigations arising under a variety of civil false claims statutes.

» Providers or entities agree to the CIA obligations, and in exchange, the OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other federal healthcare programs.

» The scope of work of the Independent Review Organization often includes a review of cost reports to determine whether unallowable costs were included for reimbursement by federally financed healthcare programs.

» Considering that an investigation and ultimate settlement may drag out over a long period time, providers and entities will save cost and time if investigation costs are tracked as unallowable costs at the front end.

Jeannie O'Donnell *(Jeannie.odonnell@altegrahealth.com) is a Senior Consultant with Reimbursement and Advisory Services at Altegra Health in Los Angeles.*

Government accounting refers to the field of accounting that specifically finds application in the public sector of government. A special field of accounting exists to assist in understanding the objectives of governmental accounting and how these objectives differ from generally accepted accounting practice.

O'Donnell

Governmental accounting is an umbrella term which refers to the various accounting systems used by various public sector entities. In the United States, for instance, there are two levels of accounting standards set forth by independent, private sector boards. At the federal level, the Federal Accounting Standards Advisory Board (FASAB) sets forth the accounting standards to follow. Similarly, there is the Governmental Accounting Standards Board (GASB) for state and local level government.

Unallowable cost in government accounting

In contracting with the government, the governing regulation for unallowable costs, general accounting practices, and other financial rules is FAR 31.2, Cost Principles for Commercial Organizations. This regulation is invoked anytime cost analysis by the government is required. The majority of government contractors are subject to these regulations. Failure to comply with FAR 31.2 results in significant burden and financial exposure. Compliance is a "given" and must be addressed in cost accounting systems, policies/procedures, and cost accounting practices.

Expressly unallowable costs

In contracting with the government, unallowable costs can be classified into two distinct categories. One is expressly unallowable costs. These costs are unallowable under any and all circumstances, no exceptions. This list includes:

1. **Interest expense** (FAR 31.205-20) – including bond discounts, and costs of financing and refinancing capital including

associated costs, such as related legal and professional fees incurred in connection with prospectuses. The costs of preparing stock rights are generally unallowable with special rules; however, interest assessed by certain state and local taxing authorities is allowable under certain conditions.

2. **Donations/Contributions** (FAR 31.205-8)
3. **Entertainment** (FAR 31.205-14) – entertainment and recreation including associated costs, costs associated with social activities including social, dining, country clubs, and similar organizations.
4. **Contingencies** (FAR 31.205-7)
5. **Bad debts** (FAR 31.205-3)
6. **Fines and penalties** (FAR 31.205-15) – fines and penalties for violating federal, state, or local laws, including associated costs; specifically, the costs associated with the mischarging of costs to government contracts.
7. **Goodwill** (FAR 31.205-49) – the write-up of assets, resultant depreciation, and goodwill from business combinations.
8. **Losses on contracts** (FAR 31.205-33) – the excess of cost over income on any contract, including the contractor's share of any cost contribution on cost sharing agreements.
9. **Organization costs** (FAR31.205-27) – organization costs and re-organization costs however represented, including professional and legal fees. However, the costs of executive bonuses, employee savings plans, and employee stock ownership plans are not considered organization or re-organization costs and are not made unallowable by this principle.
10. **Alcohol**
11. **Promotion** – if the primary purpose is to promote a company's image, products, or service.
12. **Personal use** – of anything as compared to business purpose.
13. **Profit distribution** – any cost presumed to be a distribution of profits.
14. **First class airfare** – in most cases, but there are a few exceptions in rare circumstances. (Please contact me about these exceptions as needed.)
15. **Legal costs** – claims against the government and defense of certain fraud proceedings. In order for certain legal costs to be allowable, the costs must be documented by scope of work, rate description, and work product.
16. **Travel costs** – hotel, meals, and incidentals if they exceed on a daily basis the Federal Travel Per Diem Rates published by the General Services Administration, but there are many rules and exceptions in applying this rule.

Circumstantial unallowable costs

The other category is circumstantial unallowable costs. These costs are either allowable or unallowable depending on the special and unique circumstances that embody numerous exceptions and special rules.

The purpose of accounting for unallowable costs is to establish guidelines for the early identification of unallowable costs and the treatment to be accorded such costs. It is based on the premise that costs should be allocated to their appropriate cost objectives according to beneficial or casual relationships and without regard to their allowability. The standard is concerned with the broad accounting principles that govern cost allocation, not with making otherwise allowable costs unallowable.

Generally, identification is required under varying circumstances for the following classes of unallowable costs:

- those which are expressly unallowable or mutually agreed to be unallowable;
- those which become designated as unallowable by reason of the government's determination; and

- those costs for which reimbursement has been previously withheld by the government.

Expressly unallowable costs consist primarily of those specified as unallowable in the principles of reimbursement. These costs, as well as costs mutually agreed to be unallowable or mutually agreed to be directly associated with unallowables, must be identified in the entity's accounting records and excluded from any submitted budget and cost reports. Costs designated as unallowable by the government's determination, as well as costs incurred for the same purpose under like circumstances as those mutually agreed to be unallowable, must be identified if included in a budget or cost report.

Expressly unallowable costs consist primarily of those specified as unallowable in the principles of reimbursement.

The Medicare Cost Report

The Medicare Cost Report (MCR) is an annual report required of certain healthcare entities and providers that participate in the Medicare program. The MCR records each entity's or provider's total costs and charges associated with providing services to all patients, the portion of those costs and charges allocated to Medicare patients, and Medicare payments received.

Medicare-certified entities and providers are required to submit this report to a Medicare Administrative Contractor (MAC). This cost report also contains provider information such as facility, characteristics, utilization data, cost and charges by cost center (in total and for Medicare), Medicare settlement data, and financial statement data.

CMS maintains the cost report data in the Healthcare Provider Cost Reporting Information System (HCRIS), which includes subsystems for the Hospital Cost Report (CMS-2552-96 and CMS-2552-10), Skilled Nursing Facility Cost Report (CMS-2540-96 and CMS-2540-10), Home Health Agency Cost Report (CMS-1728-94), Renal Facility Cost Report (CMS-265-94 and CMS-265-11), Health Clinic Cost Report (CMS-222-92), Hospice Cost Report (CMS-1984-99), and Community Mental Health Center Cost Report (CMS-2088-92).

All payments to providers of services must be based on the reasonable cost of services covered under Title XVIII of the Social Security Act and related to the care of beneficiaries or, in the case of acute care hospitals, the Prospective Payment System (PPS). Reasonable cost includes all necessary and proper costs incurred in rendering the services, subject to principles relating to specific items of revenue and cost.

Reasonable costs of any services are determined in accordance with regulations establishing the method or methods to be used and the items to be included. Reasonable cost takes into account both direct and indirect costs of providers of services, including normal standby costs. The objective is that under the methods of determining costs, the costs for individuals covered by Medicare, Medicaid, or other federal programs are not borne by others, and the costs for individuals not covered by federal programs are not borne by the government.

Costs related to patient care

Necessary and proper costs related to patient care costs include all costs that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. These costs are usually common and accepted occurrences in the field of the

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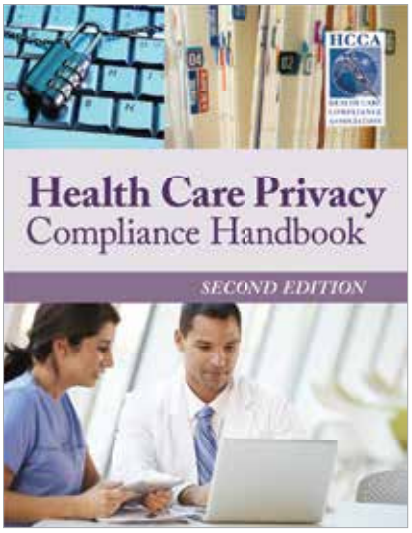

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provider's activity. They include personnel costs, administrative costs, costs of employee pension plans, normal standby costs, and others. Allowability of costs is subject to the regulations that cover the treatment of specific items under the Medicare program.

Costs not related to patient care

Costs not related to patient care, not appropriate or necessary, and not proper in developing and maintaining the operation of patient care facilities and activities include costs which usually are not common or accepted occurrences in the field of the provider's activity.

Costs not allowable in computing reimbursable costs include:

- Cost of meals sold to visitors;
- Cost of drugs sold other than to patient;
- Cost of operation of a gift shop;
- Cost of alcoholic beverages furnished to employees or to others, regardless of how or where furnished, such as the cost of alcoholic beverages furnished at a provider picnic or furnished as a fringe benefit;
- Cost of gifts or donations;
- Cost of entertainment, including tickets to sporting and other entertainment events;
- Cost of personal use of motor vehicles;
- Cost of fines or penalties resulting from violations of federal, state, or local laws;
- Cost of educational expenses for spouses or other dependents of providers of services, their employees, or contractors, if they are not active employees of the provider or contractor;
- Cost of meals served to executives that exceed the cost of meals served to ordinary employees due to the use of separate executive dining facilities (capital and capital-related costs), duplicative or additional food service staff (chef, waiters/waitresses, etc.), upgraded or gourmet menus, etc.; and
- Cost of travel incurred in connection with non-patient-care related purposes.

Home offices of chain organizations

For Medicare and/or Medicaid purposes, a chain organization consists of a group of two or more healthcare facilities or at least one healthcare facility and any other business or entity owned, leased, or, through any other device, controlled by one organization. Chain organizations include, but are not limited to, chains operated by proprietary organizations and chains operated by various religious, charitable, and governmental organizations. A chain organization may also include business organizations engaged in other activities not directly related to healthcare.

Home offices of chain organizations vary greatly in size, number of locations, staff, mode of operations, and services furnished to the facilities in the chain. The home office of a chain is not in itself certified by Medicare. Therefore, its costs may not be directly reimbursed by Medicare. The relationship of the home office to Medicare is that of a related organization to participating providers. Home offices usually furnish central management and administrative services (e.g., centralized accounting, purchasing, personnel services, management direction and control, and other services). To the extent that the home office furnishes services related to patient care to a provider, the reasonable costs of such services are included in the provider's cost report and are reimbursable as part of the provider's costs. If the home office of the chain provides no services related to patient care, neither the costs nor the equity capital of the home office may be recognized in determining the allowable costs of the providers in the chain.

Home office costs directly related to those services performed for individual providers and which relate to patient care plus an appropriate share of indirect costs (e.g., overhead, rent for home office space, administrative salaries) are allowable to the extent they are reasonable. Home office costs that are not

otherwise allowable when incurred directly by the provider are not allowable as home office costs to be allocated to providers. For example, certain advertising costs, some franchise taxes and other similar taxes, costs of non-competition agreements, certain life insurance premiums, certain membership costs, and those costs related to non-medical enterprises are not considered allowable home office costs.

Starting with its total costs (including those costs paid on behalf of providers or other components in the chain), the home office must delete all costs which are not allowable in accordance with program instructions. The remaining costs (total allowable costs) must then be identified as capital-related costs (old and new) and non-capital-related costs and allocated as stated below to all of the components (both providers and non-providers) in the chain which received services from the home office. When the home office incurs costs for activities not related to patient care in the chain's participating providers, the allocation bases used must provide for the appropriate allocation of costs such as rent, administrative salaries, organization costs, and other general overhead costs which are attributable to non-patient care activities as well as to patient care activities. All activities and functions in the home office must bear their allocable share of home office overhead and general administrative costs.

Schedule C of the MCR is used to adjust home office expenses. Types of adjustments entered on this worksheet include:

- Items needed to adjust expenses to reflect actual expenses incurred;
- Items which constitute recovery of expenses through sales, charges, fees, etc.; and
- Items needed to adjust expenses in accordance with the Medicare principles of reimbursement.

Corporate integrity agreements

The Office of the Inspector General (OIG) of the United States Department of Health and Human Services (HHS) negotiates corporate integrity agreements (CIAs) with healthcare providers and other entities as part of the settlement of federal healthcare program investigations that arise under a variety of civil false claims statutes. Providers or entities agree to the obligations, and in exchange, the OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other federal healthcare programs.

The [OIG]… negotiates [CIAs] with healthcare providers and other entities as part of the settlement of federal healthcare program investigations…

CIAs have many common elements, but each one addresses the specific facts at issue and often attempts to accommodate and recognize many of the elements of preexisting voluntary compliance programs. A comprehensive CIA typically lasts 5 years and includes requirements to:

- Hire a compliance officer/appoint a compliance committee;
- Develop written standards and policies;
- Implement a comprehensive employee training program;
- Retain an independent review organization to conduct annual reviews;
- Establish a confidential disclosure program;
- Restrict employment of ineligible persons;
- Report overpayments, reportable events, and ongoing investigations/legal proceedings; and

- Provide an implementation report and annual reports to OIG on the status of the entity's compliance activities.

Entities agree to enter into a CIA with the OIG to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other federal healthcare programs (as defined in 42 U.S.C. § 1320a-7b (f)). Along with the CIA, the entity also enters a Settlement Agreement with the United States.

Independent Review Organization

The Independent Review Organization (IRO) conducts verification reviews of specified areas, dependent on the nature of the terms of the agreement.

For the most part, the IRO is charged with validating that the terms of the CIA are met. The scope of work of the IRO in most cases includes a review of MCRs to determine whether unallowable costs were included as part of reimbursement by federally financed healthcare programs. What that basically means to the provider is that it will not be permissible to include costs incurred as a result of the governmental investigation in a cost report or any other report that results in payment by the government.

A typical CIA says the following about unallowable costs. (Note: the name of the particular organization in this case was redacted.)

> The IRO shall conduct a review of _____ compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether _____ has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by _____ or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

A standard settlement agreement defines "unallowable costs" as those costs incurred in connection with:

- Matters covered by the settlement agreement;
- Federal government audit and civil investigations of matters covered by the CIA;
- Provider's investigation, defense, and corrective actions undertaken in response to the audit and civil investigation covered by the CIA, including attorney's fees;
- Negotiation and performance of the settlement agreement;
- Payment by the provider pursuant to the agreement;
- Any payments made to the relator, including costs and attorneys' fees; and
- Costs of retaining an IRO and for preparation of reports for the OIG HHS.

Unallowable cost review

For the first reporting period, typically the OIG will require the IRO to conduct a review of the entity's compliance with the unallowable cost provisions of the settlement agreement. The IRO shall determine whether the entity has complied with its obligations not to charge to, or otherwise seek payment from, federal or

state payors for unallowable costs (as defined in the settlement agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by the entity or any affiliates.

To the extent such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the settlement agreement was executed, as well as from previous years.

The IRO will typically request the following documents from the entity in preparation of the unallowable cost review:

- Organizational charts to identify managers and employees in Accounting, Accounts Payable, and Payroll;
- Relevant policies and procedures from Accounting, Accounts Payable, and Payroll;
- List of vendors and consultants;
- List of vendors and consultants utilized in the investigation and settlement process;
- List of employees who were involved in the investigation and settlement process;
- Methods used to calculate unallowable cost incurred by employees and the results;
- Transaction file for all vendors, consultants, and employees that meet the unallowable cost definition as defined in the CIA; and
- The detailed general ledger for the period under review.

It is important to determine the starting point for incurring costs that would be defined as unallowable under a CIA. According to the OIG, this is when the organization first became aware of the issue that resulted in an investigation. Please note that the starting point would not be when the matter was disclosed to the government or the government made notification of an investigation. For example, if the entity received a hotline call that first identified the matter, the date of that call is the starting point. Any costs incurred on or after that date should be identified and segregated. Some entities will have immediately taken steps to exclude the unallowable costs from the cost report and assigned the costs to a cost center that does not distribute to a government cost report. As soon as it became apparent that the matter may ultimately lead to a settlement, it is advisable for the entity to maintain a file with documentation that evidences that the unallowable costs were in fact not included in the cost reports.

It is important to determine the starting point for incurring costs that would be defined as unallowable under a CIA.

The IRO obtains and reviews the requested documentation. A random sample is taken from the list of transactions that occurred during the review period and were related to the vendors and the consultants specifically involved in the investigation and settlement process. Negative testing should occur by sampling and reviewing vendors and consultants not reported as being utilized in the investigation and settlement. The transactions related to legal and consultant work should be given special attention.

The IRO will also analyze the amounts of time, salaries, and benefits calculated by the entity as having been excluded from the cost

reports because they pertained to the investigation and settlement of the case. The costs related to the Compliance and Legal departments should be given special attention.

After analyzing and calculating the unallowable costs that should have been excluded from the cost reports, the totals are traced to the general ledger and the costs reports for verification.

Considering that an investigation and ultimate settlement may drag out over a long period time, entities that maintained a separate set of documents to evidence that related costs were in fact segregated from the cost reports will save a lot of trouble and costs later. If done properly and thoroughly, it will be a lot easier and far less costly for the IRO to conduct its review when the CIA goes into effect. Those organizations that fail to keep separate, complete records may find they have complicated their affairs greatly. In some cases individuals knowledgeable about the investigation costs leave or documentation goes astray. Organizations may even change financial systems. Without adequate foresight and preparation, the internal staff charged with finding or recreating the necessary evidence may have a very difficult time completing their tasks. It will save a lot in terms of internal and external costs if adequate files are maintained from the beginning.

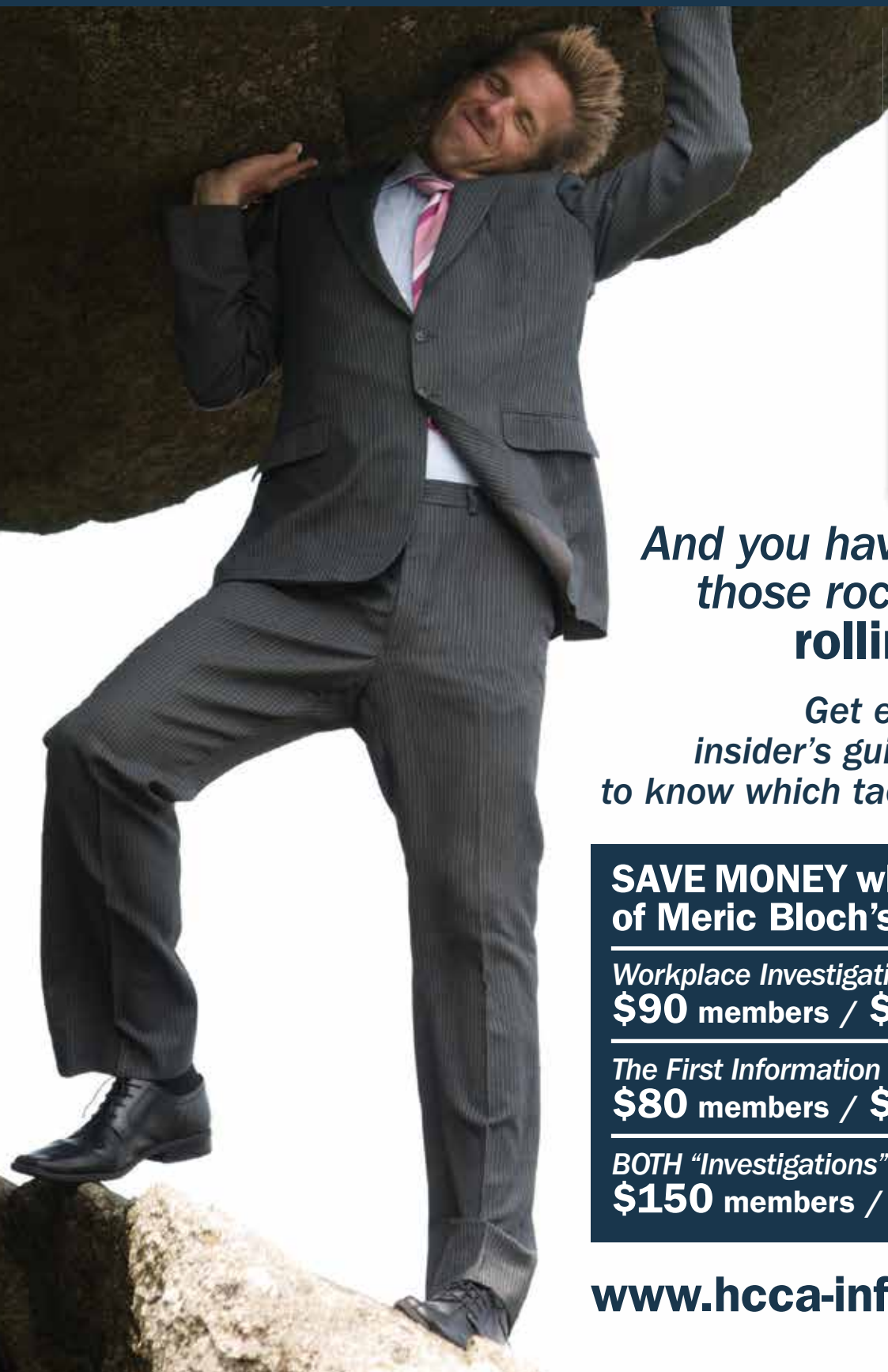
If the CIA requires IRO review of all unallowable costs, remember that it is a review of the evidence and not an audit of the MCRs. CIAs don't require an audit of the MCRs, only verification that they do not include unallowable costs. As such, the scope of the IRO work should be carefully limited to that objective. To do otherwise would invite an overly costly and unnecessary audit review.

Unallowable Cost Review report

The IRO prepares an Unallowable Cost Review report based on the review performed. The report includes the IRO's findings and supporting rationale regarding the review and whether the entity has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the settlement agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from them.

Among the complicating matters is the fact that the investigation and settlement process may have taken a considerable amount of time to complete, sometimes well in excess of a year and in some cases several years. During this time, the organization continued to operate and submit required reports as part of its normal business cycle. During this period, and particularly in the initial period, excluded costs may have been missed. Discovery by the IRO of unallowable costs not excluded from the cost reports may require additional sampling of invoices and charges and may require 100% sampling.

You have to turn over a lot of rocks **to do an investigation right**



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by Kelly M. Willenberg, MBA, BSN, CHRC, CHC

Twelve tips for clinical trial billing compliance

Kelly M. Willenberg *(Kelly@kellywillenberg.com) is President and CEO of Kelly Willenberg, LLC in Chesnee, SC.*

Each day, clinical trial billing is a necessary part of research compliance. Use these twelve tips to make your day easier!

12. If you have a Clinical Trial Management System (CTMS), make its use mandatory within compliance oversight for transparency.

Willenberg

If you have two systems at one facility, consider how they can interact or complement each other.

11. Buy or build a CTMS if you do not have one that utilizes the potential in both the billing software and the CTMS, and secure a clinical trials expert on the billing software team.
10. Provide Principal Investigators (PI) with updates by holding monthly meetings on billing compliance issues, such as denials, complications, and subject injury. Providing PIs information makes them invested in the billing compliance process.
9. Ensure physicians who serve as the lead PI, as well as sub or co-PI(s), understand that medical documentation is vital when billing routine costs in a qualifying trial. It is fine to reference the trial in documentation, but do not make it the reason for the visit or admission if you intend to bill routine cost.
8. Institute billing compliance training and maintain funding for it for all operations personnel.
7. Identify all clinical trial subjects on each study for every visit on the study calendar. This is necessary to place codes, modifiers, and the clinical trial number on the appropriate claim.
6. Understand what types of studies Medicare Advantage Plans will/may or will not/may not cover, so claims can be processed accordingly for the type of study participation.
5. Conduct internal billing assessment reviews and use them for educational moments in the operational enterprise. Learn from your mistakes.
4. Perform a coverage analysis and qualifying status on every clinical trial that you open or have occurrences on at your site. This means you must act upon a study that may not be owned by you, but has billing encounters occurring from another site/physician office. Correspond with those entities to ensure compliance.
3. Pre-authorize clinical trial subjects with their commercial payer plans. Never hide the fact that the patient has chosen to enroll on a clinical trial.
2. Review billing software/electronic medical records (EMR) for research intelligence while considering potential use. Create investment with options and benefits for every billing compliance use across the enterprise.
1. Collaborate, communicate, and coordinate study billing intelligence to both the facility/institutional side and professional side of the billing enterprise, even if you do not own one of them. This can be as simple as a phone call or a research order form.

Make billing compliance something that everyone is invested in. You'll be glad you did!

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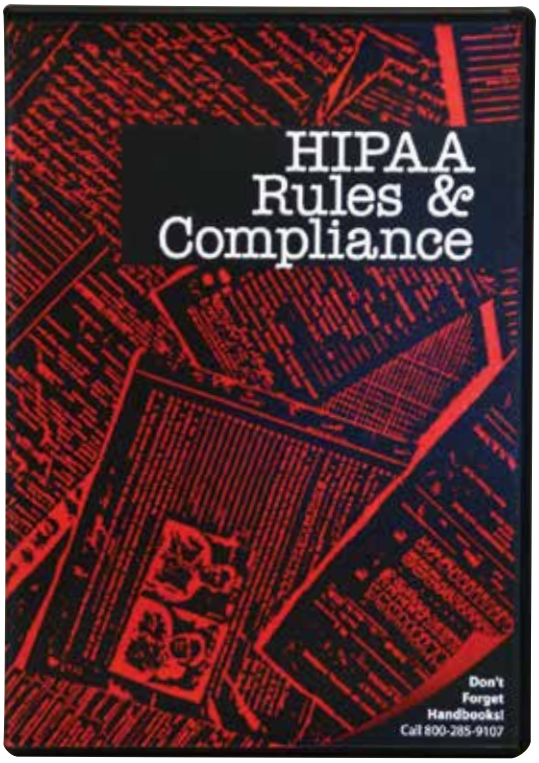
The Health Insurance Portability and Accountability Act (HIPAA) has undergone several modifications since its enactment in 1996, from the Genetic Information Nondiscrimination Act (2010) to the HITECH Act. Recently, the Department of Health and Human Services issued the HIPAA Omnibus Rule to revise, enhance, and strengthen HIPAA yet again.



With these layers of changes, how can employees know what has stayed constant, expanded, or altered altogether? And how does this new rule impact your compliance strategies?

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- **Recognize the HIPAA Breach Notification requirements**
- **Understand how HIPAA is enforced and the penalties for non-compliance**

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by Lisa Shuman, MPA

Effective compliance training for small physician practices

» Assign a well-informed individual to lead the compliance training.
» Develop effective and efficient training materials and methods.
» Create an interactive training environment with real-life scenarios.
» Ingrain compliance into the culture and daily activities of employees.
» Ensure that employees understand "duty to report" and "non-retaliation."

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To date, most smaller physician practices have not taken the time or effort to develop a compliance program, long advocated by the U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG) in their voluntary compliance guidance.[1] Physician practices may see a compliance program as just another burden on their limited resources that could be set aside for a future time. Well, that time is now approaching. Under Section 6401 of the Patient Protection and Affordable Care Act (PPACA),[2] healthcare entities and providers, including physician practices of all sizes, must establish a compliance program that will be defined by the Centers for Medicare & Medicaid Services (CMS). These core elements will be mandated, as a condition of enrollment in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Entities will have to attest to or certify their compliance with these standards as a condition of participation in federally funded programs. CMS has not yet published these standards in the Federal Register. However most larger healthcare entities have already implemented compliance programs based on the seven elements of the OIG voluntary compliance program guidance that will be the basis of the new mandated program standards. In this, they have a major jump start over those entities that have held back on their compliance program development. Now, smaller physician practices will not have the option of staying on the sidelines.


Shuman

To begin preparation for these new obligations, physician practices should review the OIG's compliance program guidance for individual and small group physician practices. What will be quickly noted is that compliance training and education is a critical element of an effective compliance program. Further, physician practices must comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Therefore, practices should incorporate HIPAA into their general compliance training and/or develop a separate HIPAA training to ensure that all employees are knowledgeable and compliant with HIPAA regulations. The compliance officer or a compliance professional is often responsible for training employees on the compliance program elements and healthcare fraud and abuse regulations.

Training materials

What this means is that even the smallest physician practice will have to develop effective

training as part of their compliance program development. The challenge will be to develop training materials that are effective in communicating the compliance obligations of the entire medical staff and employees. The most effective manner would be to use an interactive training program with real-life scenarios that illustrate what is expected of people in the work environment. In addition, the materials will have to adequately describe how the compliance program works and key laws and regulations that must be followed. It must also give guidance as to what individuals should do if they observe violations of law, regulations, or practice policies. All physician practices should ask the following questions:

- Does your practice have a tight budget that does not allow for expensive training methods?
- Is there someone prepared to manage the compliance program and administer training to employees?
- How will you update training materials on a periodic basis/as needed?
- How will you be able to document that the training was delivered?
- What evidence will there be that the training was effective in meeting its objectives?
- How can you make training an ongoing process that helps create a culture of compliance?
- How can you make sure everyone is aware of their duty to report perceived issues?

In furtherance of meeting all these objectives, physician practices may consider the following methods to implement effective and efficient compliance training and education, and to create a culture of compliance within their organization.

Find inexpensive and useful training materials and methods

Small physician practices that have a tight compliance budget may first examine government agency websites for free training resources. For instance, the Compliance 101 webpage of the OIG website (*oig.hhs.gov/compliance/101*) contains free educational materials, including the Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training (HEAT) video and audio podcasts, webcast modules, and presentation materials. The OIG's Compliance 101 webpage also provides compliance education materials specific to physicians, and healthcare boards.[3] Similarly, the Office for Civil Rights (OCR) website provides six education programs for healthcare providers on compliance with different aspects of the HIPAA Privacy and Security Rules (*www.hhs.gov/ocr/privacy/hipaa/understanding/training*).[4]

Medium or large physician practices may consider training courses from outside seminars/webinars and/or hiring outside organizations to assist with their training needs. Outside organizations can provide compliance and HIPAA training and other specialized training for the compliance officer, compliance committee (if applicable), and employees through a variety of methods that include (but are not limited to) in-person training, virtual training through webinars, training manuals/booklets, self-paced PowerPoint training presentations, and train-the-trainer presentations.

Practices should have a well-informed individual who understands the regulatory expectations to manage the compliance program and lead the trainings. Compliance officers or individual(s) who are new to the compliance field or need a refresher may consider receiving a more detailed in-person training prior to training the employees in the practice. Compliance professionals can also use a train-the-trainer presentation to train employees or to educate managers on how to train employees. Outside organizations can assist with training presentations, as well as introductory compliance training or HIPAA training packages at a reduced cost. Further, physician

practices may decide to hire consultants with compliance expertise to review their existing training materials and training methods.

General compliance training

The OIG's compliance program guidance recommends one hour of general compliance training, including the operation and importance of the compliance program, the repercussions for violating standards and procedures, and each employee's role in the operation of the compliance program. The training should emphasize that the purpose of the compliance program is to prevent, detect, and correct fraud and abuse. General compliance training should review the practices standards or code of conduct, as well as the seven components of an effective compliance program, including:

The training should emphasize that the purpose of the compliance program is to prevent, detect, and correct fraud and abuse.

1. Monitoring and auditing of claims submitted for payment
2. Written standards and procedures
3. Responsible person to manage the compliance program
4. Compliance training and education
5. System to respond to detected violations
6. Means by which individuals may report perceived problems without fear of retribution
7. Enforcing disciplinary standards

Additionally, compliance training for physician practices should provide detail on applicable healthcare regulations and high-risk areas for physicians. For example, employees should receive ample training on the following federal fraud and abuse laws: (1) the False Claims Act (FCA); (2) the Anti-Kickback Statute; (3) the Physician Self-Referral Law (Stark law); (4) the Exclusion Authorities; and (5) the Civil Monetary Penalties Law. Employees should also learn how to perform their jobs in compliance with the physician practices' standards and applicable regulations.

Employees should fully understand these regulations and be aware that violating laws or regulations could result in criminal penalties, civil fines, exclusion from the federal healthcare programs, or loss of a medical license from a state medical board. To protect the providers and the practice from receiving potential hefty fines, it is essential that all individuals in the organization are fully aware of the FCA and other regulations. Notably, physician practices should ensure that employees understand their affirmative duty to report compliance violations, and that no retaliation or retribution will be taken against an employee who reports a perceived issue or violation "in good faith."

Training on compliance high-risk areas

In addition to general compliance training, certain members of the physician practice staff should receive specialized training on risk areas. Two to three hours of specialized training per year is best practice. Examples of risk areas for physician practices include: coding and billing, reasonable and necessary services, documentation, and self-referrals. Physician practices should ensure that all physicians receive training on how to properly document medical records, including signature and date requirements. Real-life scenarios or examples that relate to the employees' job function should be part of the training. The compliance officer or the individual who serves as compliance contact can also involve management or other staff in creating and conducting trainings.

This may create more participation among employees with the training process. Policies, procedures, and training materials must also be up to date with current regulations.

Evidencing employee knowledge

Single location practice entities based out of one office may have a better idea of their employees' compliance knowledge than practices where employees work in different offices or travel to multiple locations. To make a live training more interactive, the trainer could hold discussions based on different scenarios, create compliance games, or hold a brown bag lunch. Making the training interactive will allow the trainer to evaluate gaps in compliance knowledge. To determine effectiveness of the training, employees should receive a test at the end to assess their knowledge. Once the employees have completed the test, they may also receive a certificate of training completion. Practices should maintain training sign-in sheets, versions of the training material, test results, and training certificates to document training completion and employee knowledge.

Ingraining compliance in daily operations

The OIG recommends that new employees receive compliance training as soon as possible. Existing employees should receive refresher training on an annual basis or as appropriate. Practices should also ingrain compliance into daily operations and activities. For example, billing staff may be responsible for providing weekly or monthly compliance updates to the practice manager or the individual responsible for compliance. To maintain a culture of compliance, physician practices can encourage employees to sign up for OIG's email updates to stay updated on regulations. Internal or external communications, such as email blasts and newsletters, may also contain regular compliance updates or tips that will keep employees current on new regulations. Further, the communications team can help promote compliance events, such as HCCA's Corporate Compliance and Ethics Week (in autumn in 2015).

Conclusion

Physician practices should move now to build a compliance program and not wait until regulatory mandates go into effect. Note that the government recognizes that because physician practices vary in size and operation, there is no one "best" training method. However, all practices should have a well-informed individual charged with managing the compliance program who understands the regulatory expectations. This individual and the practice manager and owners should work to form a positive culture of compliance through initial and ongoing compliance training and activities, and commend employees for maintaining everyday compliance in the organization. Everyone in the practice needs to assume responsibility for compliance. The practice should be able to provide evidence of training everyone and maintain records of training sign-in sheets, test results, and training certificates.

A final note on physician practice compliance goes back to a realization by the OIG that small practices may have difficulties in being able to meet all the obligations in the compliance guidance with only internal resources. As such, OIG states that where a practice is too small to be able to develop, manage, and operate an effective compliance program within the practice, they may engage a compliance expert or firm to perform most of the work on a part-time, outsourced basis. This is something that small practices may find worth exploring before launching their compliance program effort.

1. OIG Compliance Program for Individual and Small Group Physician Practices; Notice 65 Fed. Reg. 194; October 5, 2000. Available at http://1.usa.gov/1np3hDY
2. Patient Protection and Affordable Care Act, 42 U.S.C. § 6401; 2010.
3. Department of Health and Human Services Office of Inspector General. "Compliance Education Materials." Compliance 101 Web page. May 28, 2014. Available at http://1.usa.gov/1nAGgIF
4. Department of Health and Human Services Office for Civil Rights. "Helping Entities Implement Privacy and Security Protections Medscape Programs." Health Information Privacy Training Materials; May 28, 2014.

by Mariela Twiggs, MS, RHIA, CHP, FAHIMA

HIPAA compliance audits: Best practices for standardizing PHI disclosure processes

» HIPAA audits are resuming; the age of compliance is now.
» The risk of HIPAA breach has increased.
» Unknown PHI disclosure points can put provider organizations at risk.
» Centralizing PHI disclosure processes provides standardization across an enterprise.
» Proper documentation is vital in preparing for OCR audits.

Mariela Twiggs *(mtwiggs@mrocorp.com) is National Director of Training and Compliance for MRO Corp, in King of Prussia, PA.*

Healthcare organizations are in a constant battle against forces known and unknown that can threaten the privacy and security of an organization's patient health information (PHI). The Ponemon Institute's fourth annual Benchmark Study on Patient Privacy & Data Security[1] found that the number of organizations reporting criminal attacks on patient data has doubled since 2010, with employee negligence by far the largest reason for data breaches.

Twiggs

The risk of breach has increased, in part, due to the transition to electronic records, the rise of health information exchange (HIE), and the increased use of personal unsecured devices such as smartphones, laptops, and tablets. In this rapidly changing environment, departments outside of Health Information Management (HIM)—including Risk Management, Billing, Lab, Radiology, and hospital-owned clinics and physician practices—are accessing and/or disclosing PHI through various electronic methods. In fact, there are as many as 40 PHI disclosure points within an organization, increasing the risk of breach via improper PHI disclosure.

Adding to the mounting risk of improper disclosures are business associates (BAs) who are not yet compliant with the final HIPAA Omnibus rule. The rule, which took effect in 2013, expands the obligations of covered entities (CEs) and their BAs to protect patients' privacy and PHI. A study[2] by the Office for Civil Rights (OCR) concluded that 45% of healthcare providers and other CEs had an average of five HIPAA data breaches in a single year, with two-thirds of incidents involving a BA.

Hand in hand with the tightening of regulations are steeper penalties for data breaches. Providers that fail to comply are subject to penalties of up to $1.5 million per incident per calendar year. Criminal penalties range from $50,000 to $250,000 in fines and up to 10 years in prison. An American National Standards Institute survey[3] of hospitals found a wide range of costs associated with each incident of improper disclosure, varying from $8,000 to $300,000. In addition, due to factors such as social media and healthcare consumerism, the

damage to a hospital's reputation can have a long-lasting and far-reaching impact.

With the OCR resuming its HIPAA audit program, a good way for organizations to mitigate the potential for breaches is to eliminate gaps or weaknesses by carefully evaluating PHI disclosure management processes. Best practices for an enterprise-wide, ongoing approach to PHI disclosure management—including standardized processes, training and proper documentation—will help providers increase compliance, minimize liability, and reduce financial risk.

Standardizing processes

Federal healthcare legislation, including HIPAA, HITECH, and the HIPAA Omnibus rule, promotes patient privacy and underscores the need to manage PHI disclosures across a healthcare enterprise in order to ensure compliance. Centralizing the disclosure process into a single system overseen by a single department can eliminate many of PHI disclosure management's challenges and enables healthcare providers to use software and services that can be deployed as a common tracking platform.

By processing all PHI disclosures through one system, hospital departments that disclose PHI have the benefits of secure technology, comprehensive workflow, and quality assurance checks on the information sent through the system. It also supports the organization's efforts to standardize policies and procedures by obtaining the interdepartmental communication, policy enforcement, and level of oversight needed to comply with the increasingly complex regulatory environment.

Training

Standardization of PHI disclosure processes also allows for improved training and education. Workforce awareness about sharing and using PHI is essential. Given today's increasingly digitized environment, coupled with numerous PHI disclosure points, patient information is often accessed or disclosed by employees who may not have received full training regarding privacy and security, or may not be following the latest guidelines.

The HIPAA Privacy and Security Rules require healthcare organizations to formally educate and train the workforce to ensure ongoing accountability for the handling of PHI, as well as documentation verifying that it was provided. Although there are no set guidelines for exactly how an organization should conduct training, the American Health Information Management Association (AHIMA) recommends the following best practices:

- Provide annual training for all staff
- Include education, training, and ongoing awareness, and cover PHI in all its forms (i.e., verbal, written, electronic)
- Develop a repository of current policies and procedures
- Test staff on information to ensure that they have completed training before they are able to access PHI

Training should be based on the employee's role, access to PHI, and responsibilities that present potential compliance risk. In addition, AHIMA advises CEs to work closely with BAs to ensure that all privacy and security training has been documented.

Proper documentation

In addition to maintaining a log of all privacy and security training, healthcare providers need to have a variety of other documents in order. For example, an organization may wish to centralize documentation such as completed checklists, security risk assessments, risk management action plans, BA agreements, and HIPAA training certificates. It would be a good idea to review all of the components

of the OCR audit protocols and pull all of the policies, procedures, and other documentation that will prove compliance. The audit protocols can be downloaded from OCR's website. Because documentation is a key component of the overall plan to protect PHI, record and retain these documents for 6 years after attestation as required by HIPAA.

Healthcare providers should also track all instances of PHI disclosures. The ideal way to maintain the accounting of disclosures is for organizations to deploy a PHI disclosure platform across the enterprise. This single solution can work as a common tracking mechanism, accounting for each instance of disclosure of PHI. The date of disclosure, name of recipient and address (if known), brief description of the PHI, and purpose of the request are required data elements, but accounting of disclosures (AOD) systems also may gather many more data elements. In the future, the requirements for what is included in an accounting of disclosure system may become more complex; forward-thinking leaders in the healthcare industry are paying close attention to how they capture instances of PHI disclosure now.

Now is the time

The OCR has plans to conduct HIPAA compliance audits for hundreds of CEs and their BAs in coming months. According to data provided by CMS contractor Figliozzi and Company,[4] an estimated 80% of providers failed audits in 2012. By standardizing policies and processes, deploying the proper training and education, and documenting it all, providers can prevent significant risks associated with failing an audit.

The topic of OCR audits has gone mainstream, gleaning so much attention that the consequences of a failed audit extend beyond fines and penalties to a damaged reputation, negative media coverage, and potentially lower revenue.

In this age of compliance, providers must act now to address proper PHI disclosure. Working with a trusted and compliant BA for PHI disclosure management services will fortify the organization against possible OCR audits and absorb the risk of harm with regulatory knowledge, sophisticated systems for PHI disclosure, specialized tracking, reporting, and billing systems, along with the high-touch service capabilities.

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by Frank Ruelas

Policies and procedures alone may not assure compliance

» Policies and procedures are often the only means of providing administrative safeguards to promote compliance.

» Using only administrative safeguards may lead to a sense of false security that compliance is assured.

» An administrative safeguard is often only as effective as the willingness of an individual to comply with its associated policy or procedure.

» Physical and technical safeguards can be effective, because they do not rely on the human element to trigger or implement them.

» Using a combination of administrative, technical, and physical safeguards may help promote a higher level of overall compliance.

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How much of your organization's compliance in a particular area do you rely primarily, if not solely, on the administrative safeguards provided by a related policy and procedure (P&P)? Your answer may be similar to others in that the associated P&P's administrative safeguards may be the only safeguards in place. Even though there may be other options to implement additional safeguards, I continue to see compliance officials take the position that if they have a P&P in place, then they can make the conclusion that people will comply with the P&P and its directives and, therefore, there is no need to implement additional technical or physical safeguards to promote compliance. Unfortunately, often it is only a matter of time before these same officials realize that their conclusions do not match actual outcomes.

Ruelas

Learning by example

In my view, some of the best learned lessons occur through example or scenarios. So I am going to use a scenario to highlight several points and to show how we can all benefit from the actions of others while not necessarily going down the same bumpy road. The scenario involves a healthcare organization that has a policy that prohibits the downloading or copying of any information onto transportable media that can be plugged into the USB port of a computer workstation. In this particular example, the incident involved protected health information (PHI), but the lessons learned could just as easily apply to any type of data where the need to maintain the confidentiality applies.

Scenario

In this scenario, an employee of the healthcare organization (who was also aware of the organization's P&P prohibiting such activity) downloaded PHI onto a USB flash drive after plugging the device into the USB port of her workstation. The employee was planning to take the PHI home and catch up on some work that involved analyzing the downloaded PHI that had accumulated over the past couple of weeks. The analysis was to be used to produce various reports for the organization's management team. A day after the employee downloaded the data, an employee from another healthcare facility found a USB drive in the parking lot adjacent to the organization's administrative offices. This individual, concerned that the USB drive

may contain confidential information, thought it best to turn the USB drive over to her own employer's privacy officer. After analysis of the data on the drive by this second organization, the owner of the USB drive and the owner's employer were identified and the USB drive returned to the originating organization.

Upon presentation of the USB drive to the privacy officer of the organization where the USB originated, the privacy officer confidently declared that there was no way that the USB drive belonged to anyone within her organization. When I asked how she could make such a statement, the reply was because the organization had a P&P that prohibited anyone from downloading PHI onto USB drives. After sharing information obtained from the USB drive, the privacy officer realized that the USB drive and its data did originate from within her organization.

…administrative safeguards may be overlooked, ignored, disregarded, or compromised…

How might have this been prevented?

When considering what we can do to promote compliance in this particular example and prevent what happened from occurring, we can assess our options by looking at what safeguards were in place and then considering if additional safeguards, such as technical safeguards or physical safeguards, may be useful in promoting compliance. I realize that bringing up administrative, technical, and physical safeguards may conjure up an often used, if not overused, clipart image of a three-legged stool to illustrate how all three legs, or safeguards, provide a solid foundation. However, at the same time, this is an example which does lend itself to such an image in showing the relationship and contribution each safeguard may provide to the overall promotion of compliance as it applies to a P&P and our example.

Administrative safeguards

We already know that an administrative safeguard related to the prohibition of the downloading or copying of data existed. However, it is important that we also recognize that the effectiveness of an administrative safeguard is also a function of other related actions that are taken to effectively implement a P&P. There needs to be training and education on the involved P&P. People need the opportunity to learn about the policy. In our example, does the policy clearly identify what are USB devices? Does the policy explain clearly what is prohibited? Does the P&P identify what are the consequences of non-compliance? Does staff know where they can access the P&P on demand?[1] These are among some of the questions that need to be assessed when establishing or optimizing the effectiveness of the administrative safeguard provided by a P&P. At the same time, we must also consider that administrative safeguards may be overlooked, ignored, disregarded, or compromised, given that their effectiveness is often directly related to the willingness of the person to follow the related P&P. As happened in this scenario, the employee's need to catch up and produce reports outweighed her willingness to comply with the P&P and, therefore, essentially defeated the administrative safeguards in place. Here is where the addition of other safeguards may have prevented what happened.

Technical safeguards

These are safeguards that I like to view as the unseen sentinels that take action without relying on our interaction or involvement. Because these types of safeguards do not rely on the human factor to be used or initiated, they

essentially trigger themselves based on the identification of various factors or conditions.[2]

What technical safeguards might have prevented the incident involving the USB drive in our example? Though there are many, most if not all relate to the detection of the insertion of a USB drive into the workstation's USB port used to download the data.[3] A technical safeguard could have included an electronically generated alert to the Information Technology (IT) or other similar department that a workstation's electronics detected the insertion of the USB drive. This may have prompted a call to the particular user or other system-generated contact or notice informing the user that the downloading or copying of data onto a USB drive is prohibited by a P&P. In addition, a technical safeguard may generate some type of data log entry into a user database that could then be retrieved and analyzed to determine if and when there were attempts to use USB ports with transportable media, such as USB drives.

Other technical safeguards may include software that disables USB ports. Since USB ports may be used by a variety of devices besides USB flash drives, this same software can be set up to allow for the use of other USB-supported devices, such as portable scanners or headphones.

Physical safeguards

In my view, physical safeguards provide the element of assurance that something did not happen unintentionally by providing a barrier that otherwise would need to be defeated in order for an event to occur. In our example, one such physical safeguard would be the placement of USB port locking devices into the USB ports of workstations.

Consider the USB drive that was found in the parking lot in the example. If the organization had implemented the physical safeguard of placing USB port locks on computer workstations, then the person who downloaded the PHI would not have been able to download the data unless she intentionally defeated the safeguard by intentionally removing the USB port lock. What also makes physical safeguards useful is that they can prevent an incident, in some cases, where those involved are unaware of a P&P that prohibits a certain type of action or activity.[4] Imagine that the person who was planning to download the data saw the USB port lock. It would be a hard story to sell that this person did not make the connection that the lock on the USB port was there to prevent the use of the USB port.

Scenario revisited

So now we have come full circle. We started from an administrative safeguards-only position to one that develops the idea of using other safeguards, namely technical and physical, in combination to provide a much more comprehensive operating framework to assess compliance. It is readily apparent that, as we have explored, as effective as an administrative safeguard may be, overall effectiveness is better achieved when it is combined with other options that provide technical and physical safeguards.

In our scenario, if the organization had in place physical or technical safeguards designed to prevent the downloading of information, then it is much more likely that it would not have found itself in the position of having to deal with confidential information being found on a USB drive in its parking lot. If this involved PHI, then this situation may represent an impermissible use or disclosure that may also represent a breach. However, that's a topic for another day.

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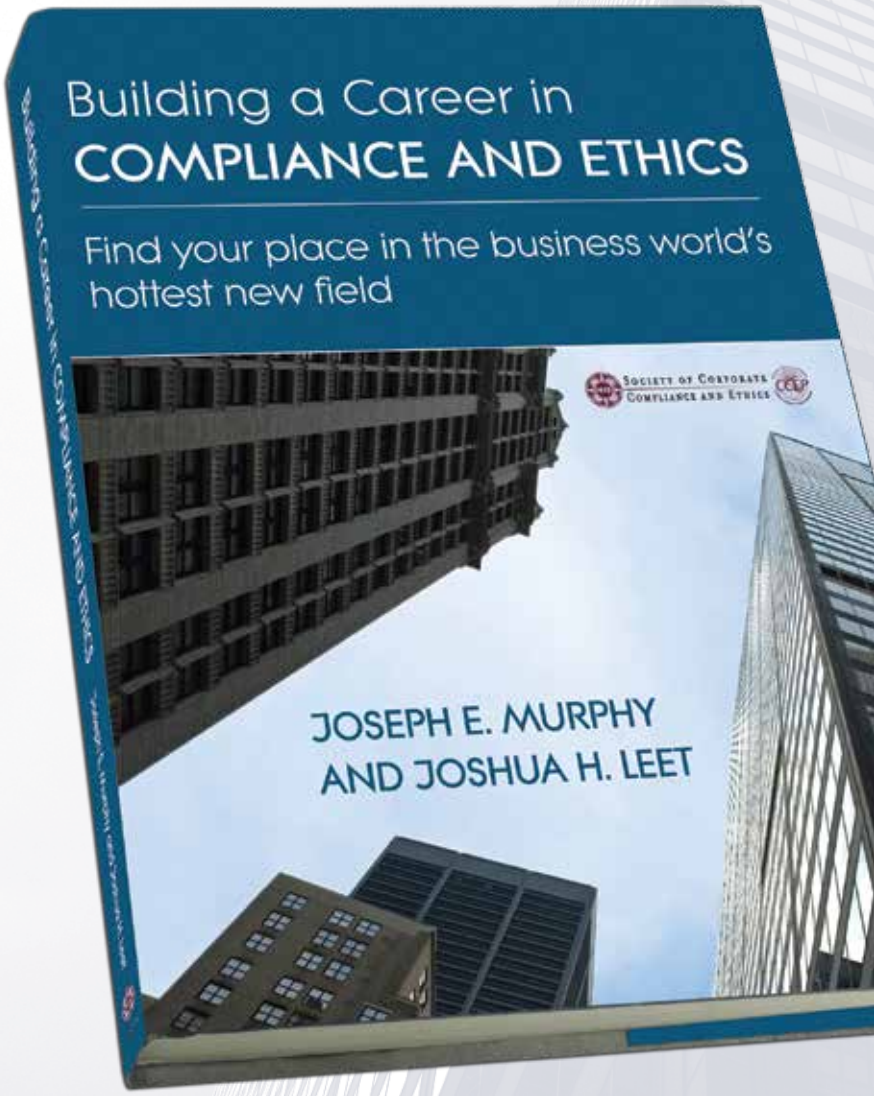

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by Nathan Fish, Esq.

Home health transactions and the 36-month rule

» Application of the 36-month rule can disrupt Medicare participation and reimbursement after a change in majority ownership.
» Buyers of HHAs should perform a 36-month rule analysis for any potential asset sale, stock transfer, merger, or consolidation.
» The due diligence process for a HHA transaction should involve a thorough search of ownership history.
» Purchase documents should include representations and warranties from sellers that address any prior changes in majority ownership.
» Currently, a holding company model may allow potential sellers of HHAs to avoid the application of the 36-month rule, although CMS is monitoring this issue.

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Changes of ownership in the healthcare industry can trigger a host of federal and state regulatory concerns. Acquisitions of home health agencies (HHAs) can raise unique issues. In particular, the buyer and the seller of a Medicare-certified home health agency must consider the applicability of 42 C.F.R. § 424.550(b)(1) and (2) (the so-called 36-month rule). This article discusses the 36-month rule and its impact on the process of selling or acquiring a Medicare-certified HHA.

Fish

Background

The 36-month rule was designed to combat HHA "flipping" and to ensure that buyers of HHAs satisfy the Medicare conditions of participation following a change of ownership.[1] In the 2000s, there was a growing trend where owners of HHAs were enrolling in Medicare for the specific purpose of immediately selling their Medicare billing privileges and Medicare provider agreements to third parties. State surveys did not occur as frequently in instances of changes of ownership as they did when providers initially enrolled in Medicare. As a result, there were instances in which a change of ownership occurred without the new owner undergoing a survey to ascertain whether the business, under new ownership, met the conditions of participation in Medicare.

According to the Centers for Medicare & Medicaid Services (CMS), HHA flipping is problematic because it "allows a purchaser of a HHA to enter the Medicare program through the back door—via the change of ownership process—without having to undergo a state survey."[2] Unless the HHA, under its new ownership and management, has been vetted via the survey process, there is a risk that the newly-purchased HHA may submit inappropriate and potentially fraudulent claims to Medicare for insufficient services provided to Medicare beneficiaries. Although concern about a potential lack of a survey exists with respect to other types of providers, CMS has explained that "this concern is more acute with HHAs" because of the frequency of inappropriate and fraudulent practices in the home health sector relative to other provider types and the home health-specific nature of the flipping phenomenon.[3] To address concerns about HHA flipping and to ensure that buyers of HHAs satisfy the Medicare conditions of participation, CMS

adopted the 36-month rule despite concerns from providers and others that the 36-month rule unduly affects legitimate transactions and blocks new investments in the home health industry. The final version of the 36-month rule, codified at 42 C.F.R. § 424.550(b), went into effect on January 1, 2011.

The 36-month rule

In general, the 36-month rule prohibits an HHA from transferring its provider agreement and provider number upon a change in majority ownership of the HHA by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, unless an exception applies.[4] If the 36-month rule applies, the new owner of the HHA must (1) enroll in the Medicare program as a new (initial) HHA, and (2) obtain a state survey or an accreditation from an approved accreditation organization.

> If an exception applies, the transfer still qualifies as a change in majority ownership…

Exceptions to the 36-month rule

To allow certain legitimate HHA changes of ownership to proceed, CMS established exceptions to the 36-month rule, which are set forth in 42 C.F.R. § 424.550(b)(2). Specifically, the 36-month rule is not implicated if any of the following exceptions applies:

- The HHA submitted two consecutive years of full cost reports. For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports.
- An HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.
- The owners of an existing HHA are changing the existing business structure (e.g., from a corporation to a partnership [general or limited]; from an LLC to a corporation; from a partnership [general or limited] to an LLC) and the owners remain the same.
- An individual owner of an HHA dies.[5]

If an exception applies, the transfer still qualifies as a change in majority ownership for purposes of the 36-month clock.[6] As a result, any change in majority ownership occurring within the 36 months after the excepted transfer must qualify for an exception or the HHA must enroll as a new HHA.

Change in majority ownership

To trigger the 36-month rule, there must be a change in majority ownership, which is defined as:

> *Change in majority ownership* occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a HHA during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.[7]

In the preamble to the final rule, CMS clarified that "indirect ownership changes are not

subject to the 36-month rule."[8] In other words, the 36-month rule only applies when the entity that directly owns and operates the HHA undergoes a change of ownership. The 36-month rule does not apply to any change of ownership of a parent company or holding company that owns and operates an HHA through a subsidiary company, because it amounts to an indirect change of ownership interest in the given HHA.[9] Although indirect ownership changes are not currently subject to the 36-month rule, the final rule suggests that CMS may consider modifying this policy in the future, if it results in widespread avoidance of the 36-month rule.

Note that Medicare treats transactions involving HHAs differently than those involving other suppliers and providers. Under the traditional regulations for Medicare Part A providers, a change of ownership does not occur as a result of the transfer of corporate stock or the merger of a corporation into the provider corporation.[10] However, the 36-month rule is unique to HHAs and does not apply to other Medicare Part A providers. An HHA transaction may be subject to the 36-month rule even if the transaction does not constitute a change of ownership under the traditional rule (e.g., there is a direct transfer of corporate stock).

Consequences of applicability

The 36-month rule can have a significant impact on Medicare reimbursement after an HHA acquisition. In an HHA acquisition where the 36-month rule does not apply, the acquired HHA typically experiences uninterrupted participation in the Medicare program unless the buyer declines to accept automatic assignment of the seller's Medicare agreement.[11] Generally, if the buyer accepts the automatic assignment, there is no required survey as a result of the change of ownership, and although Medicare continues to pay the seller while it processes the change of ownership, the buyer and seller can work out a payment arrangement for services provided after the acquisition date.[12]

Generally, if the buyer accepts the automatic assignment, there is no required survey as a result of the change of ownership, and although Medicare continues to pay the seller while it processes the change of ownership, the buyer and seller can work out a payment arrangement for services provided after the acquisition date.

In contrast, if the 36-month rule applies, the seller's Medicare provider agreement and billing privileges are not conveyed to the buyer. The buyer must, therefore, enroll in the Medicare program as a new HHA and obtain a state survey or accreditation, a costly and time-consuming process. At a minimum, the application of the 36-month rule results in a break in Medicare participation and reimbursement. However, if the acquired HHA's practice location is in a county subject to a CMS-imposed temporary moratorium on the enrollment of new HHAs, the buyer will be completely unable to enroll as a new HHA in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) until the moratorium is lifted.[13]

Conclusion

The due diligence process for potential buyers of HHAs has become more complex as a result of the 36-month rule. Potential buyers would be well-advised to conduct a thorough search of ownership history of the target HHA, including a review of Medicare change of ownership and change of information filings. Purchase documents should also include representations and warranties from sellers that address any prior changes in majority ownership. Moreover, potential sellers of HHAs should structure their ownership arrangements so that the 36-month rule does not interfere with a potential sale. As noted above, potential sellers may be able to avoid the application of the 36-month rule by using the holding company model. Even where the 36-month rule applies with no available exception, there are possible solutions for the buyer and seller. However, because it is preferable to avoid the application of the rule, both potential buyers and potential sellers should conduct a 36-month rule analysis for any potential transaction and as a part of their long-term business plans.

This material is provided for informational purposes only and is not legal advice. Readers should contact their own counsel to obtain legal advice with respect to any specific issue.

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by Shakeba DuBose

Compliance 101

The intersection between employee morale and compliance

» Low employee morale should be recognized as a compliance risk.
» Understanding contributing factors of low employee morale facilitates compliance risk assessments.
» Management may be a major factor impacting employee morale and compliance.
» Compliance and Human Resources staff must coordinate to address issues impacting morale.
» Unaddressed, low employee morale can impede an effective compliance program.

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It may seem like an elementary question but, what is employee morale? Merriam-Webster's online dictionary defines "morale" as *"the mental and emotional condition (as of enthusiasm, confidence, or loyalty) of an individual or group with regard to the function or tasks at hand."*


DuBose

Accordingly, one Human Resources (HR) expert states that "employee morale is defined by employees' outlook, optimism, self-concept, and assured belief in themselves and their organization, its mission, goals, defined path, daily decisions, and employee appreciation."[1] Now, let's look at compliance. Merriam-Webster's online dictionary defines "compliance" as *"the act or process of doing what you have been asked or ordered to do"* or *"conformity in fulfilling official requirements."* Here, one can clearly connect these two general concepts.

Employee morale: High vs. low

It does not require a comprehensive study to conclude that if employee morale is high, employees feel positive about their work environment and, in most cases, go above and beyond in completing their job responsibilities. On the other hand, if employee morale is low due to employees being overworked, underappreciated, or resentful (due to a lack of growth opportunity or because of others receiving preferential treatment), these employees may only do the bare minimum to complete their given tasks. Thus, they are not paying attention to detail or spending an appropriate amount of time to ensure that simple mistakes are avoided, which when compounded, can cause major compliance issues. Accordingly, as time passes, if the issues contributing to the low morale of one group are not addressed, eventually those who are typically positive about their roles and responsibilities are drained—they too become negative about their work environment and discontinue any exceptional efforts. And just where does this leave the unit, department, or even the entire organization? A breeding ground for compliance issues.

Compliance staff's role

As a compliance professional in your organization, what do you do? First, compliance staff

has to be aware of low employee morale by consistently assessing the environment:

- Are employees generally happy while at work?
- Do they take pride in the organization and its mission?
- Are they given the opportunity to express their ideas?
- Do most view the organization as one in which they can grow and advance?
- Are departments properly staffed?
- Are employees praising their managers or leadership with respect to their abilities to manage and lead the organization?
- Are employees open when asked for their concerns?
- Do employees feel that they are treated fairly?

If the answer to some of these types of questions is "no," there may be morale problem.

Once low morale is identified, the Compliance team should assess what risks it poses to compliance and execute a plan to address those risk areas. This plan may include: (1) working with leadership, management, and HR to identify and properly discipline problem employees and managers who are contributing to the issues that result in low morale; (2) developing or improving departmental policies and procedures and monitoring to ensure that actual practices are in accordance with these policies and procedures to minimize potential compliance issues; and/or (3) re-training and re-educating the employees on compliance policies and procedures.

Once low morale is identified, the Compliance team should assess what risks it poses to compliance and execute a plan to address those risk areas.

The reality of low employee morale

As compliance professionals, we spend a tremendous amount of time discussing one of the essential elements of a compliance program: developing effective lines of communication whereby individuals can report their concerns under the protection of a non-retaliation policy. However, the reality is, if employee morale is low—and it is low due to the actions or lack thereof of management and leadership, and it appears that the rules do not apply to them—it is most probable that employees will not engage in any disclosures of non-compliance issues for fear of retribution by management. Unfortunately, this fear is not unfounded. In many organizations, we find that certain compliance issues result from some action or inaction by management and that management is guilty of harassing or discriminating against certain employees. And, in some cases, it is not that a particular manager was unethical—he/she followed the tone set by leadership.

So, what are rank-and-file employees to do when they have made a mistake because they are overworked due to understaffing, or when they know that management is not properly instructing staff on a particular procedure, or when they see that leadership does not take any action against bad managers or fellow leadership who have displayed unethical or inappropriate behavior? We as compliance professionals say, "Report it." But, what incentive does an employee have to report compliance issues? What real assurances does an employee have that he/she will not be harassed or even worse, lose their job?

Conclusion

As compliance professionals, we must not only develop and implement "seven element" compliance programs, we must also must demonstrate that we are approachable and open to hearing about compliance issues that place the organization or even employees at risk. Moreover, we must develop and maintain a reputation for flushing out issues and working with leadership, management, and HR to resolve the issues that negatively impact employee morale, which in turn increases the potential for non-compliance. By doing so, compliance professionals build trust with the employees who view the Compliance department as one of the pillars of an ethical organizational culture. We must recognize that our roles should not be siloed; otherwise, our time and energy spent on the development and implementation of compliance programs are wasted and the programs will be ineffective.

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  by Frank Ruelas (page 67)

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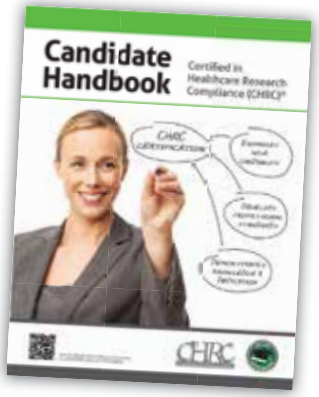

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OIG, EHR, and audit logs: Thinking ahead

Cornelia M. Dorfschmid and Bernard McClellan (page 29)

- Turn EHR audit logs on to manage logs proactively and analyze logs routinely.
- Use audit logs as part of billing monitoring and anti-fraud detection.
- Require written policies and procedures on usage, storage, and configuration management of audit logs to ensure availability and integrity.
- Be prepared to respond to ADR requests for audit logs by contractors who are doing medical reviews.
- Use EHR audit logs to detect vulnerabilities before others do.

Billing data: Tools to maximize data mining efforts

Melissa McCarthy (page 33)

- Various resources are available to assist in data mining activities.
- Documentation review is key to support initial findings.
- Make sure you can see the whole picture before you react. If the data does not match up, pieces of the puzzle may be missing, and therefore, exhaust all avenues before you report on the findings.
- CMS data shows that a small percentage of providers account for large portion of Medicare costs.
- Verify that the available data matches your data.

Getting and keeping your board engaged

Paul P. Jesep (page 37)

- As a best practice, strongly urge your volunteer board to do an annual, anonymous compliance survey and self-assessment (SSA) to measure knowledge and how well members think they and their colleagues perform fiduciary duties.
- SSAs should be crafted and strategic. It's acceptable to borrow from the many tools available, but the cookie cutter approach should not be used.
- Compile the results in an objective manner using graphs and charts. Use visuals if they enhance your ability to make a presentation and better position you to offer recommendations.
- Let the facts speak for themselves. If the survey and self-assessment questions are crafted strategically, what the board needs to act on should be self-evident.
- Enable board members to snail-mail the SSA in a stamped envelope addressed to you without anything that identifies the individual member.

Beyond the hospital walls: Compliance with provider-based clinics

Wendy Wright (page 41)

- Compliance involvement in the planning stages of implementing a new provider-based clinic is imperative to future success.
- The Office of Inspector General has placed special emphasis on provider-based clinics due to the financial impact on the Medicare program.
- Provider-based clinic policies and procedures should mimic those of the main hospital provider and the clinic should stand out to the public as such.
- Provider-based clinics typically receive higher reimbursements than services provided in professional/physician-owned clinics.
- Compliance challenges with provider-based services can be mitigated through routine auditing and monitoring of these arrangements.

Unallowable costs related to a corporate integrity agreement

Jeannie O'Donnell (page 47)

- In government, unallowable costs must be identified in the entity's accounting records and excluded from any submitted budget, cost reports, and requests for federal or state reimbursement.
- OIG negotiates corporate integrity agreements (CIA) as part of the settlement of federal healthcare program investigations arising under a variety of civil false claims statutes.
- Providers or entities agree to the CIA obligations, and in exchange, the OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other federal healthcare programs.
- The scope of work of the Independent Review Organization often includes a review of cost reports to determine whether unallowable costs were included for reimbursement by federally financed healthcare programs.
- Considering that an investigation and ultimate settlement may drag out over a long period time, providers and entities will save cost and time if investigation costs are tracked as unallowable costs at the front end.

Effective compliance training for small physician practices

Lisa Shuman (page 59)

- Assign a well-informed individual to lead the compliance training.
- Develop effective and efficient training materials and methods.
- Create an interactive training environment with real-life scenarios.
- Ingrain compliance into the culture and daily activities of employees.
- Ensure that employees understand "duty to report" and "non-retaliation."

HIPAA compliance audits: Best practices for standardizing PHI disclosure processes

Mariela Twiggs (page 63)

- HIPAA audits are resuming; the age of compliance is now.
- The risk of HIPAA breach has increased.
- Unknown PHI disclosure points can put provider organizations at risk.
- Centralizing PHI disclosure processes provides standardization across an enterprise.
- Proper documentation is vital in preparing for OCR audits.

Policies and procedures alone may not assure compliance

Frank Ruelas (page 67)

- Policies and procedures are often the only means of providing administrative safeguards to promote compliance.
- Using only administrative safeguards may lead to a sense of false security that compliance is assured.
- An administrative safeguard is often only as effective as the willingness of an individual to comply with its associated policy or procedure.
- Physical and technical safeguards can be effective, because they do not rely on the human element to trigger or implement them.
- Using a combination of administrative, technical, and physical safeguards may help promote a higher level of overall compliance.

Home health transactions and the 36-month rule

Nathan Fish (page 71)

- Application of the 36-month rule can disrupt Medicare participation and reimbursement after a change in majority ownership.
- Buyers of HHAs should perform a 36-month rule analysis for any potential asset sale, stock transfer, merger, or consolidation.
- The due diligence process for a HHA transaction should involve a thorough search of ownership history.
- Purchase documents should include representations and warranties from sellers that address any prior changes in majority ownership.
- Currently, a holding company model may allow potential sellers of HHAs to avoid the application of the 36-month rule, although CMS is monitoring this issue.

Compliance 101: The intersection between employee morale and compliance

Shakeba DuBose (page 75)

- Low employee morale should be recognized as a compliance risk.
- Understanding contributing factors of low employee morale facilitates compliance risk assessments.
- Management may be a major factor impacting employee morale and compliance.
- Compliance and Human Resources staff must coordinate to address issues impacting morale.
- Unaddressed, low employee morale can impede an effective compliance program.

HCCA's Upcoming Events

Learn more about HCCA's educational opportunities at www.hcca-info.org/events

November 2014

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
26	27	28	29	30	31	1
2 *Daylight Savings Time ends*	3 **Research Basic Compliance Academy** Lake Buena Vista, FL **Healthcare Privacy Basic Compliance Academy** Lake Buena Vista, FL	4 WEB CONFERENCE: *Breach Statistics, and How to Avoid Becoming One* *Election Day*	5 WEB CONFERENCE: *HIPAA Audits are Coming… Are You Prepared?*	6 **CHRC Exam** **CHPC Exam**	7 WEB CONFERENCE: *EHR Risks Update: How do we audit?* **Mid Central Regional Conference** Louisville, KY	8
9	10	11 *Veterans' Day*	12	13	14 **Desert Southwest Regional Conference** Phoenix, AZ	15
16	17 **Basic Compliance Academy** Lake Buena Vista, FL	18	19 WEB CONFERENCE: *Anti-Kickback Statute Bootcamp for Compliance Professionals*	20 **CHC Exam**	21 **South Central Regional Conference** Nashville, TN	22
23	24	25	26	27 HCCA OFFICE CLOSED *Thanksgiving Day*	28 HCCA OFFICE CLOSED	29
30						

December 2014

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
30	1 **Basic Compliance Academy** San Diego, CA	2	3 WEB CONFERENCE: *Effective & Meaningful Auditing & Monitoring for the Hands On Compliance Professional/Practitioner*	4 **CHC Exam**	5 **Upper West Coast Regional Conference** San Francisco, CA	6
7 *Pearl Harbor Remembrance Day*	8	9	10	11 WEB CONFERENCE: *The Expansion of OIG's Exclusion and Civil Monetary Penalty Authority Under the PPACA*	12 **Gulf Coast Regional Conference** Houston, TX	13
14	15 WEB CONFERENCE: *New Medicare Reimbursement for Chronic Care Management*	16 WEB CONFERENCE: *Bona Fide Information Security Risk Analysis & Risk Management*	17 WEB CONFERENCE: *Compliance and Internal Audit: A Collective Alliance* *Hanukkah begins*	18	19	20
21 *First Day of Winter*	22	23	24 HCCA OFFICE CLOSED *Christmas Eve*	25 HCCA OFFICE CLOSED *Christmas Day*	26 *Kwanzaa begins*	27
28	29	30	31 *New Year's Eve*	1 HCCA OFFICE CLOSED *New Year's Day*	2	3

Dates and locations are subject to change.

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November 17–20 • Lake Buena Vista, FL — **SOLD OUT**

December 1–4 • San Diego, CA — **SOLD OUT**

Research Basic Compliance Academies

November 3–6 • Lake Buena Vista, FL

Healthcare Privacy Basic Compliance Academies

November 3–6 • Lake Buena Vista, FL

Regional Conferences

Mid Central • November 7 • Louisville, KY

Desert Southwest • November 14 • Phoenix, AZ

South Central • November 21 • Nashville, TN

Upper West Coast • December 5 • San Francisco, CA

Gulf Coast • December 12 • Houston, TX

Jan–Jun 2015

Managed Care Compliance Conference

February 15–18 • Las Vegas, NV

Audit & Compliance Committee Conference

February 23–24 • Scottsdale, AZ

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April 19–22 • Lake Buena Vista, FL

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January 26–29 • San Juan, Puerto Rico

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April 27–30 • Orlando, FL

June 8–11 • Scottsdale, AZ

Research Basic Compliance Academies

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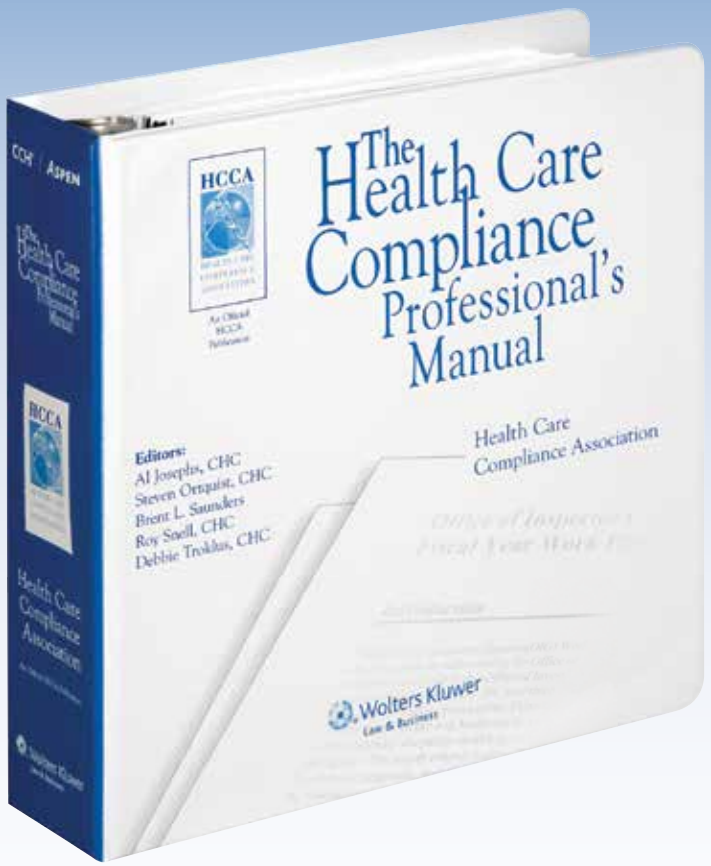

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