HCCA HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

September 2014

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

Crossing the bridge to the corporate world: Getting clinicians involved

an interview with Nancy Beckley

President, Nancy Beckley & Associates LLC

See page 16

Health Care Compliance Association's 19th Annual

COMPLIANCE INSTITUTE®

Lake Buena Vista, FL | April 19–22, 2015
Walt Disney World Swan and Dolphin Resort

5 great new reasons
to come to the 2015 Compliance Institute in Florida

Register by January 7 and save up to $575

There's no reason to wait. Register today to maximize your savings and ensure your spot at the 2015 Compliance Institute.

LEARN MORE & REGISTER AT
www.compliance-institute.org

1. Get the latest enforcement trends and expectations straight from Dan Levinson, OIG, HHS

2. Hear whistleblower and former CEO Michael Woodford tell his amazing tale of his experiences at medical device manufacturer Olympus

3. Add to your ethical insights when you learn from Marianne Jennings, noted ethicist

4. Better protect your company from cyber threats, courtesy of the insights provided by Joseph M. Demarest, Jr, Assistant Director, Cyber Division, FBI

5. Follow the new Internal Audit track, and deepen your expertise in this essential discipline

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

www.compliance-institute.org

by Roy Snell, CHC, CCEP-F

Rating popular figures as potential compliance officers

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*

I have rated a few famous people as to their potential to be a compliance officer. It's an interesting way to discuss the characteristics of a good compliance officer. While searching online for lists of well-known people to evaluate, I discovered something interesting.


Snell

Lists of famous people did not offer much in the way of people that seemed to have what it takes to be a compliance officer. Lists of smart people were not much help either. Then I found a list of the most peaceful people in history. And in my view, almost every one of those people would have made a great compliance officer. Here are my ratings:

Spock *(Star Trek)*: B-
Spock would be cool under pressure and base his actions on facts, which are great attributes of a compliance officer. However, he might come up a little short in the category of showing empathy. Empathy is an important skill because at times we are going to occasionally cause people a little tension in their lives.

Jim Carrey *(as a composite of his characters)*: D-
I love the characters he plays, but his only redeeming value would be that his typical character is not unethical. His neurotic on-screen personality would be an utter disaster. Most compliance officers benefit from being a little calm under pressure.

Rosabeth Moss Kanter
(professor at Harvard Business School): **B+**
She has the right values. She focuses on diversity and other principle-based issues. She thinks about management and business objectives, which would help her relate to those who want to comply and continue to be successful in business.

> …almost every one of those [peaceful] people would have made a great compliance officer.

Sandra Day O'Connor: A
I think she has the right stuff. She has the legal experience to be successful. Her experience as a judge, hearing both sides before making her decision, would be invaluable. She would base her decisions on the facts. She seems calm under pressure.

Here are some more:
Edward Snowden, Martin Luther King Jr., Dalai Lama, Tom Brady, Nelson Mandela, Mother Teresa, Mohandas Gandhi, David Petraeus, Rosa Parks, Confucius, Mark Zuckerberg, Eleanor Roosevelt, Oprah Winfrey, Benjamin Franklin, George Washington, Princess Diana, Socrates, Margaret Thatcher, Brad Pitt, Howard Schultz *(Starbucks)*, Greg Steinhafel *(Target)*, Tony Hsieh *(Zappos)*, Jim Skinner *(McDonald's)*.

Comment on my ratings at *bit.ly/popfigures*.

Contents

September 2014

FEATURES

COLUMNS

DEPARTMENTS

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).

> …compliance officers and administrators may be looking at the same set of data, but see different questions and different solutions.

See page 17

ARTICLES

Compliance TODAY

EDITORIAL BOARD

EXECUTIVE EDITOR: Roy Snell, CHC, CCEP-F, CEO, HCCA, roy.snell@corporatecompliance.org

NEWS AND STORY EDITOR/ADVERTISING: Margaret R. Dragon, 781-593-4924, margaret.dragon@corporatecompliance.org

COPY EDITOR: Patricia Mees, CHC, CCEP, 888-580-8373, patricia.mees@corporatecompliance.org

DESIGN & LAYOUT: John Goodman, 888-580-8373, john.goodman@corporatecompliance.org

PROOFREADER: Briana Gehring, 888-580-8373, briana.gehring@corporatecompliance.org

Compliance Today (CT) (ISSN 1523-8466) is published by the Health Care Compliance Association (HCCA), 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Subscription rate is $295 a year for nonmembers. Periodicals postage-paid at Minneapolis, MN 55435. Postmaster: Send address changes to *Compliance Today*, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435.

VOLUME 16, ISSUE 9

"10Minutes on data privacy"

PricewaterhouseCoopers has developed "10Minutes on data privacy," which provides a quick glance at the current data on this topic. "Data protection and privacy is an urgent issue for both consumers and businesses. As customers increasingly worry whether their personal information is secure and used appropriately, companies are also concerned about protecting data and their brand. This 10Minutes highlights the importance of viewing consumer privacy from more than just a compliance lens and developing a strategy and action plan that will help businesses lead on data privacy by building customer trust and enhancing their brand."

For more: *http://pwc.to/1sbs8g0*

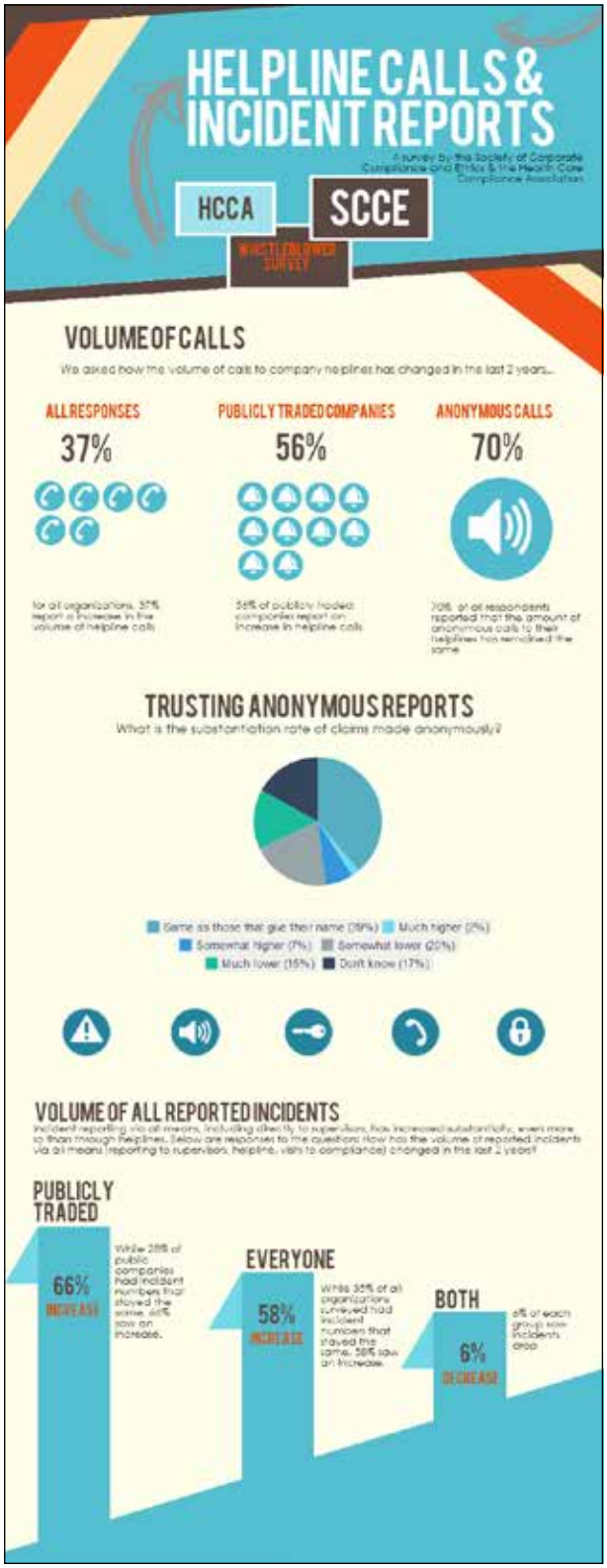
Quality measures continue to be a small yet increasing percentage of total compensation for physicians

According to the results of the recent Medical Group Management Association (MGMA) Physician Compensation and Production Survey: 2014 Report Based on 2013 Data, "primary care physicians (who indicated that they were not part of an accountable care organization or a patient-centered medical home) reported that an average of 5.96% of their total compensation was based upon measures of quality."

MGMA's press release also noted, "Specialists reported that an average of 5.70% of their total compensation was based upon quality metrics. Some specialties, including anesthesiologists, internists and hospitalists, reported that a higher percentage of their total compensation was tied to quality metrics. MGMA surmised that physician compensation would increasingly be tied to these metrics as reimbursement aligned more closely with quality and cost measures."

For more: *http://bit.ly/USzREL*

Infographic of the month



To download the full survey report: *http://bit.ly/sccehcca-survey-helpline*

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

Regulatory News

Steps to bolster management and accountability ahead of the 2015 open enrollment period announced

In a recent press release, Health and Human Services Secretary, Sylvia Burwell, announced a series of management changes designed to strengthen the implementation of the Affordable Care Act. "This new management structure comes in response to lessons learned from the rollout of HealthCare.gov and recommendations put forth to the Secretary. The Centers for Medicare & Medicaid Services (CMS) will have a new operations-focused Principal Deputy Administrator for agency-wide policy and operational program coordination. CMS will also have a single Marketplace Chief Executive Officer (CEO). In addition to the Marketplace CEO, CMS is announcing and actively recruiting a Marketplace Chief Technology Officer (CTO)."

For more: *http://1.usa.gov/1ocBKYJ*

$800,000 HIPAA settlement in medical records dumping case

The U.S. Department of Health and Human Services recently announced that "Parkview Health System, Inc. agreed to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule with the U.S. Department of Health and Human Services Office for Civil Rights (OCR). Parkview will pay $800,000 and adopt a corrective action plan to address deficiencies in its HIPAA compliance program. Parkview is a nonprofit health care system that provides community-based health care services to individuals in northeast Indiana and northwest Ohio.

"OCR opened an investigation after receiving a complaint from a retiring physician alleging that Parkview had violated the HIPAA Privacy Rule. In September 2008, Parkview took custody of medical records pertaining to approximately 5,000 to 8,000 patients while assisting the retiring physician to transition her patients to new providers, and while considering the possibility of purchasing some of the physician's practice. On June 4, 2009, Parkview employees, with notice that the physician was not at home, left 71 cardboard boxes of these medical records unattended and accessible to unauthorized persons on the driveway of the physician's home, within 20 feet of the public road and a short distance away from a heavily trafficked public shopping venue."

According to the government press release, "Parkview cooperated with OCR throughout its investigation. In addition to the $800,000 resolution amount, the settlement includes a corrective action plan requiring Parkview to revise their policies and procedures, train staff, and provide an implementation report to OCR."

OCR FAQs concerning HIPAA and the disposal of protected health information: *http://1.usa.gov/1v7NNeL*

Resolution Agreement: *http://1.usa.gov/1ssnlZD*

HCCA releases new video series

Daniel R. Levinson, IG at the U.S. Department of Health and Human Services, speaks on "big data in compliance."

Videos: *http://bit.ly/1ozj59e*

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

Clinical Practice
Compliance Conference

October 12–14, 2014 | Philadelphia, PA
Loews Philadelphia Hotel

Questions: jodi.ericksonhernandez@hcca-info.org

LAST CHANCE
REGISTER TODAY

Why should you attend?

Get updated on government initiatives specific to physicians and their practices

Network with your peers

Hear the latest enforcement trends

Learn about correct documentation, billing and coding practices, and operating on a limited budget

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

Learn more at www.hcca-info.org/clinical

HCCA *conference news*

Join us at the Clinical Practice Compliance Conference in Philadelphia, October 12–14

We are thrilled to be participating in the 2014 HCCA Clinical Practice Compliance Conference at the Loews Philadelphia Hotel. It's the only HCCA conference specifically targeted to physicians and their practices; the expertise and talent of the speakers is laudable.

As a result of Patient Protection and Affordable Care Act (PPACA), the changes we are all experiencing in our health systems are gaining momentum at a rapid pace. 2015 through 2017 promise to force change through new regulations and requirements. You need to be ready to help your healthcare practice weather the storm and effect the change necessary to survive, so your physicians and healthcare providers at all levels can continue to provide high quality healthcare in an efficient and compliant manner.

Help your healthcare practice weather the storm and effect the change necessary to survive.

We are seeing a transition from the private practice model to an employed physician model to provide care for patients. Health systems and physician consortiums are trying to develop brand recognition. The government and health insurance companies are pushing the envelope to decrease reimbursement and restrict utilization of healthcare services, including discharging patients from the hospital sooner. This transfers the burden of care to families and patients themselves, as well as providers such as physicians, midlevel providers, and ancillary healthcare workers. Governmental regulations with severe penalties are growing by leaps and bounds, putting added risk and pressure on our health system entities and compliance officers. The physician comparison and hospital comparison websites are up and running. Quality reporting has started. Reimbursement anchored to arbitrary quality parameters is coming soon.

Learn how to build an effective compliance program and deal with the law and regulations of PPACA. We are excited to present a general session on the integration of quality and compliance. The future is now on this issue! Find out what your physicians are thinking, how they are reacting, and what needs to be done as more of PPACA's requirements and regulations come online.

ICD-10 is not gone and it is not forgotten! The ICD-10 train is still on the track and will arrive in the fall of 2015. Hear what Betty Bibbins, MD and Nicole Harper, PhD suggest for approaching and teaching your physicians.

Learn about handling audits from the experts at the session presentations of Wendy Wright and Lauren Wright, in addition to Kim Garvey and Jenifer Carey. Dr. Robert Ossoff will complement the conference with "Challenges and Helpful Hints for Turning Low Performers into Compliant Performers," a hot topic he has identified as a physician. Additional topics include risks associated with HIPAA breaches and coding problems.

There is another added bonus for those who attend… Richard's recommendation of restaurants in the area! Philadelphia is beautiful in October. We look forward to seeing you.

—Richard E. Moses, DO, JD
and D. Scott Jones, CHC

www.hcca-info.org/clinical

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 | My Account | Events | Add CEUs

Number of website visits last month
50,232

Social Media

Our websites aren't the only way to keep up with us. HCCA is present on a number of social media outlets. You can find us on our own HCCA*net*, Facebook, LinkedIn, Google+, YouTube, Flickr, Twitter, and Pinterest. We're also exploring some other social media avenues.

You can find us in three ways: (1) Go to the chosen social media site and search for us, (2) look to the links below or on the next page, or (3) visit our website—the icons in the upper right hand corner of each page link directly to our page on each of the sites.

Video of the month

What processes are healthcare organizations using to prioritize risks that are most critical?
http://bit.ly/votm-2014-09

Get Connected

hcca-info.org/hccanet | facebook.com/hcca | hcca-info.org/google | twitter.com/theHCCA | pinterest.com/theHCCA | [GROUP] hcca-info.org/linkedin [COMPANY] hcca-info.org/li | youtube.com/compliancevideos

Find the latest HCCA website updates online ▶ www.hcca-info.org

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 18,000 members and growing, our LinkedIn group fosters more than 75 new discussion posts every week. Here are some recent highlights:

HIPAA Violation Fines to Increase with New Round of Audits
Susan Klasic

Latest findings on how thousands of doctors appear to be gaming Medicare with billings for questionable and rarely used procedures.
Gordon Schnell
Partner at Constantine Cannon – Antitrust, Fraud and Whistleblower Law

Medicare on drugs: 24,000 tests for 145 patients http://reut.rs/1hgLos7
Kortney Nordrum
Digital Content Editor at SCCE & HCCA

Physician Compensation & False Claims
Rick Hindmand
Member at McDonald Hopkins LLC

A gaze into the HIPAA crystal ball...
Art Gross
President and CEO at HIPAA Secure Now!

SlideShare — *www.slideshare.net/theHCCA*

We love sharing. Download informative and helpful presentations from every one of our conferences and presenters—free! Some of our recent favorites include:

Twitter — *www.twitter.com/theHCCA*

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

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 Pinterest boards. Feel free to re-pin anything you see.

Reddit — *www.reddit.com/r/HCCA*

We're on Reddit, too. HCCA's Reddit page houses a link to every article we post, tweet, blog, pin, or share. It's a fun repository of healthcare compliance information.

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

▶ **Christos Arvanitis** is now the Ambulatory Surgery Center Compliance Officer at Sutter Health in Sacramento, CA.

▶ **David Berry** has been appointed Corporate Compliance Officer for Group Health Cooperative of South Central Wisconsin in Madison, WI.

▶ Astellas Pharma US, Inc. has named **Tatjana Dragovic**, JD, Vice President and Regional Compliance Officer for its Americas region. Astellas Pharma US is in Northbrook, IL.

▶ **Troy Kishbaugh** has rejoined GrayRobinson, PA as a shareholder and as chair of the healthcare practice group in the firm's Orlando office.

▶ **Donald R. Riggs** of Crestwood, KY has been named Chief Compliance Officer for Baptist Health in Louisville, KY. Riggs is a certified internal auditor and is certified in healthcare compliance.

PEOPLE *on the* MOVE

▶ **Franklin West** is now the Chief Compliance Officer: Director, Practice Support, Compliance, and Health Policy at Society for Vascular Ultrasound, in Lanham, MD.

▶ On September 15, 2014, the Society of Corporate Compliance and Ethics (SCCE), HCCA's sister association, is presenting the **2014 SCCE International Compliance and Ethics Award** to a group of individuals and organizations—**Donna C. Boehme**, **Daniel E. Levinson**, **Smith Debnam LLP**, and ***The WSJ's Risk and Compliance Journal.*** —for the significant contributions each has made to and for championing compliance and ethics in business.

▶ Fifteen **Consulate Health Care** centers have been recognized as 2014 recipients of the **Bronze – Commitment to Quality Award** for their dedication to improving the lives of residents through better care. The award, presented by the American Health Care Association and National Center for Assisted Living, is the first of three distinctions possible through the National Quality Award Program.

▶ Ernst & Young LLP recently announced that **James (Jamey) Edwards**, CEO of Emergent Medical Associates, Southern California's leading emergency physician's group, was named a finalist in the Ernst & Young **Entrepreneur of the Year®** 2014 program in the Greater Los Angeles region.

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*

Help Keep Your Compliance Program Fully Staffed

List Your Job Openings Online with HCCA

It's hard to have an effective compliance program when you have openings on your team. Help fill those openings quickly—list your compliance job opportunities with the Health Care Compliance Association.

Benefits include:

- Listing is posted for 90 days to maximize exposure
- Targeted audience
- Your ad is also included in our biweekly HCCA Jobs Newsletter, which reaches more than 25,000 emails

Don't leave your compliance positions open any longer than necessary. Post your job listings with HCCA today.

Visit www.hcca-info.org/newjobs
Or call us at 888-580-8373

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

How do compliance officers of leading healthcare providers across America keep millions of employees compliant?

HCCS ONLINE COMPLIANCE COURSES

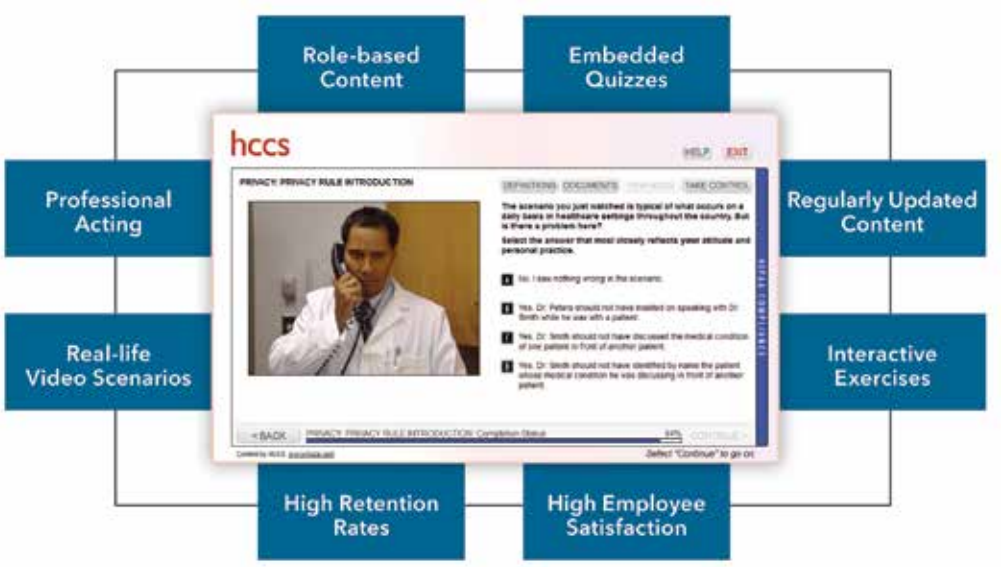
General Compliance Suite

Professional Compliance – Health System and Physician Office Versions
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.



At HCCS we've always recognized the importance of people in the learning process. Computers may deliver the content, but real people administer and take the training.

Our online courses are designed to meet the needs of EVERYONE involved in the learning process. We rollout training quickly and efficiently. After the rollout, your staff won't complain of poor quality content or inattentive customer support.

> Role-based content ensures that learners receive information that's relevant to THEIR job function. **When employees pay attention, you reduce your risk.**
>
> Text-based courses with static, outdated information are boring! **Engaging, professionally designed multimedia content is more effective than page-turning text.**
>
> HCCS is the leading provider of online multimedia compliance and competency training courses with **over 2 million registered learners.**

All of this contributes to a better, more effective educational experience, greater compliance and reduced risk for your organization.

Research Compliance Suite

Grants and Contracts
Human Subjects Protection
Conflicts of Interest and Research Misconduct
Professional Relationships and Data Issues

Workplace Compliance Suite

Preventing Sexual Harassment for Healthcare Organizations
Identity Theft Prevention
Preventing Conflicts of Interest
Responsible Use of Social Media in Healthcare - ***New***

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

hccs
A *HealthStream*® Company

Nancy Beckley, MS, MBA, CHC
President
Nancy Beckley & Associates LLC
Milwaukee

an interview by Adam Turteltaub, CCEP, CHC

Meet Nancy Beckley

This interview with **Nancy Beckley** (nancy@nancybeckley.com), President of Nancy Beckley & Associates LLC, was conducted by **Adam Turteltaub** (adam.turteltaub@corporatecompliance.org), SCCE/HCCA Vice President of Membership Development, in late spring 2014.

/in/nancybeckley *@nancybeckley* *+NancyBeckley*
bit.ly/in-AdamTurteltaub *@AdamTurteltaub*

AT: Compliance people come from a lot of different backgrounds, but not too many have a background as a therapist. How did your career there turn into one in Compliance?

NB: My inpatient career was spent in two major hospitals with inpatient rehab facilities, where I enjoyed experiences with spinal cord injured patients, as well as developing wheelchair sports and community integration programs. When I started as a consultant, the hot topic was managed care. Shortly thereafter however, the Balanced Budget Act of 1997 created havoc throughout the post-acute industry and consulting demand was in the Medicare sector. In 1998, the OIG published the first compliance guidance for hospitals, and I quickly pulled together a national seminar for rehab hospitals on corporate compliance utilizing the OIG compliance guidance. That was my official debut in Compliance.

AT: How does your therapy background help you in the position?

NB: I can remember the day that charges for therapy went to $60 per hour at my rehab hospital, and thinking to myself, "Wow, therapy is $1 per minute." Since that day over 30 years ago, I have had a keen sense for looking at things from an ethical and compliance

perspective. During much of my inpatient career, I was involved in wheelchair sports, adapted aquatics, and community recreation integration programs, with the hospital risk manager on speed dial to approve everything from pet therapy, wheelchair boating and water skiing, quad rugby (called "murder ball"), and wheelchair basketball games with local NFL celebrities, as well as being involved in sponsorship of the wheelchair division of a sanctioned 15K road race. Little did I know that vetting all these risk-taking recreational activities for those in inpatient rehab (and recently discharged) would be a foundation for a compliance career.

AT: You also served for many years as a healthcare administrator. What do you think compliance professionals don't get about healthcare administrators?

NB: As a consultant I have the pleasure of working with providers both large and small, from small therapy practices to hospitals and networks. The challenge I most often see is that compliance officers and administrators may be looking at the same set of data, but see different questions and different solutions. Nowhere is this more readily apparent than in audit findings that may suggest concerns over billing practices, policy implementation, and/or potential refunds and paybacks.

AT: What do you think they don't get about clinicians?

NB: In the therapy world, there are a lot of clinicians who move up into administrative roles. There is a voice in the back of their head that speaks "therapy." Inherent in that is a passion for patient care and ensuring that patients receive the best they have to offer. Now I see a movement in the therapy (and other clinical areas) world of clinicians becoming compliance officers and seeking certification. When I first joined HCCA, there was less than a handful of therapy professionals certified, now there are enough that I am hoping to reach out through social networking to communicate on common issues and concerns, and have a meet-up at the Compliance Institute at Disney next year.

AT: Anyone who works in healthcare or has ever had a procedure knows we increasingly work in an outpatient world. What are some of the particular compliance challenges of outpatient practices in general?

NB: Outpatient often falls off the radar in the compliance world, until there is an audit at the facility. This can be a probe audit, RAC audit, or a survey and certification site visit. Even though the Medicare Strike Force dragnets often focus on outpatient services (including a lot of sham therapy services), most providers don't relate to the lessons learned from these criminal take-downs. To address this challenge, I suggest outpatient providers, particularly those not in the comfort of a healthcare system, undertake a risk assessment and begin developing an audit plan as well as scheduling routine monitoring activities that are designed to prevent problems as they are about to happen (or be billed!). Another thing that is essential for the small provider is what I call a "Red Envelope Policy," which includes what to do when an investigator/auditor knocks on your door. The packet includes the facility policy on cooperation, a "Dear Investigator" letter, guidance to the employee on how to proceed based upon the credentials that are presented

Outpatient often falls off the radar in the compliance world, until there is an audit at the facility.

(including search warrant vs. subpoena). I had the pleasure of presenting on the Red Envelope several years ago at the Compliance Institute, along with co-presenters Lynn McGivern and Brian Annulis.

AT: Are there unique challenges for rehab programs, both inpatient and outpatient?

NB: Do we have all day to discuss? Indeed, there are challenges. For example, there is a different definition of "group therapy" for inpatient skilled nursing facilities (SNF), inpatient rehab facilities (IRF), and for outpatient therapy. Supervision requirements for students and therapy assistants vary by type of Medicare status and/or certification. For example, in an outpatient setting a physical therapist assistant must have direct supervision in the office suite, whereas the same therapy assistant needs only general supervision in a rehab agency, SNF, hospital, or comprehensive outpatient rehab facility (CORF). Small providers are challenged to stay abreast of all the rules and regulations, train their employees on the regulations, and audit to determine compliance. Many small providers seek information in general list serves, or other web-based groups. Often the information is inaccurate, but it is relied on when making coding and billing decisions. In fact, at one of the CI sessions this year, a speaker from the OIG indicated that when a provider pleads ignorance of a rule or policy, and it is found out that they sought information (that they relied on) from a non-official source, that it can be discovered through software that scours the provider's emails.

AT: How did your membership in HCCA help you transition into the Compliance profession?

NB: It wasn't so much a transition as an immersion. After joining HCCA, I immediately sought out ways to be involved (which I recommend to all new members). I have spoken at the Florida Regional Conference, the Physician Practice Compliance Conference, and the Compliance Institute. At the CI, I have volunteered every year to introduce a speaker and have participated in a Saturday community volunteer project. I have also authored articles for *Compliance Today*, and I have been asked to write a bimonthly column on social media. Attending my first Compliance Institute as a member was incredible, and I still have that name badge with the ribbons—CHC, Rehabilitation, and HCCA Member—to remind me of the incredible thought provoking learning experience it was.

AT: I see you are Certified in Healthcare Compliance (CHC). Why did you seek that certification?

NB: My compliance career was well underway when L.T. Lafferty, then an AUSA [Assistant U.S. Attorney] in Tampa convinced me that seeking certification would open up the world of compliance in a totally different way, and I would never look back. At the time he was convincing me, we were in a group bonding/trust exercise as part of the leadership development program for the local Chamber of Commerce, and I trusted him to catch me if I fell off the log we were on. I didn't fall off the log as we crisscrossed each other to the end! I quickly enrolled in the next available Compliance Academy! (BTW, L.T. was right—I was opened up to a whole new world of compliance.)

AT: You're an avid user of social media. Which ones do you use the most?

NB: I like the fast pace of Twitter and find value in the fast access to information, particularly healthcare topics and compliance topics. Facebook is second, but I use that to connect with childhood pals, college friends, and family, and keep it strictly personal. I find YouTube invaluable for a variety of topics such as the OIG videos, compliance training videos others have posted, and of course, for finding

MEDITRACT®

A new chapter starts today...

For over a decade, MediTract has earned the trust of many of the most respected hospitals in the U.S. by transforming their contract management processes and reducing their risk of non-compliance.

We are now proud to unveil our bold new look. A look that embodies our continued evolution as the leading healthcare-focused compliance and contract management company and illustrates our tireless commitment to our hospital clients.

MediTract®

Call or email one of our trusted advisors today.
Or go to MediTract.com/getanswers

meditract.com • info@meditract.com • (423) 414-3788

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.

To learn more about Compliance 360 for Healthcare: please visit www.compliance360.com/healthcare

GET THE 360° VIEW.

www.compliance360.com

SAI GLOBAL
COMPLIANCE 360® GRC SOLUTIONS

my way out of computer and software dilemmas. I am experimenting with others. Stay tuned to the social media column.

AT: Many in Compliance find social media to be a bottomless hole of risks. Are they right to be so concerned?

NB: No argument from me on the myriad risks involved in today's media world—and compliance officers have to be concerned over their organization's policy on the use of social media during work hours, as well as the official social media presence that is managed by their Marketing or Public Relations department. But the flip side is the tremendous value that is probably yet to be realized or understood. As compliance officers, we just have to keep pace with the associated risk assessments.

The one mistake all compliance officers want to avoid is not having a social media policy that is current and up to date…

AT: We certainly see the concern in our own social network. Of the thousands of members we have on our social media site (HCCA*net*®, *hcca-info.org/hccanet*), just a few hundred (if that) post messages, while the rest just read. How would you advise someone thinking about jumping in?

NB: Just recently I jumped in at HCCA*net*, looking for a fellow compliance colleague to offer advice on the DME [durable medical equipment] competitive bidding process. I got a response immediately. That is the value in reaching out, as HCCA members are there to lend a helping hand. The value in the HCCA website is that compliance professionals tend to offer citations and references, whereas in other forums there may be a lot of opinions offered, but as we know, compliance folks like to nail down the regulatory information and statutory references. It is acceptable to lurk to follow the threads. That way, a new user can get a sense of the community that is present and willing to assist, and feel more confident about jumping in to make a comment or post a request.

AT: What are some mistakes for compliance people to avoid with social media?

NB: I think a good policy is to "look before you leap." If you are posting from a business account, and using a platform that can aggregate postings to multiple social media platforms for both personal and business, it is important to ensure posting from the right account. The one mistake all compliance officers want to avoid is not having a social media policy that is current and up to date, which should go without saying, that your social media policy may be a provider's most frequently updated policy.

AT: Do you see it as being a communications tool for compliance teams and the businesses they serve?

NB: Each compliance team has to see a particular social media platform as a tool for effective use. For example, using YouTube for training videos may be something more concrete than Facebook or Twitter for the compliance officer to understand in this context. YouTube can be used for internal compliance training videos, compliance refreshers following an audit, or simply to provide a compliance commitment statement from the CEO that is posted to your website. I listened to a webinar the other day on compliance related to checking for excluded individuals and entities. Live

during the webinar, we had the opportunity to Tweet responses to polling questions. The numbers rolled up "live" as the Tweets came in. Another great opportunity is in doing compliance surveys that are scheduled for a pre-set time. I worked with a large provider on a survey that was rolled out during Compliance Week, and I watched the survey results come in live on my smartphone and tablet in graphic chart form as well as numerically. There was absolutely no waiting, and the metrics had a beautiful graphical interface in pie charts and bar graphs in real time.

AT: How do you see social media evolving?

NB: I am going to defer that question to colleagues in Silicon Valley! Seriously we know that Twitter and Facebook have a huge base, and are finding their way not only with making revenue, but technologically evolving. The way we think about data, photos, security, communication, privacy, security, and compliance in general not only has to evolve real time, but perhaps be part of the time-lapse photography, so to speak.

AT: And how do you see Compliance evolving?

NB: Each year at the CI I see more clinicians involved and engaged, and that will continue to evolve. But I also see the bridge being crossed to our friends in the corporate world through the Society for Corporate Compliance and Ethics. Compliance professionals in healthcare can learn much from colleagues in the corporate world, and we have much to share. My own evolution in this area has come from following corporate compliance Tweeters for their tidbits of wisdom and insight into valuable compliance resources.

AT: Thank you, Nancy, for sharing your insights with us.

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

Get your foot in the door

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

As compliance professionals, we sometimes receive inquiries on how to get into the compliance profession. Many who have been in the profession for more than 15 years entered the career out of default, and certifications and courses were not available. Further, there is no definitive degree or background that ensures a position in the field.

DeGroot

First, be self-aware of your motivation for joining the field. Salary is important; however, if that is the motivating factor, the career choice may not be long-term. There are a couple key characteristics needed to be successful:

Ability to multi-task

Individuals enter the career thinking a typical day involves writing policies and attending meetings. In fact, a typical day is multiple "fires" and prioritizing what emergency, identified by others, needs immediate attention. Add to it the workload of investigations, potential whistleblowers, and the pressure that can mount when discerning the truth and consequences.

Skills in messaging

- Delivering a concise message is important. More important is the ability to speak to the audience, at their level, in an applicable format for true understanding and comprehension.
- Accept that you will be the messenger, whether good or bad news. Don't take resistance to the message personally.

Now, if your motivating factor for joining the field is to enhance business integrity, then it is time to take the next step.

Once you are aware of your motivation, there are other actions to consider:

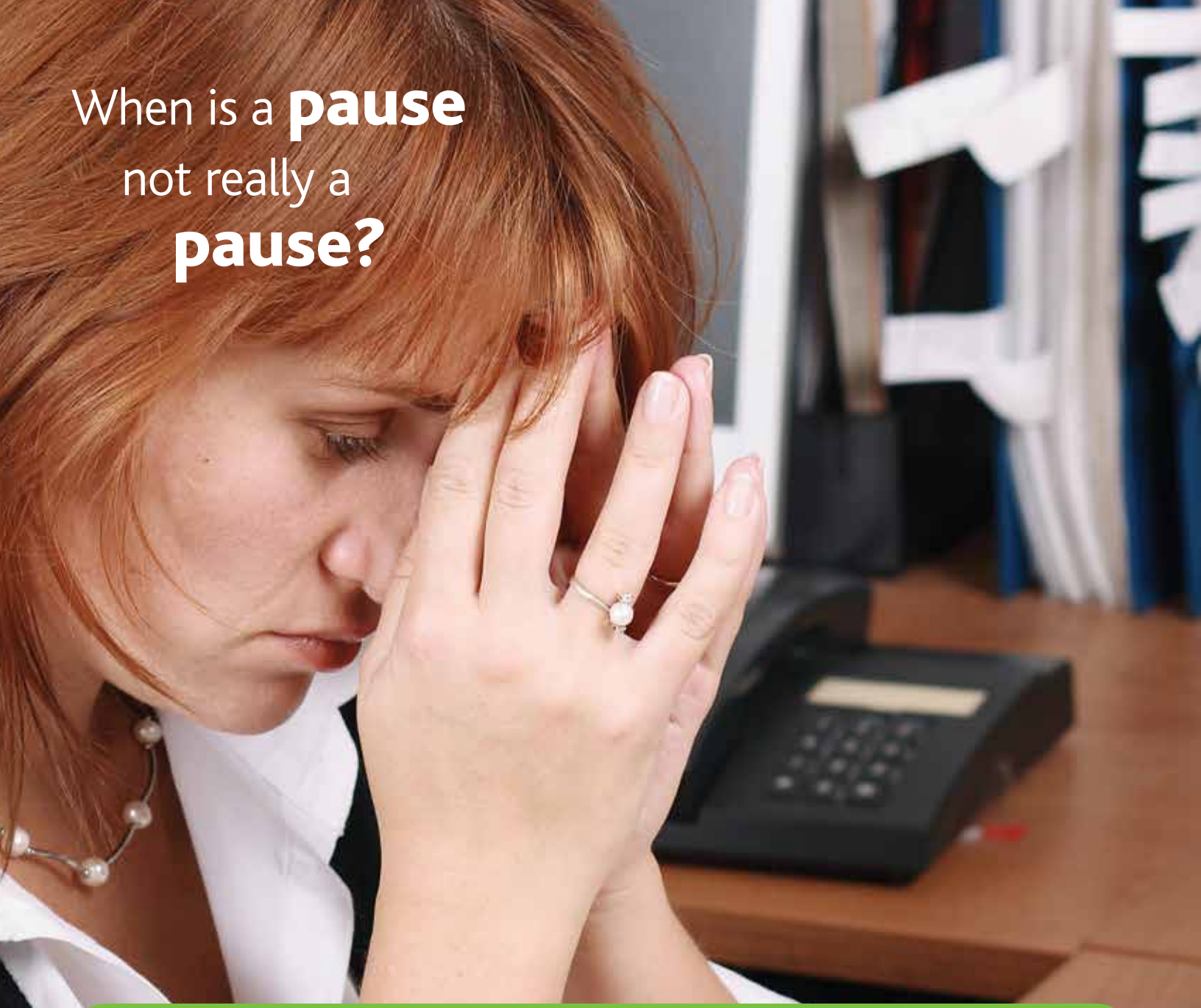
When an open position is posted

- Follow up with HR on every level, and attempt to work with one individual on the application, interview schedule, and tentative timeframe.
- Update your LinkedIn page regularly by highlighting your strengths, community, and professional association involvement.
- Following an interview, always send a letter (within 24 hours) to the person(s) you met —including the HR representative—and re-emphasize your desire for the role and your top three strengths of what you could offer the organization. An email simply does not suffice.

When no open position is posted

- Send a letter to the HR vice president or a contact within the organization who could facilitate sharing your contact information.
- Inquire/offer to perform an internship (without a salary). Consider the act an investment in your future.
- Schedule a 15-minute meeting with the current compliance officer and introduce yourself.
- Network with multiple compliance professionals through HCCA and LinkedIn proactively, prior to needing a job.
- Market yourself by writing, speaking, co-authoring, and/or co-speaking.

Finally, believe in yourself, because with the right attitude and passion, a door will open.



Proactively manage all your claims-based audits with

ComplyTrack Claims Audits

While the CMS RAC program is on temporary hiatus, the other auditors are not. And with $5.7B already collected from providers and the funding for the ACA on the line, you can be sure the RAC program will return with a vengeance. **ComplyTrack Claims Audits**, designed to put you in control of the complete claims audit life cycle, provides the flexibility to manage not only requests from RACs, but also from MACs, MICs, ZPICs, and commercial payer audits. Take advantage of this time—get the solution you need to stay ahead of all the auditors and protect your bottom line.

complytrack.com

Wolters Kluwer
Law & Business

by Tomi Hagan, MSN, RNC

Supervision of outpatient therapeutic services in the critical access hospital

» Critical access hospitals are now required to comply with the Supervision of Hospital Outpatient Therapeutic Services policy as a condition for Medicare payment.

» Direct supervision is required for all outpatient therapeutic services except for those designated for modified levels.

» Modified levels of supervision include general, personal, and the two-tiered non-surgical extended duration therapeutic service.

» Challenges facing critical access hospitals include identification of services, availability of qualified supervisory practitioners, mid-level provider restrictions, and limitations in the Emergency Department and rural health clinic.

» Steps to compliance include assessment of services provided, identification of supervisory practitioners, documentation, education, and monitoring.

Tomi Hagan *(tkhagan@saint-lukes.org) is Ethics & Compliance Program Manager for Saint Luke's Health System in Kansas City, MO.*

bit.ly/HCCAnet-TomiHagan *bit.ly/in-TomiHagan* *@TomiHagan*

The release of the 2014 Outpatient Prospective Payment System (OPPS) final rule signaled an end to the four-year moratorium on enforcement of the Supervision of Hospital Outpatient Therapeutic Services policy (aka, the Direct Physician Supervision of Outpatient Therapy rule) for critical access hospitals (CAHs). Despite the efforts of several state hospital associations, the American Hospital Association, and various legislators, the Centers for Medicare & Medicaid Services (CMS) maintained that direct supervision is the most appropriate level of supervision for outpatient therapeutic services. Compliance with this Medicare condition of payment may be burdensome and even impossible for some rural hospitals.

Hagan

History

In the 2009 OPPS final rule, CMS clarified their policy on direct supervision, stating, "It has been our expectation that hospital outpatient therapeutic services are provided under the direct supervision of physicians in the hospital and in all provider-based departments of the hospital, specifically both on-campus and off-campus."[1] The guidance pointed out that Medicare payment for the services in question is provided "incident to" the services of the physicians. In 2010, the OPPS final rule noted that the standard does apply to CAH; however, enforcement for CAHs was delayed due to concerns regarding CAHs' and small rural hospitals' ability to comply with the standard.[2] That delay continued through the end of 2013.

According to CMS, direct supervision requires the physician or non-physician provider to be "immediately available to furnish assistance and direction throughout the performance of the procedure."[3] The definition of "immediately available" has evolved over the past four

years, with no specified physical boundary in the current definition; however, the supervisory provider must meet the following criteria:

- Nearby physical presence (telephone and telemedicine do not meet the standard)
- Able to be interrupted
- Knowledge, skills, ability, and hospital privileges to perform the service

Direct supervision is the standard established by CMS, but they have created modified standards for certain services. In 2012, the Hospital Outpatient Panel (HOP, formerly the Advisory Panel on Ambulatory Payment Classification Groups) was charged with evaluating concerns and making recommendations to CMS regarding levels of supervision for specific outpatient therapeutic services.

Modified levels of supervision

General supervision does not require the supervisory practitioner to be immediately available. The procedure is provided under his/her overall direction and control, with the supervisory practitioner responsible for the training of the personnel performing the procedure and the maintenance of the equipment and supplies. Personal supervision is provided with the supervisory practitioner in the room throughout the procedure.[4]

A two-tiered supervision category, nonsurgical extended duration therapeutic service (NSEDTS) is gaining favor with the HOP panel. These services require direct supervision during the initiation period of the procedure, switching to general supervision when that period is complete. Initiation ends when the supervisory practitioner deems the patient to be stable.

Challenges

CAHs and other small rural hospitals face many challenges to compliance with the direct supervision requirements. Legislators and healthcare leaders fear that these challenges may lead to closure of facilities, thus further limiting access to care. Concerns include identification of services required to be provided under direct supervision, availability of qualified supervisory practitioners, mid-level provider restrictions, and limitations on reliance of Emergency Department (ED) and rural health clinic providers for direct supervision.

Legislators and healthcare leaders fear that these challenges may lead to closure of facilities…

CMS does not provide a list of services that are required to be provided under direct supervision. Hospitals must assume that all outpatient therapeutic services are to be provided under direct supervision, unless otherwise specified in the CMS Supervision File for hospital outpatient services.[5] CMS defines these as:

> Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities and drugs and biologicals that cannot be self-administered) which are not diagnostic services, are furnished to outpatients incident to the services of physicians and practitioners and which aid them in the treatment of patients.[6]

The hospital must also consider that outpatient status includes services provided in the clinic, ED, and under Observation. Physical therapy, occupational therapy, and speech therapy are reimbursed under the Medicare Physician Fee Schedule rather than OPPS; therefore these services are not subject to the same supervision requirements.

The provider must have hospital-granted privileges and be able to perform the outpatient therapeutic services that he/she is supervising. This can prove to be difficult for certain specialty services, such as chemotherapy. Prior to the implementation of this policy, many CAH-administered chemotherapy procedures were ordered and managed by specialty clinic providers who see patients at the CAH periodically. Family practitioners and other providers at the CAH were not necessarily privileged for chemotherapy or other specialized services. Compliance with the direct supervision policy may require additional education and training for physicians and mid-level providers.

Hospitals must exercise caution when utilizing mid-level providers to meet the direct supervision requirements. The list of qualified non-physician practitioners (NPPs) is specific and does not include certified registered nurse anesthetists (CRNAs). As with physicians, the mid-level provider must have the knowledge, skills, ability, and hospital privileges to perform the procedure. Also, cardiac rehabilitation, pulmonary rehabilitation, and intensive cardiac rehabilitation services covered by Medicare are required to be furnished under the direct supervision of a physician only, not an NPP.

The use of ED providers for direct supervision has been discussed at length. One concern is that these providers may not always be "interruptible." CMS had advised CAHs that ED providers may directly supervise outpatient services; however, the provider must be immediately available and "clinically appropriate."[7] The CAH must carefully assess the risk associated with providing outpatient services under the direct supervision of an ED provider; however, it may be acceptable for some small hospitals with low volumes. Outpatient therapeutic services may not be billed to Medicare if the supervisory practitioner cannot be interrupted to furnish assistance and direction in the treatment of the outpatient. The 30-minute response time required of ED providers in the CAH does not eliminate the "immediately available" requirement for direct supervision.

In January 2014, guidance was issued to the Kansas Hospital Association (KHA) advising that providers working in a rural health clinic (RHC) in close proximity to the hospital may not provide direct supervision for outpatient therapeutic services at the hospital at the same time. In a subsequent Open Door Forum on February 20, 2014, the CMS representative reiterated that position, citing potential issues with credentialing, RHC availability requirements, and cost reporting. Many RHC providers are, in fact, credentialed at CAHs. Furthermore, many of the RHCs employ more than one provider, thus ensuring that a provider is available for RHC patients, even if one is called to the hospital to provide direct supervision services. Follow-up emails from CMS suggested that utilizing the RHC provider to perform direct supervision may be acceptable, but could become a cost reporting issue if the provider is called away frequently for long periods of time, thus requiring his/her time to be carved out. To date, no official policy has been issued by CMS regarding RHC providers meeting direct supervision requirements at the CAH.

Future

Legislation (Senate bill 1954), designed to ease the direct supervision burden on CAHs by delaying once again the enforcement passed the Senate on February 10, 2014, and H.R. 4067 was referred to Committee on February 18, 2014. The Protecting Access to Rural Therapy Services (PARTS) Act was introduced in 2013 as an attempt to provide a permanent solution by changing the default supervisory requirement to general rather than direct, while acknowledging that certain complex services may still require direct supervision. The PARTS Act remains in Committee at this time. Amendments to the Sustainable Growth

Rate (SGR) replacement legislation to return the supervision requirement to general for CAHs have also been introduced. The outcome of any or all of this legislation would greatly impact the financial and regulatory burden on CAH.

CMS has released preliminary recommendations for the 2014 level-of-supervision changes suggested by the HOP.[8] The recommendation for chemotherapy remains direct supervision, while the recommendation for blood transfusion changes from direct to NSEDTS. Other changes include decreasing level of supervision from direct to general for activity therapy, declotting of an implanted vascular access device or catheter, arterial puncture, and manipulation of the chest wall. Change from NSEDTS to general is suggested for subcutaneous infusion in subsequent hours; however, the initial procedure and up to one hour after remain under NSEDTS. Decisions were final and effective on July 1, 2014.

Compliance

An initial assessment of the types of outpatient therapeutic services provided, location of the services provided, and the hours of service gives the CAH a starting point for compliance with the direct supervision for outpatient therapeutic services requirements. Then, the CAH can identify the providers available and qualified to provide the appropriate level of supervision for each service, and determine the best methods to document compliance. A simple spreadsheet tool can be utilized to provide initial assessment and ongoing monitoring.

The only documentation required in the medical record is the transition from direct supervision to general when providing services under NSEDTS. Nursing or physician notes should include a clear, timed statement indicating that the patient is stable and the level of supervision is changing. Many CAHs have opted to take the documentation a step further and include the name of the supervisory

practitioner and/or level of supervision provided for the service. This documentation serves to show compliance as well as to ensure that the staff members providing the care are clear as to who is providing supervision.

The details regarding the provision of outpatient therapeutic services under the appropriate supervision level should also be memorialized. One option is to include in the departmental Scopes of Services the manner in which the department will meet the requirements. Hospitals may have to make operational changes to comply with the requirements, including alterations in scheduling to ensure that Medicare patients are billed only for services provided during specific hours when a supervisory practitioner is immediately available, implementation of a hospitalist program, and changes in physician privileges.

The CMS Medicare Benefit Policy Manual indicates that CMS expects hospitals to have credentialing procedures, bylaws, and policies in place to ensure compliance with the direct supervision requirements.[9] Privileging procedures should include provisions for ensuring that physicians and NPP are appropriately privileged for the outpatient therapeutic services they will be supervising. Hospital medical staff bylaws must be reviewed and revised to include language indicating that hospital outpatient services provided to Medicare beneficiaries will be appropriately supervised. Additional policies and procedures should be implemented to provide guidance to staff and providers.

Education to staff and physicians regarding the direct supervision requirements is crucial. Supervisory practitioners need to understand what services they are supervising, what their obligations are, and how to meet the "immediately available" standard. Staff providing the services must also know who is providing the supervision and what levels of supervision are required for the various procedures. Physicians, NPPs, and staff need to understand that the direct supervision rule goes beyond emergency response; the provider must be prepared to take over the performance of the procedure, change the procedure or course of treatment, and provide direction to staff.[10]

Compliance staff should conduct a periodic assessment of outpatient therapeutic services provided and compliance with direct supervision requirements. As service lines are added, discontinued, and changed, the Compliance department should be made aware so that policies and Scopes of Services may be updated.

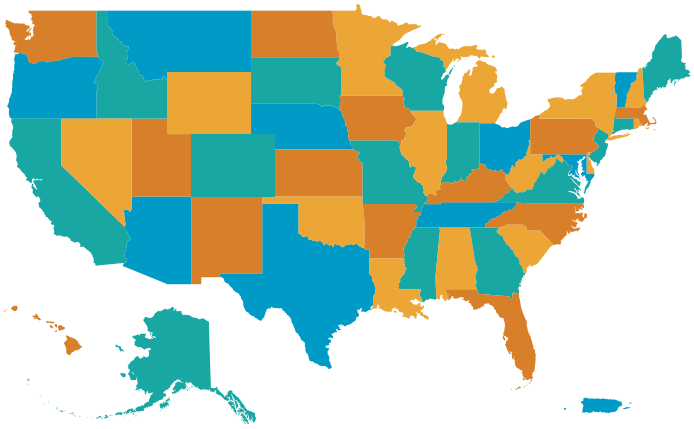
Conclusion

Compliance with the Supervision of Hospital Outpatient Therapeutic Services policy can be daunting for the CAH. Although national and state hospital associations and legislators continue to lobby for relief, CAHs must be in compliance at this time to meet the Medicare conditions of payment. Steps to compliance include assessing the services provided at the facility, identifying the individuals available and qualified to provide the appropriate level of supervision, determining the best method to document compliance, and implementing policies and procedures. Periodic assessment should be performed to monitor for continued compliance with the requirements.

1. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates. 73 Federal Register, 68702, November 18, 2008. Available at: http://1.usa.gov/1sclZDK
2. Department of Health & Human Services, CMS: Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates. 74 Federal Register, 60575, November 20, 2009. Available at: http://1.usa.gov/1zTWRTg
3. Code of Federal Regulations: Supplementary Medical Insurance (SMI) Benefits, Title 42, sec. 410.28. Available at http://bit.ly/1svBDHZ
4. Id at sec. 410.32.
5. CMS: Supervision File-Hospital Outpatient Therapeutic Services, June 2014. Available at: http://go.cms.gov/1scnz8I
6. CMS: Diagnostic x-ray test, diagnostic laboratory tests, and other diagnostic tests: Conditions. Code of Federal Regulations, Supplementary Medical Insurance (SMI) Benefits, title 42, sec. 410.27.
7. CMS: Common Questions about Supervisions Requirements for Medicare Payment of Hospital Outpatient Services, April 23, 2010. Available at: http://bit.ly/1pakSCe
8. CMS: CMS' Preliminary Decisions on the Recommendations of the Hospital Outpatient Payment Panel on Supervision Levels for Select Services, March 10, 2014. Available at: http://go.cms.gov/1svDCfC
9. CMS: Medicare Benefit Policy Manual, Chapter 6, Section 20.5, March 21, 2014. Available online at: http://go.cms.gov/1nMKVwM
10. Id.

Register now for HCCA's remaining
2014 Regional Conferences

Get high-quality, convenient, inexpensive education and networking opportunities. Don't miss the chance to attend an HCCA Regional Conference in your area!



Questions: beckie.smith@hcca-info.org

New England
September 12 • Boston, MA

Upper Midwest
September 19 • Minneapolis, MN

Midwest
September 29 • Overland Park, KS

North Central
October 6 • Indianapolis, IN

East Central
October 10 • Pittsburgh, PA

Hawaii
October 16–17 • Honolulu, HI

Mountain
October 24 • Denver, CO

Mid Central
November 7 • Louisville, KY

Desert Southwest
November 14 • Scottsdale, AZ

South Central
November 21 • Nashville, TN

Upper West Coast
December 5 • San Francisco, CA

Gulf Coast
December 12 • Houston, TX

LEARN MORE & REGISTER AT
www.hcca-info.org/regionals

by Karen Nelson

Regulatory delays: Hurry up and wait

» Regulatory delays can create challenges for healthcare organizations.
» New laws are subject to interpretation by governmental agencies and courts.
» The regulatory process allows for public participation and readjustment, giving healthcare organizations an opportunity for advocacy.
» Governmental agencies seek to balance the needs of healthcare organizations and other stakeholders.
» Regulatory delays can be managed successfully.

Karen Nelson *(karen.nelson@dlapiper.com) is Of Counsel in the Austin, TX office of the DLA Piper law firm. She is a former Chief Counsel to the Texas HHS Commission Office of Inspector General.* bit.ly/in-KarenNelson

Although the phrase "Hurry up and wait" has been associated most commonly with the military, it is also applied to businesses when the speed of incoming communications outpaces an office's ability to process the information. Now, it may also be appropriate to apply the phrase to healthcare regulatory deployment and enforcement.

Nelson

In recent months, the government has scheduled and postponed a number of regulatory initiatives. The most widely publicized delays involved the enrollment deadlines associated with the insurance exchanges and the *healthcare.gov* website. Other examples include the two-midnight rule for hospital observation periods, Medicare RAC audits, and the crossover to ICD-10.

This trend presents a unique set of challenges for the compliance professional. For those who are fortunate enough to work in an environment that takes a proactive approach to compliance, the organization may be disadvantaged by investing resources too soon. For those who work in institutions with more resistance toward compliance, the consequences can be even worse, because regulatory delays, even though they are out of the compliance professional's control, can undermine the Compliance function's credibility. Therefore, it becomes critical for compliance professionals to understand how to explain and manage delays in regulatory initiatives with key executives and stakeholders.

Why does this happen?

To place these delays into a broader context, it is helpful to review how regulatory changes occur. For example, many of the recent healthcare integrity initiatives stem from the Affordable Care Act (ACA). Some of the legislators who voted in favor of the ACA had developed expertise in healthcare policy, but many others ran for Congress due to their interest in other issues, such as education, crime, taxation, or foreign policy. Legislators are responsible for passing bills on an astonishing range of subjects, and most do not have the resources to research the operational details of every bill. Therefore, statutes tend to be drafted in very broad language that identifies the objectives of the law, and Congress leaves the details of implementation to federal and state agencies.

Agencies like the Department of Health and Human Services are vested with authority to interpret, implement, or prescribe law or policy. They are also authorized to describe the agency's policies, procedures, and practice requirements, as well as to set and approve rates or prices.[1] States and federal agencies generally exercise these powers through the administrative rule-making process.

Under most circumstances, an agency must notify the general public of any proposed rule. The notice must include the time, place, and nature of the rule-making proceedings, such as public hearings, a reference to the legal authority that supports the rule, and either the text of the proposed rule or a description of the subjects and issues involved.[2]

If the agency does not conduct a public hearing, it must give any interested persons an opportunity to participate in the rule-making process by submitting written data, views, or arguments, and the agency must consider those submissions before publishing the adopted rules.[3] If a public hearing is held, the agency has the burden of proof in propounding the rule. Interested parties may submit oral or documentary evidence, but the agency can exclude immaterial, irrelevant, or unduly repetitious evidence and may require that all submissions be in writing.[4]

When a proposed rule package contains significant changes, the public response period may remain open for months. Agencies review each submitted comment and may make changes to the final rule in response to compelling arguments. If the agency disagrees with the commenter's position, it will still submit its response and rationale to the Federal Register when the final rules are published. The final rules must be published at least 30 days before their effective date.[5]

Some delays in rule adoption arise out of the public comment process. Although the delays may seem inconvenient, they are often a sign that the system is working.

Some delays in rule adoption arise out of the public comment process. Although the delays may seem inconvenient, they are often a sign that the system is working. Providers and stakeholders have been given an opportunity to provide comments on proposed regulations, and delays can indicate that the public's concerns have been heard and considered seriously. An agency may be persuaded that its proposed rule creates unforeseen obstacles or is particularly unworkable for major stakeholders. In that event, it may completely reassess certain rule provisions and start crafting other solutions, extending the comment period in the meantime.

Some delays occur because agencies may be just as ill-equipped as the private sector to meet the requirements of new legislation. Agencies may find that they must first reorganize their own processes before they are in a position to exercise oversight.

Some delays occur due to litigation and court opinions that add interpretative layers or set aside portions of the underlying law. Such opinions may cause legislators and agency officials to redefine their understanding of the law, reevaluate their prior efforts, and make necessary adjustments to their processes, all of which require time to implement.

Effects on healthcare organizations

When a regulatory change is announced and then retracted, the events can affect healthcare organizations and other stakeholders in various ways. Some find it frustrating to deal with a shifting target. Agencies may publish ambiguous or even conflicting guidance in the early days of implementation as the parameters of a new law are established, and the uncertainty can cause discomfort.

A healthcare organization may find it necessary to repeat training modules as the new deadline approaches, maintain the cost of ongoing transitional systems, and invest the man-hours needed to duplicate its rollout efforts. It may find that it invested in automated solutions or other systems that no longer satisfy the requirements of a revised regulatory framework. Also, organizations sometimes spend funds on new implementation measures long before they become necessary, thus losing the opportunity to apply those resources toward other objectives in the meantime. All of these circumstances may create negative fiscal impacts to the organization.

A healthcare organization may find it necessary to repeat training modules as the new deadline approaches, maintain the cost of ongoing transitional systems, and invest the man-hours needed to duplicate its rollout efforts.

Delays in regulatory implementation and enforcement can reinforce the viewpoint that it is not necessary to prepare properly, and thereby erode confidence in the need for an effective compliance program. The compliance professional may be undermined after his/her calls to prepare for new regulations seem unnecessary. Once this credibility is compromised, it becomes more difficult to build support for future compliance-related initiatives.

Opportunities for solutions

Although democracy is a messy, uneven process, it creates opportunities to participate in the dialogue before new regulatory schemes are finalized. Healthcare organizations that participate in the process are often rewarded with more workable, attainable regulatory requirements. Even if a final rule has already been adopted, any interested person has the right to petition for the issuance, amendment, or repeal of a rule.[6] The best results, however, will come from commenting early in the process, before regulators have already invested resources in a different approach.

Providers should confer with legal counsel and experts who are experienced in the administrative process, and work collaboratively with them in advocating before agency officials. A fundamental premise of administrative law is that regulations cannot contradict their enabling statues. Moreover, agencies are vested with a certain amount of implied authority to develop regulations, but that power has limits. Experienced counsel can help organizations understand the limits of agency authority.

Adopt a long-term viewpoint. With major pieces of legislation, such as the Affordable Care Act, it may take years for the initial challenges and interpretations to work their way through the administrative and judicial processes. Although agencies may find it necessary to delay enforcement, they cannot disregard statutory requirements. The final rule or enforcement date may change in some respects, but eventually enforcement will come.

In the meantime, appreciate the inherent gifts in a delay. If an organization has already implemented new solutions, the delay provides an opportunity to refine its processes and to work out any difficulties before the deadline, allowing for a more efficient transition. Delays may also afford an opportunity to spread related expenditures over a longer period. Furthermore, an organization can adjust its training schedules to allow for the absorption of less information over longer periods of time, resulting in better retention. By analogy, new training can be treated like a semester of learning, rather than cramming for an exam.

Finally, recognize that rule or enforcement delays often work to the benefit of healthcare organizations. Government agencies depend upon members of the healthcare industry to deliver legally-required healthcare services to our most vulnerable citizens. Officials must sustain a delicate balance between collaboration and enforcement. Agency officials generally try to remain sensitive to healthcare organizations' concerns, and delays are often designed to afford more time or flexibility to them. It is in the government's best interest to help these organizations succeed.

Conclusion

Although enforcement delays create challenges for healthcare organizations, they also open opportunities for improvement in rapidly-changing regulatory schemes. This is the time to develop familiarity with the process and begin exploring the advantages of healthcare advocacy.

1. 5 U.S.C. §§ 551(4), 553.
2. 5 U.S.C. § 553(b).
3. 5 U.S.C. § 553(c).
4. 5 U.S.C. § 556(d).
5. 5 U.S.C. § 553(d).
6. 5 U.S.C. § 553(e).

by Dean Boland

Be prepared for eDiscovery

» Litigation is inevitable and electronic data is the first front.
» Updating/auditing IT in preparation for litigation is necessary.
» eDiscovery is not a set-it-up-and-forget-it proposition.
» Inside counsel must understand technology sufficiently to manage eDiscovery.
» Different technology specialties have different functions; not all are eDiscovery capable.

Dean Boland *(dean@complyus.com) is the founder and CEO of ComplyUS, LLC in Cleveland. ComplyUS provides outsourced healthcare and HIPAA compliance program services to small healthcare providers and business associates.*
www.complyus.com

Since the adoption of the amendments to the Federal Rules of Civil Procedure, the presence of eDiscovery issues in litigation has increased annually.[1] That is not solely a result of those rules, but also stems from the inevitable increase in the use of electronic devices to store and transmit information. To be sure, eDiscovery was an issue before 2006. I had been teaching courses on eDiscovery to lawyers, judges, and others for years before the federal rules were adopted. What came from those rules was, of course, litigation. Out of that litigation, some general directives emerged for lawyers and other professionals creating, using, and managing electronically stored information (ESI) in their business operations.


Boland

Keep it or destroy it

Any good lawyer today will include in any initial discovery requests (i.e., the court-backed requests for information during litigation) the request to see the opposing side's ESI. No matter the size of organization, the availability of ESI means it will always be subject to those requests. In fact, a savvy lawyer should make it his/her first request for information.

Your organization ought to have a written document destruction/retention policy that encompasses ESI. But, it is not enough to merely have the policy; it has to be regularly applied and updated as necessary. In my experience, this is where the slippage often occurs. Referring to that policy manual only when litigation is upon you is too late and an invitation to mistakes. More importantly, confirming that policy is being followed before litigation and while litigation is ongoing protects your organization from claims of intentionally destroying what is later determined to be critical evidence. This is often referred to as "spoliation of evidence" (root word "spoil"), which refers to the intentional or unintentional destruction or alteration of evidence.

So, now you have a solid policy you are implementing, and then litigation hits. First thing, ensure the policy is suspended immediately, at least as to documents in the relevant area of the litigation. It doesn't hurt to stop shredding or wiping all data for a short period to insure the further destruction, otherwise neutral, isn't later argued to be nefarious. Other than some cost regarding suspending an ongoing operation, the risk to temporarily stopping the destruction of documents is negligible.

Properly responding to eDiscovery requests requires knowledge of the organization's network. The case law (see *Zubulake v. UBS Warburg*[2]) is clear that a lawyer or person within an organization who seeks to respond

to ESI discovery orders with "I have no idea where that data is," is insufficient. Someone in your organization does (or should) know how your network is structured. It may take more than one person's expertise to provide a complete picture of where the sought-after data can be found. And, inevitably, that structure will cause documents to be replicated in various locations. Initial creation of the document, backup copy of that local machine, a network copy of that file is on a server, and that server is backed up, etc. Courts have little patience for mishandled discovery responses justified by a shoulder shrug from counsel offering, "I didn't know that data was there." It's the duty of the lawyer and the point person(s) inside an organization to either attend discovery hearings on ESI with the full knowledge of where the data is or bring someone to that hearing who does know.

As with anything else in healthcare compliance, the network setup and the organization of data on a system are not static. At least annually, the Legal department should be informed when data storage is being updated or changed. This is definitely a compliance risk of some degree, because of the aforementioned responsibilities in inevitable discovery matters. For example, if a patient attends a clinic in the suburbs and the new computer system is redesigned to no longer store information about that visit at the local clinic, but instead interfaces with a centralized system and only that system, that is something that the Legal department needs to know. Unless this important change is communicated to Legal, it will be easy for a lawyer thereafter to assure a judge in a discovery dispute that he/she will "get the data from the clinic, which is where we store data about that patient doctor interaction."

At least annually, the Legal department should be informed when data storage is being updated or changed.

Then, sometime later, the lawyer has to admit he/she unintentionally mislead the court. Of course, tech savvy lawyers ought to know enough to periodically request a refresher from the IT or IS departments regarding updates to data storage processes as it relates to discovery responses. In my practice, I have found lawyers, as a group, to be technophobic. This reality makes the collision of discovery requests and "what-the-heck-is-on-your-network?" conversations with counsel likely.

Lawyers, even today, constantly have to educate courts and opposing counsel regarding the way data is stored on computer systems in a healthcare environment. Do staff have the ability to copy data to other devices? Can they offload the data entirely to other systems for some reason? Is the data in imaging devices compatible with other EHR data, or is the provider of that system still not making that data compatible for some reason? Is there a known defect in some device that corrupts or improperly records or stores ESI?

Finally, it is helpful for the healthcare compliance professional, when dealing with inside counsel or outside litigation counsel, to know whether those lawyers are technologically sophisticated. The risks of litigation increase significantly if data is intentionally or unintentionally destroyed during or even on the eve of litigation. A physician or other staff member may have some notion that a lawsuit is coming related to patient care and could make decisions adverse to the organization regarding the management of that patient's data. So, instead of looking for seminars about healthcare compliance ESI techniques, it's far better to know on an ongoing basis that the lawyers who will respond to eDiscovery requests actually understand how the organization's data is being stored on your system.

1. Amended Federal Rule of Civil Procedure 26(a)(1)(B) mandates disclosure of ESI during the initial stages of a case.
2. *Zubulake v. UBS Warburg*, Southern District of New Yor, 2003. Brief available at http://bit.ly/1qWT7Qo. The leading case forming the basis of electronic discovery handling in federal cases is so well known that it has its own very informative Wikipedia page at http://bit.ly/1y5R0rg.

An intensive three-and-a-half-day program focusing on subject areas at the heart of healthcare compliance practice, designed for participants with a basic knowledge of compliance concepts and some professional experience in a compliance function.

Questions: jennifer.parrucci@corporatecompliance.org

Want to become Certified in Healthcare Compliance (CHC)®?

Take the optional CHC exam on the last day of the Academy

2015 Basic Compliance Academies

from the Health Care Compliance Association

REGISTER EARLY TO RESERVE YOUR PLACE

Limited to 75 for each Academy

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

November 16–19 • Orlando, FL

Nov 30–Dec 3 • San Diego, CA

Learn more and register at
www.hcca-info.org/academies

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

by David Hoffman, Esq.

Adverse drug reactions in hospitals: Effective reporting

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

The Pennsylvania Patient Safety Authority recently published an advisory titled "An Analysis of Reported Adverse Drug Reactions" which used data accumulated over the course of a year. In total, 4,875 adverse drug reaction events were reported to the Safety Authority. The number one adverse drug reaction was linked to contrast agents. Specifically, 851 reports were contrast-related and the reactions included headache, nausea, vomiting, itching, rash, and sensation of heat—all of which are consistent with product labeling for contrast agents. In an additional 484 cases, there were severe reactions; and in 130 cases, the patient had a documented history of an allergy to a contrast agent (106 cases had a premedication protocol documented).

Hoffman

The second most common adverse drug reaction was linked to opioids, with a total of 416 reports. As reported, these medications caused generalized itching and rash, shortness of breath, excess sedation, and respiratory depression. Interestingly, the use of naxolone to address the patient's level of sedation was noted in almost a third of the cases. Compliance officers should consider reviewing reports of naxolone usage in order to evaluate adverse drug event reporting.

One of the keys to ensuring patient safety is to have a good internal reporting system to identify adverse drug events. In 2005, the FDA issued a Guidance for Industry on Good Pharmacovigilance practices and Pharmacoepidemiologic Assessment. The FDA stated "[g]ood pharmacovigilance practice is generally based on acquiring complete data from spontaneous adverse event reports." It noted that good case reports contain the following information:

1. Description of the adverse events or disease experience, including time to onset of signs or symptoms;
2. Suspected or concomitant product therapy details, including over-the-counter (OTC) medications, dietary supplements, and recently discontinued medications;
3. Patient characteristics, including demographic information, baseline medical condition prior to product therapy, co-morbid conditions, use of concomitant medications, relevant family history of disease, and presence of other risk factors;
4. Documentation of the diagnosis of the events, including methods used to make the diagnosis;
5. Clinical course of the event and patient outcomes;
6. Relevant therapeutic measures and lab data baseline, during therapy and subsequent to therapy, including blood levels, as appropriate;
7. Information about response to dechallenge and rechallenge; and
8. Any other relevant information.

Having a robust adverse drug event reporting system will assist the compliance officer in ensuring that an appropriate investigation into the adverse event is performed and that further adverse events may be avoided through proactive clinical interventions.

Healthcare Privacy
Basic Compliance Academies

Questions: jodi.ericksonhernandez@hcca-info.org

San Francisco, CA
September 8–11, 2014

Orlando, FL
November 3–6, 2014

ACADEMIES FILL FAST
Register early

HCCA's Healthcare Privacy Basic Compliance Academy® is comprehensive, covering a broad spectrum of laws and regulations that affect healthcare organizations: HIPAA privacy, general compliance, the Federal Privacy Act, and other privacy-related topics relative to healthcare. The faculty has many years of experience in healthcare compliance and is well-versed in healthcare privacy. The Academy is also helpful in preparing for healthcare privacy certification.

Learn more & register at
www.hcca-info.org/academies

by Eugene A. (Tony) Fay, CPA, MBA, CCEP

Stark compliance: A focus on medical office building leases

» The Stark Law could be implicated if a hospital leases space to a referral source at rates below fair market value (FMV) or on terms that are not commercially reasonable.

» Medical office building (MOB) leases are complicated, and the FMV rental rate could vary on a suite-by-suite basis.

» Determining FMV requires a real estate appraiser with direct experience in MOB leases.

» The lease agreement or legal file should contain a copy of the fully executed lease agreement, along with a floor plan of the leased premises and the summary page from the FMV rental rate study.

» A compliance monitoring plan should be developed to monitor the accuracy and timeliness of rental payments.

Tony Fay *(Eugene.fay@gmail.com) is an Ethics & Compliance professional practicing in the greater Nashville area.* */in/eugenefay* *@eugenefay*

Recent news indicates there is a new and heightened law enforcement effort with respect to Stark and Anti-Kickback Statute (AKS) violations. More chilling, the Department of Justice has been using its authority under the False Claims Act (FCA) to settle alleged violations or improprieties regarding Stark. In fact, only recently, a Florida hospital system agreed to settle part of a federal FCA action for $85 million. The civil action alleged the hospital made improper and above-market payments to employed physicians.[1] In a similar case, a Utah-based hospital network last year self-disclosed improper financial arrangements with referral sources and agreed to pay $25.5 million to resolve claims regarding improper bonuses paid to doctors, referral payment arrangements, and improper office leases.[2]

Fay

Lease arrangements between providers and potential referral sources represent a significant risk area for Stark compliance. An analysis of the Stark regulations is beyond the scope of this article, but the following Stark safe harbors apply to lease arrangements:

- The lease agreement must have a term of at least one year;
- The agreement must be signed in advance by both parties;
- The rental amounts must be at fair market value (FMV); and
- Rents must be remitted by the potential referral source on a timely basis in accordance with commercially reasonable standards that would otherwise be applied to non-referral sources.

The key risks in complying with this safe harbor are determining FMV and collecting rents on a timely basis.

Fair market value

It is quite easy to determine FMV for apartment buildings or commercial properties by referencing local publications such as newspapers,

online advertisements, and real estate surveys. Determining FMV for medical office building (MOB) space is much more complicated. MOB space is unique in that it is usually in close proximity to a hospital and is constructed to accommodate medical equipment, such as imaging equipment or office-based surgery. Moreover, each referral source may negotiate an à la carte rental arrangement whereby, for example, the hospital pays for utilities but the referral source provides for its own janitorial service. On the other hand, a medical office that houses imaging equipment may be required to pay for their utilities, because their electricity consumption is most likely higher than the average for the MOB.

MOB space is unique in that it is usually in close proximity to a hospital and is constructed to accommodate medical equipment, such as imaging equipment or office-based surgery.

To further understand rental arrangements, it is helpful to understand the three ways which the FMV of rental rates are determined.

- A **gross lease**, wherein the landlord pays all expenses such as utilities, insurance, janitorial, taxes, etc. This results in the highest rental amount.
- A **net lease**, wherein the tenant pays these expenses. This results in the lowest rental amount.
- A **modified gross lease**, wherein the tenant pays the gross lease rental amount less any expenses the tenant will make under the terms of the lease agreement. This results in a rental amount that is somewhere between a gross amount and a net amount. In my experience, this tends to be the most common form of rent payment.

Because a variety of modified gross rental arrangements could exist within a single MOB, it is very likely that most lease arrangements will be based on different FMV rental rates. Therefore, it is important to engage a qualified appraiser with experience in MOB FMV rentals to conduct an appraisal that will determine the gross and net FMV rates and the FMV of the expense items, such as utilities, insurance, janitorial, taxes, etc. The lease agreement should clearly reflect the expense items that are being paid by the tenant as a reduction to the gross FMV rental rate.

Other factors to consider include:

- Ensure the square footage represented in the lease arrangement is accurate. It is recommended that a floor plan be appended to the lease agreement.
- Ensure the FMV rental rate includes an allocation of the common areas. This may vary by market, because some markets include common space in the square footage comparisons and other markets base FMV on "usable square footage."
- Ensure the FMV rental rate is documented as part of the arrangement. It is recommended that a summary page from the FMV study be included in the contract file or appended to the agreement. Further, in the case of modified gross leases, a calculation of the modified rental rate should also be included with the agreement.

- In the case of time-share leases (wherein space is leased on a part-time basis), a calculation of the rental amount should include a detailed calculation of the time-share rental amount plus an add-on for the furniture, fixtures, and equipment in the time share unit.
- Lastly, a best practice is to have the FMV rental survey updated annually.

Timely collection of lease payments

Most hospitals either manage their MOB rental portfolio or outsource that management to a third-party property manager. In either case, it is important to manage the collection of rents in a commercially reasonable manner, just as one would manage any other book of business. For example, a hospital could employ commercially reasonable collection practices against individuals who do not pay their co-pays and deductibles. If rental payments from referral sources were treated differently and more leniently, this could implicate the hospital under the Stark regulations.

For hospitals that manage their own portfolio, the responsibility for collecting rental payments usually belongs to the Finance department. From a financial perspective, this is logical because Finance is usually charged with collecting payments and posting accounts. However, from a compliance perspective, there could be many issues that fall through the cracks.

For example, lease arrangements usually provide for an annual escalation of the rental amount on each anniversary of the lease agreement. Often the anniversary date is in the middle of a month, which is problematic for a Finance department, given they work within the perspective of month-end accounting cycles. Because the Finance department may not know the intricate details of each lease agreement (which tend to be wordy and complicated), it is possible that the rental amounts would continue to be collected without the annual escalator. In my experience, many hospitals do not actually send invoices for monthly rents, but rely on the physician's accountant to remit the proper amount. Often, this can lead to missed escalation payments and even lapsed lease agreements.

In the event the hospital has a property manager, it is still incumbent upon the hospital to ensure the rental amounts are being collected timely and at the proper rental amount. In either event, it is important that the Compliance Office or Internal Audit Office develop a monitoring plan to ensure that rental amounts are collected timely and are in harmony with the lease arrangement.

1. *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, MiddleDistrict of Florida., No. 6:09-cv-01002-GAP-TBS, *settlement* March 10, 2014. Available at http://bit.ly/1y5RqxV
2. Department of Justice, press release: "Intermountain Health Care Inc. Pays U.S. $25.5 Million to Settle False Claims Act Allegations." April 3, 2013. Available at http://1.usa.gov/1or5wE8

Research Basic Compliance Academies

Orlando, FL

November 3–6, 2014

Questions: jennie.nguyen@corporatecompliance.org

With a wide range of research-related issues becoming hot topics with enforcement agencies, HCCA's Research Basic Compliance Academy® provides the opportunity to get information on many areas that affect research compliance officers and their staff on a day-to-day basis. A small audience encourages hands-on educational techniques, small group interaction, and networking.

ACADEMIES FILL FAST

Last chance to attend in 2014

Learn more & register at

www.hcca-info.org/academies

HCCA

HEALTH CARE COMPLIANCE ASSOCIATION

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

Infra*structure* vs. infra*stricture*—Sometimes a misstep

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

In the past five years of working with clients, I have witnessed just about every form of infrastructure. There are three types of infrastructure models in clinical trial offices: centralized, de-centralized, or a hybrid model of the two (semi-centralized). We will explore the three types in this article and the challenges associated with them.

Willenberg

The first type is a centralized model. Shared resources for labor optimization in this type of structure can sometimes be resource intensive. The positives found in this type are consistency and transparency with less duplication of effort. There can be more self-monitoring with this type of organizational structure leading to process improvement. Policies and procedures are memorialized and official. There are a number of academic medical centers that have centralized offices in oncology clinical trials but not in other key disease areas, which leads to disorganization. This type of office can also establish a strong self-monitoring program. One key area that is usually positive in a centralized office is training, which can be consolidated.

The second type of infrastructure is a de-centralized model. This type takes much more involvement from the Principal Investigator and research team, because they have to take initiatives. The problem that arises is that policies and procedures sometimes do not sync up institutionally. Duplicative processes and disjointed communication are normal with this type of structure. Training may be *ad hoc*, disorganized and inconsistent.

The third type of structure is a hybrid of both, sometimes called semi-centralized. Some institutions have pieces of the centralized office solidified while other parts may not be, such as the oversight of study coordinators. These types of offices may have specific policies and procedures for certain areas, but not for others. Study teams may drive process, and the more active teams may lead it. This type is less labor intensive, because the process is segregated and relies on communication. Self-monitoring may take place, but on a somewhat sporadic basis. These types of offices have much less structured educational programs than a centralized model.

Find the standard you need and establish it for success.

What type of structure do you have? Does your office have limitations due to the structure? Does this cause any stricture or constraints? Find the standard you need and establish it for success. Having viewed many sites and seeing all types of structures, I understand the need for self-assessment and gap analysis to see where your structure puts you. Do not be afraid to evaluate the structure and establish a model of office composition that can help your team to strive and thrive. Sometimes your deficiencies can be tied to the type of footing you have. Don't misstep!

HCCA Training Resources

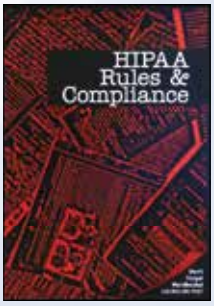
GUIDEBOOKS & VIDEOS TO TRAIN YOUR HEALTH CARE WORKFORCE

Compliance and Ethics: An Introduction for Health Care Professionals

HCCA's top-rated DVD covers 7 key compliance areas in a 23-minute program split into 7 dramatized scenarios. Includes a trainer's guide with suggested agendas and discussion outlines.

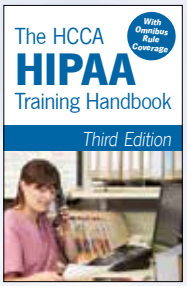
Compliance, Conscience and Conduct

HCCA's classic compliance training DVD is still available! The 17-minute video overviews what compliance means and walks viewers through seven common case studies. Includes session leader guide and reproducible participant worksheets.



HIPAA Rules & Compliance

This 15-minute video reviews basic, unchanged requirements and the latest, critical changes, including the Omnibus Rule.



The HCCA HIPAA Training Handbook, Third Edition

The new, third edition of this handbook covers the privacy and security regulations that frontline health care workers need. This 40-page primer clearly explains the essential, basic workings of HIPAA, HITECH, and the Omnibus Rule.

A Supplement to Your Deficit Reduction Act Compliance Training Program

This 13-page handbook offers an easy way to educate your employees about the basics of Medicare and Medicaid, the Federal False Claims Act, and the whistleblower protections that help health care workers fight fraud.

Workplace Investigations: Techniques and Strategies for Investigators and Compliance Officers

Get step-by-step guidance for planning, conducting, and reporting results of internal investigations.

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

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

by Alice G. Gosfield

How clinical integration lowers fraud and abuse risks

» Clinical integration can only begin with physicians working with each other.
» The standardization in clinical integration can lower false claims liabilities.
» Clinical integration requires that the collaborators adopt "value" as a value.
» The Stark regulations allow hospitals to offer free compliance training to staff members with continuing education credit.
» Hospitals that employ physicians will not succeed if they do not help their recruits to clinically integrate.

Alice G. Gosfield *(agosfield@gosfield.com) is Principal in the law firm of Alice G. Gosfield and Associates PC in Philadelphia.*

It has now become almost a truism that for providers to survive in the changing healthcare environment, clinical integration will have to become widespread. Yet few have taken the opportunity to articulate what clinical integration ought to mean and how it can be accomplished. Even less well understood is how clinical integration can lower fraud and abuse risks.

Gosfield

Essential concepts

Although many make the argument for physician engagement with institutional providers, in the last analysis, if physicians do not engage with each other around changing both their clinical processes of delivering care and the administrative mechanisms to support those changes, facilities such as hospitals and nursing homes that seek physician engagement will confront chaotic, individualized behaviors which will not advance the common goals at work in the healthcare system. A practical, fundamental definition of today's sought-after clinical integration would be:

> Physicians working together systematically, with or without other organizations and professionals, to improve their collective ability to deliver high quality, safe, and valued care to their patients and communities.[1]

The key words here are (1) "systematically"—not episodically, not from time to time, not when the surveyors are coming, but as part of an organized, ongoing cultural change; and (2) "collective,"—that the success of all will matter, especially as payment models change and physicians are more accountable for care delivered to more than just their own patients.

As the architecture within which physicians' collective activities alter, the fundamental need to clinically integrate remains, regardless of setting. This is true, whether physicians act in a stand-alone group practice, within the hospital's organized medical staff, in a newly forming accountable care organization (ACO) structure, as hospital or system-employed physicians, or in a network which has come together just to participate in a bundled payment model. They cannot integrate with others, especially within complex institutions and organizations, without having a driving sense of what they are doing with each other.

Attributes of clinical integration

Across a range of contexts, there are common factors to take into account in developing a

clinical integration strategy. These can be seen through a framework of the "Four Fs":

- the Form of the enterprise,
- its Function,
- its Finances, and
- its Feeling or culture.[1]

To get from the status quo to a more fully clinically integrated undertaking, it is essential to start with an assessment of where things are. Two tools have been created to facilitate this work for the physicians who would seek to come together, as well as those who would seek to work with them. One has been developed for medical groups, employed physicians, the organized medical staff, and a newly forming ACO-type entity. The other is for otherwise independent providers to join together in a network. For each of 17 attributes, the tools postulate what it would look like if the participants were barely in the game, to making an effort, to committed and capable. The tools give participants a vehicle through which to contemplate specific actions that would have to be taken to move from the left side of the chart to the right.[2]

Two tools have been created to facilitate this work for the physicians who would seek to come together, as well as those who would seek to work with them.

Among the Four Fs are attributes not particularly relevant to fraud and abuse concerns. Included under Form and Function are the clarity of mission, confidence in management and leadership, expectations regarding leadership and followers, and patient centeredness. Finance and Feeling include far more that touches on the fraud and abuse pitfalls that clinical integration can mitigate.

The extent to which new payment models predominate (including bundled payments, bundled budgets, episode rates, capitation, or full risk), rather than the fee-for-service model is a primary marker of clinical integration. There is now agreement among more clinically integrated entities that they do not want fee-for-service payments.[3] That shift moves the participants considerably away from the type of fraud and abuse risks associated with documentation of services and their medical necessity, and toward the use of delivery models such as group visits, which are barely recognized in fee for service. Next, where physician compensation models within the integrating entity reflect external market drivers for efficiency, economy of resources, patient satisfaction, and quality performance, the venture moves away from the traditional emphasis on either high work Relative Value Unit (wRVU) services, or a high volume of services to meet productivity measures, thereby decreasing risks of over-utilization.[4]

How physicians engage with others financially in joint ventures, co-management arrangements, or other forms of explicit collaboration is an attribute of clinical integration as well. The more clinical collaboration among them the better, but when payers bolster these arrangements with support, as they increasingly are doing,[5] the integration gets stronger while the false claims liability and Stark-type referral worries decrease. Another significant theme of clinical integration is standardization: (1) to guidelines, clinical protocols, and the evidence base; (2) in to whom referrals are given and from whom referrals are taken; (3) in documentation; (4) in deployment of non-physician

practitioners; and (5) in implementation of electronic health records. Where the expectations are that physicians, other clinical team members, and those with whom they work will all be following the same musical score, using standardized techniques, the false claims risks that come from idiosyncratic practice styles, particularly in Medicare and Medicaid, are significantly lowered.

To know that standardization is occurring depends on measuring performance. Being transparent with the results is part of the concerted data-sharing policies that provide the foundation for clinical integration. The whole point of clinical integration is to increase quality performance while lowering costs. Unlike a fee-for-service driven setting, it is hard to imagine a truly clinically integrated enterprise where cardiologists would be criminally charged with over-stenting patients who did not need the procedures. At the same time, clinical integration can help avoid the pitfalls of new forms of "quality fraud" in terms of both improper care and inaccurate reporting of care and results.[6] In addition, a principal tenet of clinical integration is to make "value" a value of the collaborators. Of necessity, this means confronting both capacity control and utilization, which will be increasingly important as the fraud and abuse enforcers focus more and more on over-used procedures and waste.

Although the primary emphasis in this consideration has been on physicians integrating with each other and in relationship to hospitals, nursing facilities, and other organizations, many of the same issues will have to be confronted in a collaboration among all the parties focused around the institutional manifestations of the attributes of integration. Because so many of them depend on physician engagement and the clinical integrity of the decisions made, the self-assessment tools can serve as a conversation starter as the parties come together in new ways.

Practical considerations

How to get started has confounded many physicians who would like to come together to change the way they conduct business. One of the major positive supports that institutions could offer in these contexts is education that the physicians can apply, even in their own practices. In fact, the Stark regulations have provided a safe method to permit what they refer to as free "compliance training" for which the hospital can make continuing medical education credits available as well. The training can extend to family members of the physician along with office staff, as long as the physician practices in the entity's local community or service area and the training is held in the local community or service area. When the regulation was published in 2007, there was a relatively bounded concept of what compliance training entailed. For purposes of the regulations:

> Compliance training means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring or reporting); specific training regarding requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal, State or local laws, regulations, or rules governing the conduct of the party for whom the training is provided.[7]

Seven years later, with the passage of the Affordable Care Act and multiple other regulatory initiatives, the education that could be made available is far broader. Clinical integration itself could be the subject of education, as could standardization and other techniques, under the compliance training rubric. These approaches can be a significant bonding strategy for hospitals with their staff physicians

or community-based physicians, but where hospitals employ physicians, the movement towards formal clinical integration among them is just as important.

Many of the recent hospital employment relationships into which physicians and their employers have entered have done nothing to help physicians come together to work better. Because the impetus to many of these employment relationships was the desire for financial security from highly compensated specialists, many of the employment transactions have little core content to them.[8] Implementing the Clinical Integration Self-Assessment Tools in the employed physician context can begin the process of creating more value in these transactions. The transactions will be unsustainable if all they do is offer physicians increased compensation with no change in their behavior.[9]

Conclusion

The fraud and abuse enforcement environment is unquestionably heating up. New focuses on overuse, inadequate quality, and inaccurate data reporting join the traditional fee-for-service-based false claims liabilities that have long plagued physician practices and those doing business with them. The purpose of clinical integration is to improve the quality and value of services rendered. The mechanisms by which those changes can be achieved entail significant standardization as well as careful attention to the financial context for the operations. A deliberate focus on a clinical integration strategy can lower fraud and abuse risks. Above all, however, it can improve the health of patients.

1. Alice G. Gosfield and James L. Reinertsen: "Achieving Clinical Integration with Highly Engaged Physicians" 2010. Available at http://bit.ly/1mmt0L9
2. Gosfield and Reinertsen: "Clinical Integration Self Assessment Tool v 2.0" 2011. Available at http://bit.ly/UWlIqa
3. Jaqueline Fellows: "Physicians at the Cross Roads." *Health Leaders,* April 11, 2014. Available at http://bit.ly/1zU1Xiy
4. Alice G. Gosfield: "Bolstering Change: Physician Compensation for Quality and Value" *Health Law Handbook,* 2012 ed., pp. 59-85. Available at http://bit.ly/1lAmPTv
5. Tandigm health website. Available at www.tandigmhealth.com
6. Alice G. Gosfield: "Quality fraud: Two pathways to trouble" *Compliance Today,* June 2013. Available at http://bit.ly/1swgFdd
7. CMS: 42 CFR §411.357(o): Exceptions to the referral prohibition related to compensation arrangements. Available at http://1.usa.gov/1lAqcdg
8. Gosfield and Reinertsen: "Informed Consent to the Ties that Bind" *The Physician Executive,* January/February 2010, pp. 6-13. Available at http://bit.ly/1qVZiPK
9. Alice G. Gosfield: "Is Physician Employment by Health Systems an Answer?" *Journal of Oncology Practice,* October 22, 2013, pp 1-3. Available at http://bit.ly/1kHyBAy

by Emmelyn Kim, MA, MPH, CCRA, CHRC

Maximizing research compliance reviews as part of your human research protections program

» Employ targeted, risk-based compliance reviews to enhance program efficiency.
» Work with the Human Research Protection Program (HRPP) staff to maximize reviews.
» Standardize assessments, tools, and reports for consistency and ease of data analysis.
» Ensure transparency after the review process.
» Use metrics to streamline your compliance program and inform policy and education.

Emmelyn Kim *(ekim@nshs.edu) is Director, Research Compliance, Office of Research Compliance, North Shore-LIJ Health System in New York.*

Research compliance programs at academic medical institutions are often necessary to evaluate and ensure the responsible conduct of research. However, Compliance departments may have limited resources to evaluate the entire portfolio of ongoing research, particularly at large, decentralized institutions. Hence, program efficiency and strategic use of resources are crucial elements for success.


Kim

The Quality Assurance and Monitoring division of the Office of Research Compliance (ORC) at North Shore-LIJ Health System (NSLIJ) regularly evaluates and monitors the conduct of human subject research as part of the accredited Human Research Protection Program (HRPP) to ensure compliance with regulatory requirements and institutional policies and to promote best practices. There are more than 2,000 active research studies at NSLIJ with a majority representing investigator-initiated research. NSLIJ has 3.5 full-time employees (FTEs) who are dedicated to the Quality Assurance and Monitoring division consisting of a director and 2.5 FTE managers. The following are some key considerations for maximizing research compliance reviews, based on the program at NSLIJ.

Strategically target reviews

Performing random reviews on all research protocols may not be the most strategic way to evaluate research, because this will likely require vast resources. Instead, perform a risk assessment by evaluating your research portfolio and categorizing studies as low, medium, or high risk. Certain factors to evaluate include the experience level of the investigator and research team, type and complexity of the study, and the population under study. For example, a new investigator conducting a complex interventional study that involves a vulnerable population may be categorized as

higher risk than an experienced investigator conducting a less complex study. Use a stratification method where a greater percentage of reviews are conducted on higher-risk research. For large, decentralized institutions, rotation of reviews throughout the various facilities or departments should be considered, ensuring that any newly integrated sites are included.

Various kinds of reviews can be performed, based on the type of research. ORC reviews include focused (e.g., informed consent) and comprehensive or Good Clinical Practice (GCP) reviews.[1] GCP reviews are typically chosen for complex, higher-risk clinical trials that involve evaluation of regulatory and institutional review board (IRB) documentation, consent forms, and subject case reviews. Informed consent reviews focus on the consent process and documentation, and are chosen for simple or lower-risk studies. Choosing the right type of review for the appropriate study allows for more resourceful sampling of research.

Work with HRPP staff to maximize reviews

Our Compliance division operates independently from the HRPP Office (also known as the Institutional Review Board Office), but we work closely to maximize reviews of research. One practice we have instituted is for the HRPP to request the last two executed consent forms from each active research study during the time of continuing review. This allows for an enterprise-wide evaluation of consent and an opportunity to provide education. Information from submitted consent forms allows the ORC to determine where reviews should be focused. The HRPP Office may also refer reviews to the ORC, based on study integrity, safety, or ethical concerns.

Another way to maximize reviews is to train HRPP staff on performing focused reviews of areas where the Compliance division may not have enough resources to evaluate. This year, HRPP staff will perform on-site informed consent process and documentation reviews to allow for the ORC to conduct a greater number of GCP reviews.

Standardize assessments, tools, and reports

Review checklists are created based on regulatory, institutional, and HRPP requirements, which are evaluated and updated regularly. All reviewers use the same checklists to ensure consistency and comprehensiveness of reviews. This is essential when many people are involved in the review process. HRPP staff also use a standardized checklist when evaluating consent forms during continuing review. What is even more important is ensuring consistency of reports and identification of minor versus major issues. Consistency of information is also required to facilitate analysis of data for metrics. Standard operating procedures (SOPs) are used to promote consistency of assessments and use of tools among staff. SOPs are created for the various types of reviews and used to train staff.

Ensure transparency after reviews

Compliance reports are sent to the research team as well as research and institutional leadership to promote transparency and reinforce expectations. Reports summarize findings, and corrective and preventive actions reviewed with the research team. Significant issues found from reviews are presented at the HRPP Committee for determination of any further actions, which can include an enrollment hold or study suspension.

We have seen positive responses as a result of the reviews. In some cases, significant issues were found due to lack of resources or qualified staff. As a result, the departments restructured their research program, hired dedicated research personnel, and required staff training. Most researchers have been receptive to compliance reviews and often

reach out to us afterwards. Compliance review statuses and reports are also presented to the executive audit and compliance committees. It is important for leadership to be aware of any issues that may be either specific to a group or more systemic that may require additional institutional resources.

Use metrics to streamline your program and inform policy and education

Key data variables captured during reviews are analyzed biannually and shared with HRPP staff, research leadership, and researchers. Weak compliance areas are evaluated and used to inform policies and education. For example, an online interactive consent process and documentation course was created to reach a broader audience. Metrics were used to inform the content of the course, and case studies were created, based on areas where most deviations were seen. Institutional policies are created or revised to set standards and expectations as a result of compliance gaps detected during reviews. If used wisely, metrics can help streamline your compliance efforts and effectively target root causes to enhance the quality and conduct of research at your institution.

Conclusion

When thinking about ways to maximize your compliance reviews of research, it is important to evaluate all aspects of your research portfolio and use a risk-based approach. When resources are limited, working collaboratively with other offices may provide collective benefits. However, it is important to ensure standardization of assessments and tools to effectively allow for data-driven targeting of compliance programs and policy development. Finally, transparency helps to set expectations for research and promotes greater awareness of compliance efforts that support effective human research protections for institutional leadership.

1. International Conference on Harmonisation: Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance. April 1996. Available at: http://1.usa.gov/1pawbdI

by Kelly J. Skeat, JD and Ari J. Markenson, JD, MPH

New CMS guidelines for acquiring a Medicare provider: Buyer beware

» Buyers face delays, surveys, and lost reimbursement under the new guidelines.
» Conducting due diligence in transactions is more important than ever.
» Representations, warranties, and indemnification provisions must be carefully negotiated.
» Purchase agreements must address who owns and controls Medicare records.
» The compliance team is integral to the entire transaction process.

Kelly Skeat *(kskeat@beneschlaw.com) is an Associate in the Cleveland office of Benesch, Friedlander, Coplan & Aronoff LLP law firm's Health Care Practice Group.* *www.beneschhealthlaw.com*

Ari J. Markenson *(amarkenson@duanemorris.com) is a Partner with DuaneMorris in New York City.* */in/arimarkenson*

When acquiring a Medicare provider—such as a hospital, hospice, home health agency, or skilled nursing facility—one significant decision that the buyer must make is whether or not to assume the seller's Medicare provider agreement.

Assuming the Medicare provider agreement generally provides for uninterrupted reimbursement and a smooth transition in operations. It also typically requires less surveys and inspections by state agencies. However, regulations and Medicare policies also require that the buyer assume all of the seller's historic liabilities under the Medicare provider number, including for overpayments, false claims, fines and other penalties, and even potentially Stark Law or Anti-Kickback Statute violations. For instance, if a Medicare audit takes place after the transaction closes and it is discovered that the seller submitted claims that did not meet Medicare's reimbursement criteria, the buyer will have assumed the obligation and be required to repay those amounts to Medicare. The buyer will then have to seek recovery from the seller through indemnification, lawsuits, escrow claims, or other means, assuming some means of redress has been negotiated in the purchase agreement.


Skeat


Markenson

Because of this potential liability, many buyers desire to structure a transaction so that they do not assume the seller's Medicare provider agreement. However, refusing assignment of a Medicare provider agreement is far more difficult than many buyers realize. It can lead to costly gaps in reimbursement and burdensome surveys and inspections. Recent policy guidance issued by the Centers for Medicare & Medicaid Services (CMS) created further disincentives for buyers to refuse assignment of the Medicare provider agreement. Rejecting assignment is often not feasible because of these delays. Buyers in such a situation must look to alternative methods to protect themselves and minimize liability exposure.

The Medicare "CHOW"

Medicare regulations and policies have created a complex system where, depending on the structure of the transaction, the buyer may have the option of deciding whether or not to assume the seller's Medicare provider agreement. In certain structures, such as stock transactions, the acquirer has no choice but to assume all of the acquired company's liabilities, including past Medicare liabilities.

Medicare regulations and policy guidance define other transactions as a "change in ownership" (CHOW). The most common CHOWs are asset transactions and mergers where the seller is not the surviving entity. In such situations, the buyer has two choices: (1) elect to assume the seller's Medicare provider agreement and all associated Medicare liabilities; or (2) reject assignment of the Medicare provider agreement and seek a new Medicare provider number.

Assignment of the Medicare provider agreement

If the buyer decides to assume the Medicare provider agreement, the seller and buyer must submit notice of the transaction and detailed information to the appropriate Medicare Administrative Contractor (MAC) or Fiscal Intermediary (FI) through completion of CMS Form 855. The MAC or FI initially reviews the CHOW application, determines that all required information has been submitted and is correct, and recommends approval or denial to the CMS regional office. The CMS regional office then reviews the information and makes a final determination.

Approval of a CHOW can take several months. However, when the CHOW is approved, the authorization is made retroactive to the date of the closing of the transaction. The buyer can continue to use the seller's old Medicare number and bill and seek reimbursement for all Medicare services provided during this time period. While there are sometimes temporary holds placed on reimbursement during the CHOW approval process, once the approval is received, the buyer can generally recover any such amounts placed in hold.

Rejection of Medicare assignment

When a CHOW takes place, the new owner also has the option to reject assignment of the seller's Medicare provider agreement. When this decision is made, the buyer must submit a new Medicare enrollment application. For most providers, this also requires a lengthy state survey and approval process that is not required when the buyer assumes the seller's Medicare provider agreement. Once approved, however, the buyer will have a new Medicare provider agreement and provider number and will not be subject to the seller's Medicare liabilities.

Many surveying bodies are taking months or even years to complete this process…

However, when the buyer rejects assignment, it cannot seek Medicare reimbursement until the effective date of its new Medicare provider agreement. This typically requires the buyer to go through a full, unannounced survey by a designated state surveying agency or accreditation organization to verify the buyer's compliance with Medicare conditions of participation. Many surveying bodies are taking months or even years to complete this process, depending on the provider type and the enrollment application backlog. The effective date of the new provider agreement will typically be after the date the survey is completed.

Because Medicare and Medicaid enrollment are often tied, in many states, a provider that is not enrolled in Medicare also cannot complete the Medicaid enrollment process until Medicare approval has been received, increasing the potential for lost reimbursement.

Furthermore, the buyer is required to have a fully operational facility at the time of the unannounced survey. This means the buyer cannot temporarily cease operations while waiting for the survey to take place. Rather, the buyer has to continue to operate the business and treat patients, even if it cannot seek reimbursement for the care provided.

Finally, rejecting assignment also means that the buyer loses the benefit of any grandfathered Medicare designations that are no longer available. For instance, many Medicare-recognized critical access hospitals are operating under special state designations that could no longer be made after 2006. A buyer of such a hospital must accept assignment of the Medicare provider agreement in order to continue to receive enhanced reimbursement the seller had received under this designation.

New policy guidance creates further disincentives to reject assignment

On September 6, 2013, CMS issued policy guidance that created further disincentives for a buyer to reject assignment of the seller's provider agreement. CMS expressed concern that some state survey agencies or accreditation organizations were not conducting full surveys or were conducting surveys on an expedited basis for the new owner when the buyer decided to reject assignment of the seller's provider agreement. CMS laid out the following policy clarifications for all surveying organizations:

- The organization must conduct the same full survey as it would do for initial certification of a new Medicare provider, even if the buyer is continuing to operate the Medicare provider on the same basis as the seller prior to the CHOW.
- The survey must be conducted after the date of the CHOW and cannot be conducted until the FI or MAC has issued a recommendation for approval of the new owner's Medicare enrollment.
- The survey must be unannounced.
- If the survey takes places within 14 days after the date of the transaction, CMS may imply that the surveyor and provider had coordinated the survey, and CMS will subject the survey to heightened scrutiny.
- CMS requires initial surveys for Medicare enrollment, including CHOWs where the buyer has rejected assignment, to be given the lowest priority in the agency's workload. The surveying agency should show that all higher priority workload was completed before it conducted the initial survey.
- The effective date of the buyer's Medicare provider agreement will be the date all federal requirements (including successful completion of a state survey) are met for a new enrollment, not the date of the CHOW.

> CMS expressed concern that some state survey agencies or accreditation organizations were not conducting full surveys…

State agencies have now been specifically instructed to make these surveys a low priority, effectively moving them to the bottom of the pile. Buyers had previously had some success in informally talking to state agencies and arranging

for quick surveys after a transaction; however, CMS has now stated that any such surveys will be reviewed with heightened scrutiny. The combined effect of the policies outlined in this new CMS policy memorandum is that buyers who decide to reject assignment are likely to face more extensive and in-depth surveys and even longer delays before they can begin receiving Medicare reimbursement. Having a provider agreement made retroactive to the date of the CHOW, or as close as possible, has now become a virtual impossibility.

Protecting buyers from a seller's past

Because of the lengthy delays and extensive surveys required for new enrollments, many buyers decide to assume the seller's Medicare provider agreement even though they must also accept historic Medicare liabilities. In this day of RACs, ZPICs, and other post-payment reviews, significant liabilities are often assessed years after claims were paid. A seller's potential Medicare liabilities are an unknown quantity that could potentially far exceed the purchase price in a transaction.

There are a number of ways buyers can seek to protect themselves from a seller's past. Sellers, on the other hand, want to have a defined limit as to how long they will be held liable for their old business and a clear cap on how much liability exposure they will face. This tension often means provisions relating to Medicare liabilities are highly negotiated and contentious points as the parties go through the transaction process.

The compliance team of both the buyer and seller play an important part in any transaction process. Specific areas of focus often include the following.

Compliance program

Sometimes the best defense is a good offense. Sellers who maintain an active and effective compliance program that quickly and effectively address compliance issues will be more attractive to buyers, complete the transaction more quickly, and face less liability after the closing. When a buyer acquires an existing Medicare provider, the buyer's compliance team must act quickly to bring the new provider and its employees into its compliance program, identify and resolve any ongoing compliance issues, and otherwise make sure nothing falls through the cracks, either during or after the transition.

Diligence

Conducting proper due diligence of a seller is more important than ever. In addition to legal and financial review, buyers should consider coding and billing audits that examine claims for coding accuracy, medical necessity, documentation requirements, and other areas that are frequently targeted in post-payment reviews. Coordinating audits through legal counsel to preserve privilege may protect both parties if any liabilities are discovered. Diligence should involve not only reviewing documents and billing claims, but ongoing discussions with the seller's compliance and billing teams regarding historic compliance problems, areas of concern, and other compliance issues. The diligence process does not end with closing, and the new owner's compliance team must review materials and information discovered after closing to stay on top of any compliance-related issues.

Self-disclosures

Any Medicare compliance issues that are discovered during the diligence process should be dealt with through self-disclosures and/or overpayment refunds by the seller prior to the closing. This allows a buyer to protect itself from undefined liabilities down the road and, depending on the circumstances, may allow the seller to resolve Medicare noncompliance issues for reduced penalties. The buyer should be involved with and review any self-disclosures

made by the seller to be sure that behavior is appropriately disclosed and the buyer is as fully protected as possible. Compliance issues discovered after closing can also often be resolved favorably through self-disclosures when the new owner can show it stopped the noncompliant practices and moved to address the issue as soon as it was discovered.

Assumed liabilities

CMS will not allow a buyer that assumes a provider agreement to avoid assuming the seller's past Medicare liabilities, but a buyer can still attempt to shift these liabilities back to the seller through the purchase agreement. Any purchase agreement should clearly define what liabilities the seller will remain responsible for as a contractual matter between the parties. Those involved in compliance and billing issues should carefully review the scope of the assumed liabilities and make sure they agree on the covered behavior.

Representations and warranties

Representations and warranties relating to Medicare billing practices, fraud and abuse compliance, and other health care compliance matters must be carefully negotiated between the parties. The compliance team plays an important part in reviewing the scope of the representations and identifying issues discovered in diligence that should be disclosed or addressed through the purchase agreement.

Indemnification

The scope of the indemnification offered by the seller to the buyer for the seller's historic Medicare liabilities must be clearly defined and is often highly negotiated between the parties. The buyer's compliance teams need to monitor any Medicare audits, claims denials, and other investigations and reviews relating to the time period when the seller operated the Medicare provider. Keep management and legal counsel informed so that appropriate indemnification claims can be made.

Records

In an asset transaction, a buyer who is assuming the Medicare provider number should be careful to also acquire all historical records relating to Medicare billing practices, including claims submissions and supporting documentation. If such records are not acquired, then the seller should agree to provide the buyer access to the records and to maintain them through at least the applicable statute of limitations. No buyer wants to face a demand for repayment and discover that the records to defend the claims have been destroyed or are no longer accessible. The compliance team must review and make sure that they have the records they need to continue to operate the Medicare provider after closing.

Conclusion

The parties considering the acquisition of a Medicare provider will need to consider the decision of whether or not to assume the seller's Medicare provider agreement very carefully and determine whether the delays and losses in Medicare reimbursement outweigh the risk of assuming the seller's provider agreement. Buyers who decide to assume the seller's Medicare provider agreement will need to protect themselves through the diligence process and the purchase agreement in order to minimize the risk of unpleasant surprises after the transaction closes.

The compliance team is an important part of the decision-making process in whether or not to assume a provider agreement as part of a transaction. More importantly, if a decision has been made to assume a seller's provider agreement, the compliance team is integral to determining potential risk areas, informing the negotiation of the transaction agreement, and mitigating risks—both before and after the closing.

by Tom Fox

The definition of "instrumentality" under the FCPA

» The *Esquenazi* decision is the first time a Court of Appeals discussed the definition of instrumentality under the FCPA.

» The Court developed a two-pronged test to determine if a state-owned enterprise is an instrumentality under the FCPA: the Control and Function tests.

» The Control test looks at how much control a government has over a state-owned enterprise.

» The Function test reviews how a state-owned entity functions in a country.

» The common test found in case law to determine if a state-owned enterprise is an "instrumentality" under the FCPA is actual control.

Tom Fox *(tfox@tfoxlaw.com) is Principle for Tom Fox Law in Houston.*

In what can only be called a judicial decision based on common sense, the 11th Circuit Court of Appeals, in an opinion released on May 16, 2014 upheld the convictions of Joel Esquenazi and Carlos Rodriguez for violations of the Foreign Corrupt Practices Act (FCPA) and certain US anti-money laundering (AML) laws. The two had engaged in a long-running bribery scheme with the Haitian telephone company, Telecommunications d'Haiti, S.A.M (Teleco). The pair were convicted and sentenced to lengthy jail terms, Esquenazi receiving 15 years and Rodriguez receiving seven years.[1]

Fox

This opinion was the first time that a Court of Appeals had reviewed the FCPA question of what is an "instrumentality" under the FCPA. Both defendants had argued that instrumentality could only mean (1) that only an actual part of the government would qualify as an "instrumentality" or (2) the FCPA should be construed to encompass only foreign entities performing "core" governmental functions similar to departments or agencies. The Court rejected both arguments.

As to the first argument, the Court said "that contention is too cramped and would impede the 'wide net over foreign bribery' Congress sought to cast in enacting the FCPA." The Court rejected several points that the defense raised in the second argument. In addition to some rejections of technical statutory constructions, the Court went into detail about two separate Congressional actions regarding the FCPA.

Grease payments

The Court noted that the facilitation payment exemption to the FCPA specifically excepted liability "to FCPA liability for 'any facilitating or expediting payment to a foreign official… the purpose of which is to expedite or to secure the performance of a routine governmental action by a foreign official.'" Further, a "routine governmental action" is defined as "an action…ordinarily and commonly performed by a foreign official in," among other things, "providing phone service." If an entity involved in providing phone service could never be a foreign official so as to fall under the FCPA's substantive prohibition, there would be no need to provide an express exclusion for payments to such an entity. In other words, if we read "instrumentality" (as the

defendants urge) to categorically exclude government-controlled entities that provide telephone service, like Teleco, then we would render meaningless a portion of the definition of "routine governmental action" in section 78dd-2(b) [all Opinion citations omitted]. In other words, to say that Teleco could not be an instrumentality would render meaningless the plain words of the statute.

US treaty obligations

Next the Court turned to the 1998 amendments to the FCPA, which Congress enacted, in part, to ensure that the U.S. was in compliance with its treaty obligations, as a signatory to the Organization for Economic Cooperation and Development's (OECD) Convention on Combating Bribery of Foreign Public Officials in International Business Transactions (the Convention). After noting that, in joining the OECD Convention, the United States agreed to:

> …take such measures as may be necessary to establish that it is a criminal offence under [United States] law for any person intentionally to offer, promise or give … directly or through intermediaries, to a foreign public official … in order that the official act or refrain from acting in relation to the performance of official duties, in order to obtain or retain business or other improper advantage in the conduct of international business.[2]

The Court then said that under the OECD treaty, a "foreign public official" is defined to include "any person exercising a public function for a foreign country, including for a… public enterprise." Finally, the Court stated:

> An official of a public enterprise shall be deemed to perform a public function unless the enterprise operates on a normal commercial basis in the relevant market, i.e., on a basis which is substantially equivalent to that of a private enterprise, without preferential subsidies or other privileges.

With these definitions as a backdrop, the Court found that in making the 1988 changes to the FCPA, the law itself was changed to meet the OCED Convention. The Court stated that Congress had affirmatively changed the law to meet certain requirements in the Convention which the prior version of the FCPA did not cover. The fact that Congress did not see the need to change the definition of instrumentality to meet the treaty obligations was evidence that Congress believed that the FCPA definition of instrumentality met the language of the OECD Convention. To conclude otherwise "would put the United States out of compliance with its international obligations."[1]

With these definitions as a backdrop, the Court found that in making the 1988 changes to the FCPA, the law itself was changed to meet the OCED Convention.

The test to determine instrumentality

Here the Court started with the premise that "Specifically, to decide in a given case whether a foreign entity to which a domestic concern makes a payment is an instrumentality of that foreign government, we ought to look to whether that foreign government considers the entity to be performing a governmental function." From this starting point, the Court

said that "An "instrumentality" under section 78dd-2(h)(2)(A) of the FCPA is an entity controlled by the government of a foreign country that performs a function the controlling government treats as its own."

From this the Court developed two key analyses. First, does a foreign government "control" an entity (what I call the "Control test")? Second, is "deciding if the entity performs a function the [foreign] government treats as its own" (what I call the "Function test")?

The Control test

With the caution that "It would unwise and likely impossible to exhaustively answer them in the abstract," the Court said, "For today, we provide a list of some factors that may be relevant to deciding the issue" of the Control test. These factors are:

- The foreign government's formal designation of the entity;
- Whether the government has an interest in the entity;
- The government's ability to hire and fire the entity's principals;
- The extent to which the entity's profits, if any, go directly into the governmental fisc [state treasury];
- The extent to which the government funds the entity if it fails to break even; and
- The length of time these indicia have existed.

The Function test

As to this second analysis, the Court set out the following factors to determine if the entity performs a function the government treats as its own:

- Does the entity have a monopoly over the function it exists to carry out?
- Does the foreign government subsidize the costs associated with the entity providing the services?
- Does the entity provide services to the public at large in the foreign country?
- Does the foreign government generally perceive the entity to be performing a governmental function?

The Court then went on to analyze the trial court's jury instructions in light of their two-part formulation, which was the following:

> One, whether it provides services to the citizens and inhabitants of Haiti.
>
> Two, whether its key officers and directors are government officials or are appointed by government officials.
>
> Three, the extent of Haiti's ownership of Teleco, including whether the Haitian government owns a majority of Teleco's shares or provides financial support such as subsidies, special tax treatment, loans or revenue from government mandated fees.
>
> Four, Teleco's obligations and privileges under Haitian law, including whether Teleco exercises exclusive or controlling power to administer its designated functions.
>
> And five, whether Teleco is widely perceived and understood to be performing official or governmental functions.

The Court of Appeals found that the trial court jury instructions met the formulation it had set out by stating, "Read in context, the district court's instructions make plain that provision of a service by a government-owned or controlled entity is not by itself sufficient." The district court explained only that an entity that provides a public service "may" meet the definition of "instrumentality," thus indicating that providing a service is not categorically excluded from "a function of the foreign government." But the sentence just before explained with no equivocation that only

"a means or agency [that performs] a function of the foreign government" would qualify as an "instrumentality."

I want to drill down further and examine the test developed by the Court of Appeals to use in determining whether an entity is an instrumentality under the FCPA and compare it with the two prior formulations developed by district courts in the *Carson*[3] and *Lindsey*[4] cases. Table 1 below consolidates the factors raised by the courts.

The *Esquenazi* decision separates the analysis into two basic questions (a) Does a foreign government *control* an entity and (b) Does the entity perform a *function* the foreign government treats as its own? The Court of Appeals then breaks the analysis of these two questions into a series of inquiries. The prior district court opinions in *Lindsey* and *Carson* did not have such an initial dichotomy; nevertheless the 11th Circuit's analysis has clear overlap with the prior district court

Table 1: Comparison of the district court rulings in Lindsey, Carson, and Esquenazi

Key Inquiry	Lindsey	Carson	Esquenazi
1. Characterization of services	Entity is the sole or majority provider of services to citizens in that country	Foreign state's characterization of the entity and its employees	**Function test** – Does the entity provide services to the public at large in the foreign country? **Control test** – the foreign government's formal designation of the entity.
2. Hiring and Firing	Are key officers/directors government employees or appointed by government employees?	Foreign state's control over the entity	**Control test** – the government's ability to hire and fire the entity's principals.
3. Financial control/ Funding	Is entity financed, in large measure, by government appropriations or through government mandates?	The foreign state's extent of ownership of the entity, including the level of financial support by the state	**Function test** – Does the foreign government subsidize the costs associated with the entity providing the services? **Control test** – the extent to which the government funds the entity if it fails to break even.
4. Foreign government control of administrative functions	Is entity vested with or does it exercise exclusive/controlling power to administer its designated functions?	The entity's obligations and privileges under the country's laws, including whether it exercises exclusive/controlling power to administer its designated functions	
5. Perception as governmental entity	Is entity widely perceived and understood to be providing official functions?	Purpose of the entity's activities	**Function test** – Does the foreign government generally perceive the entity to be performing a governmental function? **Control test** – Whether the foreign government has an interest in the entity
6. Creation		Circumstances around the entity's creation	
7. Length of time			**Control test** – the length of time the indicia have existed.
8. Monopoly over market			**Function test** – Does the entity have a monopoly over the function it exists to carry out?

formulations. Between the *Lindsey*, *Carson*, and *Esquenazi* factors, we see the following:

Identical—Does the government appoint the officers/directors and is the entity understood to be owned by or an agency of the government in the home country? In *Lindsey* and *Esquenazi* (Control prong), the courts agree on Inquiry 2 (see Table 1), the Hiring and Firing inquiry, but *Carson* says the inquiry is simply over foreign government control of the entity. Inquiry 5 in both *Lindsey* and *Esquenazi* (Control and Function prongs) is the Perception inquiry, whereas the *Carson* court denominates this inquiry as the Purpose inquiry. Finally, in Inquiry 3 all courts consider the financial support provided to the entity by the foreign government, with the *Esquenazi* court (Control and Function prongs) adding the analysis around the "Extent of obligations and privileges under its country's laws."

Similar—Inquiry 1 - Are the services provided by the entity available to all citizens of the home country? and Inquiry 4 - Does it exercise exclusive/controlling power to administer its designated functions and the extent of obligations and privileges under its country's laws? In *Lindsey* and *Carson*, the similar factors are in Inquiry 1, the Characterization of the services provided. The *Esquenazi* opinion has this Inquiry 1 in both the Function and Control prong analysis. Under the Function prong analysis it asks "Does the entity provide services to the public at large in the foreign country?" and under the Control test it inquires into the foreign government's formal designation of the entity. In Inquiry 4, both the *Lindsey* and *Carson* courts said that a foreign government's control over the administrative functions of the entity was a key inquiry but interestingly, this factor was not present in the *Esquenazi* analysis, under the analysis of either the Control or Function prong. In Inquiry 6, the *Carson* court looked into the creation of the entity and the *Esquenazi* opinion (Control prong) inquired into the foreign government's designation of the entity.

Stand-alones—Interestingly, *Esquenazi* has two factors for analysis not found in either of the district court opinions. The first, Inquiry 7, is from the Control prong and asks the question of the length of time the various factors listed have existed. The second, Inquiry 8, is from the Function prong and is whether the entity has a monopoly in the foreign country. *Carson* also has a stand-alone inquiry, which is found at Inquiry 6 and inquires into the facts and circumstances surrounding the creation of the entity. I believe this could well be the last factor in your analysis, it can be the one which is most easily ascertained. Most government entities will disclose how they were formed; this information can be found on their website or within their company history. If you cannot determine how a business was formed, perhaps you need to think hard about doing business with them.

Comparison of approaches

At first blush it may appear that the *Esquenazi* court took a slightly different approach by dividing the two initial prongs of inquiry into Control and Function. If one examines the individual *Esquenazi* factors in detail, they are not significantly different from *Lindsey* and *Carson*, with the exception noted above of the two stand-alone inquiries. One clear factor that *Esquenazi* has in common with *Lindsey* and *Carson* is the factor of the entity's obligations and privileges under its country's laws, including whether it exercises exclusive/controlling power to administer its designated functions. *Carson* combines two of the *Esquenazi* factors of the extent of government ownership and financial support by the foreign government. Although *Carson* does not speak to financial ownership, it does have the factor of government financing and government appointment

of officers and directors. *Carson* speaks to the entity's purpose but *Lindsey* and *Esquenazi* list the factor of providing services to the country's citizens. Indeed the only factor included in *Carson* and not found in *Lindsey* and *Esquenazi* is the following: the circumstances around the entity's creation. It is incumbent to note that both the *Lindsey* and *Carson* court opinions and the *Esquenazi* 11th Circuit opinion all have language that indicates these factors are not exclusive, and no single factor will determine whether an entity is an instrumentality of a foreign government.

What can we make of the two standalones found in *Esquenazi* (i.e., length of time the entity has existed [Function prong] and whether it has monopoly power [Control prong])? I would have to opine that these are the two least important factors listed. I say this because if there is clear indicia that an entity is (1) controlled by or financed in whole or in part by a foreign government; (2) perceived to be run by a foreign government; and (3) the entity provides services to the citizens of the foreign country; it really does not matter when it was created (i.e., yesterday or 50 years ago). It will be considered as an instrumentality under the FCPA. Similarly, even if there is no monopoly present, if these other factors are present, it will still be considered an instrumentality under the FCPA.

Lessons learned

With all this information in mind, what inferences can a compliance practitioner draw for guidance on whether a business is an instrumentality under the FCPA? Reviewing the foregoing, the factors can be distilled down to a manageable list, which I believe is as follows:

1. **Ownership/Financial control**—There is no percentage amount listed, but the inclusion of financial control would clearly indicate that anything over 50% would be a significant factor.
2. **Actual control** is key in all three court decisions. In *Lindsey* and *Esquenazi*, it is characterized as the government's right to appoint key officers and directors. In *Carson*, it is called government control. But this means that if actual control is exercised by the government in question, it may trump the 50% guidance stated above.
3. **Privileges and obligations** are also mentioned in all three. Does the entity have the right to control its own functions?
4. **Financing**—Is the entity a for-profit entity, financed through its own revenues, or does it depend on financing by its government?
5. **Perception is reality**—André Agassi's immortal words ("Image is everything") appear again. If it is widely perceived to be providing an official function, then it is an instrumentality under the FCPA.

The *Esquenazi* Court of Appeals decision is a very welcome addition to the dearth of case law interpretation of the FCPA. The 11th Circuit has seemingly put to rest the question of whether an instrumentality means only a government agency or something else. Clearly it means something else. The *Esquenazi* decision also provides significant guidance on what type of inquiry a company should use to determine if an entity is a part of a foreign government and, therefore, subject to FCPA scrutiny. Whatever specific facts or indicia you are looking at, it now boils down to (1) Does a foreign government control the entity? and (2) Does the entity function as part of the part of the foreign government?

1. *United States v. Esquenazi*, 11th Circuit Court of Appeals No. 11-15331. May 16, 2014. Available at http://bit.ly/usvsesq. All citations are to *Slip Op.*
2. Organization for Economic Cooperation and Development (OECD): Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. *Slip Op. at 15.* Available at http://bit.ly/oecdbribery
3. *United States v. Carson, 2011 WL 5101701, No. 09-cr-77 (C.D. Cal. May 18, 2011), ECF No. 373.* Available at http://bit.ly/decisionincarson
4. *United States v. Aguilar, et al. No. 2:10-cr-01031-AHM, ECF. 474 (C.D. Ca. 2011)* Available at http://bit.ly/decisioninlindsey

by Tod Ferran

The final BAA deadline is September 22, 2014. Are you ready?

» Business associates (BAs) include transcriptionists, pharmacies, and shredding companies.
» Satisfactory assurances demand BA patient data-handling processes be checked.
» Business associate agreements (BAAs) should include both covered entity and business associate obligations.
» Validation can be obtained in-house or through a trusted vendor.
» Updating BAAs provides opportunities to reevaluate relationships and organizational security.

Tod Ferran *(tod@securitymetrics.com) is a Security Analyst for SecurityMetrics in Orem, UT.* *bit.ly/in-TodFerran* *@todferran* *blog.securitymetrics.com*

Although compliance is much more than signing a business associate agreement (BAA), these contracts are still vital for the Health Insurance Portability and Accountability Act (HIPAA) compliance—and for good reason. According to Redspin, around 20% of breaches have involved a business associate (BA) each year from 2009–2013.[1]


Ferran

Some entities have chosen to completely ignore the new requirement to update all BAAs. Perhaps they are lazy, busy, or worried that asking for a new signature might negatively affect the relationship or open the door for the BA to negotiate new terms. Some believe signing a BAA is all it takes to become compliant.

I'm hoping to change that mentality.

Who are your business associates?

BAs are parties who transmit, process, access, or otherwise handle electronic protected health information (ePHI) on behalf of your entity. Typically, they don't generate or gather new ePHI from patients. I've listed a few by associated department to show the breadth BAs may have in a single organization.

- **Healthcare:** e-prescribers, pharmacies, external labs
- **IT:** network/server, third-party IT, external auditors, software companies
- **Financial:** claims processing, CPA firms, clearinghouses, re-pricing
- **Insurance:** insurers, benefit managers
- **Services:** answering services, third-party call center, consultants, translators, transcriptionists, coding auditors, data processing, utilization reviewer, accreditation organization, shredding, documentation, facilities managers
- **Law firms:** patient litigation

Are you a business associate?

Do you have relationships with hospitals or other healthcare entities? Do you handle ePHI for patients who may not have originated with your organization? If you are receiving ePHI for any reason other than for treatment purposes, then congratulations, you're also subject to a BAA!

If you haven't signed a BAA already with the entity you share ePHI with, it's time to take the initiative. Reach out to your partnered entity and explain your willingness to sign a new BAA to comply with recently updated HIPAA requirements.

If you've already signed a BAA, be prepared for the entity to request an in-depth scope or review of your environment. Because a covered entity is equally as responsible as the BAA for a HIPAA violation, they'll likely want to validate that you truly comply with HIPAA.

Remember, the final deadline for updated BAAs per Omnibus[2] dictation is September 22, 2014. Some industry experts speculate that after that date, the Department of Health and Human Services (HHS) will hit sub-par BAA agreements and consider any data passed to BAs as impermissible disclosures (i.e., subject to penalties.)

What should a BAA entail?

After skimming the list of possible business associates above, it may not be realistic for your practice to require immediate contact from each associate. I suggest prioritizing your business associates by riskiness.

As far as actual contract wording goes, business associate agreements should include the obligations of both the covered entity and business associate (e.g., use and disclosure of PHI, agreement to comply with HIPAA). Ensure your BAA explicitly outlines how your BA will report a data breach, because this also directly involves you. As a covered entity, the HHS starts your disclosure clock when your BA is breached, not when your BA notifies you of their breach. Just remember, a BAA does not protect you from an audit if your business associate experiences a breach.

Agreements should also include a section outlining the responsibilities of a BA when it comes to agents and subcontractors. If a BA discloses an entity's PHI to a subcontractor, the BA is directly liable for any failures of the subcontractor.

Please make sure you follow your own contract. I've seen many contracts that include rules on minimum disclosure, but one of the most common HIPAA violations I see is that entities are giving BAs too much ePHI. It's against HIPAA to provide more protected health information than a BA needs to perform a required task.

Satisfactory assurances

It's quite concerning to note that only 30% are confident their BAs are appropriately safeguarding patient information.[3] Perhaps that is why the HHS specifically stated in new HIPAA documentation that covered entities are required to take dual-responsibility for patient data protection, and signing a new agreement just isn't enough anymore. The HHS calls this new business associate responsibility "obtaining satisfactory assurances."[4]

> …only 30% are confident their BAs are appropriately safeguarding patient information.

Although government documentation does little to explain the phrase, "satisfactory assurances" essentially means covered entities must personally take measures to check BA patient data-handling processes and review BA security measures. New BAAs that include satisfactory assurances help prevent BAs from signing contracts without actually implementing HIPAA practices.

How do you audit or validate a business associate?

You should diligently work to ensure business associates are truly HIPAA compliant and securely handling patient data before accepting any new/updated agreements and before transmitting any ePHI to the BA.

To meet the satisfactory assurances requirement, some healthcare entities take the hands-on approach and manually track all their BAs to obtain satisfactory assurances. This may be realistic for smaller practices with less than 15 BAs, but may not be the best option for mid-to-large entities.

In addition to reviewing the BAA, the covered entities require evidence from each BA that may include their completed risk analysis, risk mitigation strategies, incident management programs, risk management plan, documented data-security procedures, and updated HIPAA Privacy patient disclosure documents.

Another (more realistic) way to audit a business associate is to use a compliance monitoring tool. Through a dashboard, typically provided by a trusted third party, entities can track the validation status of BAs. Some vendors conduct BA compliance validation for the entity as well.

Encouraging positive negotiation

Before you start negotiating new contracts, tread lightly. Many business associates are still unaware they are subject to HIPAA at all. I suggest the best way to start the negotiation is to create a checklist of items to address. Prioritization helps to avoid getting bogged down with trivial issues.

Next, decide what you're willing to compromise. If BAs are reluctant to sign new agreements, try the "carrot" approach. Is a new signature worth a small discount for their services? On the other hand, if the carrot approach isn't working, you might be forced to use the "stick." You may need to withdraw the contract altogether if they are unresponsive for a long period of time. With recent class-action lawsuits (such as the Kaiser Permanente class-action lawsuit in January[5]) seeking $1,000 *per compromised individual*, it's worth it to be choosy.

Not to mention, it's also a HIPAA requirement to terminate the relationship if the covered entity becomes aware of a pattern or practice that constitutes a material breach or violation, and the entity has taken "reasonable steps" to cure the breach or end the violation unsuccessfully.[6]

Conclusion

During contract negotiation, be positive! This isn't just a law, it's an opportunity to reevaluate security and make sure your organization doesn't end up on the five o'clock news! Let your business associates know what HIPAA regulations you are under, including your obligations to obtain satisfactory assurances. Seize the occasion to manage exposure to liability!

Whether you choose to personally audit each BA or require documented data-security procedures, take the initiative to secure the future of your organization and safety of patient data.

1. Redspin Breach Report 2013: Protected Health Information (PHI), February 2014. Available at http://bit.ly/1paAlSK
2. Health and Human Services: Omnibus Rule. Available at http://1.usa.gov/V1Qu0v
3. Ponemon Instituite: Fourth Annual Benchmark Study on Patient Privacy and Data Security. March 12, 2014. Available at http://bit.ly/1qW5ibj
4. *45 CFR §164.308(b)(1)*
5. Patrick Ouellette: "Patients file class action suit v. Kaiser for data breach damages." *Health Security IT* website, January 2, 2014. Available at http://bit.ly/1vbdJWX
6. Health and Human Services, Assistant Secretary for Planning and Evaluation: Standards for Privacy of Individually Identifiable Health Information. October 1, 2007. Available at http://1.usa.gov/1y62MlF

by Adam K. Weinstein, FACHE and Cindy Hart, LPN, CPA, CPC, CHC

Compliance 101

The seven essential elements, Part 2: Designating a compliance officer and compliance committee

» The purpose of a compliance officer is to be neutral and free of bias.
» Every large organization needs a compliance committee.
» Key starting points will help guide you as a compliance officer.
» The compliance officer should participate in designating members of the compliance committee.
» Preparing for challenges associated with the role will ease the transition.

Adam K. Weinstein *(aweinstein@nyp.org) is Vice President, Regulatory Affairs and Corporate Compliance at New York Hospital Queens in Flushing, NY.*
Cindy Hart *(cindy.hart@ctca-hope.com) is Senior Physician Compliance Specialist with Cancer Treatment Centers of America in Schaumburg, IL.*
bit.ly/HCCAnet-CindyHart

Part 1 of this series was published in the June 2014 issue of Compliance Today.

Congratulations! An organization designated you as its compliance officer (CO). Are you ready? This role is exciting, rewarding, and challenging from all directions. Before you strap on your helmet and grab your gear, let's remember your role is not that of a fire marshal or police officer.

As a newer profession, several organizations continue to struggle with defining the role of the compliance officer. On the other hand, there are several organizations that understand the role completely, support the profession, and readily receive compliance guidance necessary to survive in an increasingly regulatory climate. Be sure to reference appropriate resources to remain grounded to the true purpose of the role.


Weinstein


Hart

Why should the organization need or designate a CO?

Many organizations acknowledge their need for a compliance officer and designate one. Other organizations are not quite convinced there is a need, but designate someone who fulfills multiple roles. Fortunately, your organization understands the need and designates you to eliminate the void.

The CO is instrumental in assisting the organization to avoid exposure to risk and reduce the potential for whistleblower actions. Although appointing a CO is not a legal requirement, the Office of the Inspector General

(OIG) and the Federal Sentencing Guidelines recommend designating a compliance professional. Organizations need an individual who is "neutral, unbiased and un-conflicted" and capable of influencing and working collaboratively with all levels of management. The compliance officer must have the authority to "prevent, identify, and fix problems." The CO should be a part of senior management (the executive team), reporting directly to the CEO with a dotted line to the board of directors; however, in order to maintain independence, the CO should not also fill the role of CEO, CFO, or general counsel.

What should you do for the organization?

Although there are numerous resources available online and at local bookstores, a compliance officer must reference the core materials initially. The core materials are Chapter 8 of the Federal Sentencing Guidelines, OIG compliance program guidance, and regulations impacting their organization's industry. Understanding the core materials initially provides the compliance officer with a foundation to remain grounded.

The organization expects the compliance officer to deliver on the responsibilities of the job description. At the same time, the compliance officer is to lead the organization by providing guidance consistent to the core materials previously mentioned. To do this, the CO must remain visible; the role needs to remain visible. If these items are not aligned, the compliance officer is responsible for ensuring these items become aligned. According to *Compliance 101*,[1] "The main focus of the position should be the implementation, administration and oversight of the compliance program." Because the organization's goal is to implement an effective compliance program, the compliance officer has a duty to ensure the program mirrors, to the extent possible and based on size and culture, an effective compliance program as defined by the Federal Sentencing Guidelines and OIG compliance program guidance.

On the first day, you as the compliance officer must equip yourself with your best smile and introduce yourself to the key operational leaders. During the introduction, inform each operational leader that you look forward to scheduling a more formal meeting to learn more about their operations. Eventually, you will recruit these individuals as members of the compliance committee.

Establish a plan. Advise your direct report, for example, that you need a 30-day plan (or longer) before contributing certain findings or even establishing a compliance committee. Make yourself visible, depending on the size or type of organization; make visits to all the patient care units, clinical departments, service departments, and community centers. Attend as many committee meetings as you can. The business is probably a 24-hour operation, so make time and meet with supervisors and staff on the off hours. You are now ready to establish a compliance committee.

The compliance committee is an effective means to focus on difficult compliance issues, demonstrate a management commitment to compliance, and facilitate communication on compliance issues within an organization. The committee must have the support, the resources, and the dedicated members with real experience in the compliance area. The compliance committee helps you to navigate legal obligations and serves a proactive role separate from the audit committee.[2] The compliance committee is responsible for many functions, but the primary function is to support the compliance officer.

When establishing your committee, include senior leadership from all disciplines. Many organizations are already experienced enough to know their leadership needs to be involved. Meet with members of the leadership and every other key member of your soon-to-be committee. See what their experiences are, understand their roles, their needs, their understanding of the compliance committee, and explain your vision.

To implement, administer, and provide oversight of the compliance program, the compliance officer must conduct a risk assessment to determine the existence of the seven elements of the compliance program, which are:

1. Implementing written policies, procedures, and standards of conduct
2. Designating a compliance officer and compliance committee
3. Conducting effective training and education
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing
6. Enforcing standards through well-publicized disciplinary guidelines
7. Responding promptly to detected offenses and undertaking corrective action

Does each element exist? If so, determine each element's effectiveness level. If any element is missing, determine an implementation strategy and timeline to ensure you have a complete and effective compliance program. Effectiveness can be determined with probe audits, surveys, or informal meetings with department heads and frontline staff. Meeting with frontline staff also provides you with knowledge of the awareness level for the compliance program.

The compliance committee can assist in meeting many needs, by establishing a mission and vision, by conducting ongoing audits with meaningful reports, and by developing an air of free discussion on hard-pressed topics.

How do you meet the challenges?

Many leaders describe the changing regulations as a roller coaster ride. As a roller coaster rider, you are aware that the ride is unpredictable with sharp turns, huge drops, and loops. The goal is to walk away with a new experience while maintaining your possessions (e.g., sanity, loose change, keys, caps, etc.). To prepare, many riders move loose items from their front pockets into their back pockets. Additionally, they double- or triple-check seatbelts and lock bars before the attendant initiates a final check. Finally, those with less experience grab and brace the lock bars during the ride; those with more experience wave their hands.

> Regulations are rapidly changing, so remaining in sync with these changes is very important.

Similar preparations are necessary as a compliance officer. Regulations are rapidly changing, so remaining in sync with these changes is very important. A compliance officer should have the applicable industry regulations readily available for reference. Whether it is a set of hardbound books updated regularly, smartphone apps, a list of applicable websites, or all of the above, compliance officers prepare for the unpredictable by equipping themselves with these items. Many smartphone apps and regulatory websites offer notification services that provide instant, daily, weekly, or monthly updates. Be sure to create a login and sign up for notifications.

Unpredictable with sharp turns, huge drops, and loops

The second delay of ICD-10 is a recent example of an unpredictable sharp turn, huge drop, or loop. Depending on the professional, the response may be to gather more information, revise your plan, panic, or all three. Nonetheless, not many industry professionals predicted the ICD-10 delay. Many people in organizations throughout the industry felt the impact of the decision to delay the

implementation date with a funny feeling in their abdomens, similar to that on a roller coaster ride. The ability to provide compliance guidance during and after an unpredictable event may reduce the intensity of the challenge. For the ICD-10 roller coaster, the CO must apply the steady hand by focusing on the positives of the delay. Emphasize staying the course for coding education and clinical documentation improvement efforts. Safeguard your organization's financial outlay by continuing to utilize applications, training, and testing of systems. Just as you feel more confident knowing the roller coaster has regular maintenance and safety checks, testing systems during the ICD-10 delay will provide additional assurance.

Walk away with an experience but maintain possessions

Being a compliance officer is a challenging and often, rewarding experience. Confidently approaching each challenge that results in positive or negative outcomes is draining. According to participants of HCCA's "Compliance 101" sessions at the New York Regional Compliance Institute, compliance officers may face several challenges when implementing an effective compliance program. A few of the challenges are lack of commitment and buy-in, lack of funding, lack of resources and staff, no internal enforcement, and resistance to change.

To consistently meet each challenge with the same amount of energy requires maintaining a healthy balance between professional, social, and physical activities to prevent premature burnout. Socially, spend time with relatives and friends. These individuals are your support structure outside of the organization. Ensuring your schedule contains a designated timeslot for relatives and friends may eliminate premature burnout.

Physically, make sure to designate time for an activity that protects you from fatigue. Walking between facilities, arranging walking meetings, or working out prior to or after work will keep you physically and mentally prepared for challenges.

Check seatbelts and lock bars

As members of the Health Care Compliance Association and/or Society of Corporate Compliance & Ethics, compliance officers have access to a network of compliance professionals and resources. Networking with other compliance professionals may confirm or even expand your understanding of a regulation. Additionally, other compliance professionals may have addressed a topic within their organization; sharing the experience through communication is beneficial. The combination of referencing regulations and reference materials, applying what you've learned, and engaging the network may reinforce the guidance the compliance officer is attempting to deliver.

Compliance officers abide by the three principles of the Code of Ethics[3] published by HCCA: (1) obligation to the public, (2) obligation to the employing organization, and (3) obligation to the profession. As the new CO for your organization, you are the operator of the roller coaster (subject to industry changes) and responsible for the safety of the riders (your organization and its patients). You alert the maintenance department (CEO or board of directors) to potential risks, and ensure a positive experience for all involved. Thank you for accepting this role. We look forward to you contributing positive change to your organization and sharing your experiences with the compliance community.

The authors would like to extend a special thanks to John E. Retlaw for his contribution to this article.

1. Debbie Troklus and Greg Warner: *Compliance 101.* Third Edition. September 1, 2011. Health Care Compliance Association
2. Carla Wallace, Karen Voiles, Julie Dean: Health Care Compliance Program Tips. *QHR;* Article Number 68. Available at http://bit.ly/1umYeXB
3. HCCA: Code of Ethics for Health Care Compliance Professionals. Available at http://bit.ly/hcca-code-of-ethics

Congratulations, newly certified designees!

Achieving certification required a diligent effort by these individuals. Certified individuals promote organizational integrity through the development and operation of effective healthcare compliance programs.

Certified in Healthcare Compliance (CHC)®

- Lee O. Barron
- Wanda L. Bell
- Kenneth Bivens
- Irene Borgen
- Kevin P. Cahill
- Daryl F. Cannon
- Tarra S. Carey
- Steven Chiem
- Holly A. Conner
- Patty E. Dal Soglio
- Jamella L. Davis
- Valerie M. Dixon
- Cecile R. Favreau
- Maggie M. Feener
- Leslie L. Flake
- Pamela S. Fowler
- Aaron J. Goldstein
- Tamar Gorenyuk
- Heidi Heilemann
- Linda Heller
- Robert S. Hinyub, Jr.
- Todd Jacobson
- Jessica L. Johnson
- Kristin A. Jordan
- Renee Jordan
- Beth A. Katzenberg
- Michelle D. Kirby
- Diane M. Lerch
- Laurena S. Lockner
- Barbara Lowman
- Sandra J. Lyons-Jackson
- Hazel M. Mahoney
- Joann E. Martinez
- Marcos R. Mata
- Gregory G. Meredith
- Elizabeth F. Montemayor
- Jenna Morgenthaler
- Shira Mowlem
- Melanie O'Neill
- Allison M. Orlina
- Valorie Palmer
- Jami R. Papenberg
- Randall K. Patton
- David Porter
- Nan E. Rayburn
- Caterina A. Scianna
- Dena M. Sites
- Ann Marie M. Skullr
- Mary E. Smalle
- Michael H. Tokash
- Nikki C. Torento
- Lisa Traudt
- Staci Trolian
- Diana M. Visconte
- Shalen Young

Certified in Healthcare Research Compliance (CHRC)®

- Salima J. Ali
- Trissi S. Gray
- Vachiraporn Jaicheun
- Emily R. Kam
- Andrew Mahler
- Polly Mock
- Jennifer M. Morrison
- Tonya Okon
- Susan Robb
- Rebecca C. Rogers

Certified in Healthcare Privacy Compliance (CHPC)®

- Angela B. Anderson
- Bryant B. Belarmino
- Bess Ann Bredemeyer
- Louise Bucolo
- Miranda Burnett
- Lisa A. Burroughs
- Gail L. Campanale
- Teresa Carver
- Michelle L. Castle
- Michele Cianfrani-Pain
- Terri L. Dorazio
- Kristi N. Ford
- Gino Garcia
- Rachel Haczewski
- Kevin Haralson
- Christopher K. Hart
- Sergio Herrera
- Steven Johnson
- Stephen M. Kelly
- Dawnese Kindelt
- Michelle L. Knowles
- Mary Ann LeVesque
- Cara A. Lisica
- Heather Lorenzetti
- Aaron W. Mallin
- Rebecca L. Martin
- Brenda McMillin
- Susan P. Montiel
- Garland M. Morton
- Laura M. Naredo
- Lisa J. Paige
- Robin M. Pearsall
- Grace Rawlins
- Donna Schneider
- Lisa M. Silveria
- Sherrie L. Sorenson
- Peter C. Spratt
- Caren J. Sullivan
- Beau Sylvester
- Colleen Thompson
- Sue Ulrey
- Barbara Walro
- Francine Wojton-Grisanti

CCB offers these certifications: Certified in Healthcare Compliance (CHC)®, Certified in Healthcare Compliance Fellow (CHC-F)™, Certified in Healthcare Research Compliance (CHRC)®, and Certified in Healthcare Privacy Compliance (CHPC)®. To learn more, please contact us at ccb@compliancecertification.org, visit *www.compliancecertification.org*, or call 888-580-8373.

Want to become

Certified in Healthcare Compliance (CHC)®?

BE RECOGNIZED for your experience and knowledge!

The Certified in Healthcare Compliance (CHC)® designation demonstrates expertise in the healthcare compliance field. Earn yours today:

- Meet eligibility requirements in both work experience and continuing education
- Pass the CHC exam
- Maintain your designation by earning approved continuing education units

CHC™
Certified in Healthcare Compliance

Questions? Contact
ccb@compliancecertification.org

For more details on earning and maintaining this designation, please find the *CHC Candidate Handbook* or other information at www.compliancecertification.org under the "CHC" tab.

COMPLIANCE CERTIFICATION BOARD®

HCCA *welcomes* NEW MEMBERS

ARIZONA
- Amanda Dean, Arizona Department of Health Services Bureau of Corporate Compliance
- Sarah Keown, Arizona Health Care Contract Management Services
- Andrew Mahler, The University of Arizona
- Marc Pruzansky
- Danielle Schwartz, Arizona Digestive Health
- Mehlanee Stuart, Spectrum Healthcare Group, Inc
- Shalen Young, Banner Health

ARKANSAS
- George Platt, Arkansas Superior Select, Inc

CALIFORNIA
- Alissia Aguayo, San Diego Imaging
- Bahea Albarghoute, L.A. Care Health Plan
- Kathleen Bates, University of California, San Francisco
- Shivani Bhambri, Stanford Hospital & Clinics
- Lowell Brown, Arent Fox LLP
- Elaine Cooperstein, University of California, San Francisco
- Paul Filice, Kaiser Permanente
- Teresa Hayman, Dignity Health
- Sergio Herrera, L.A. Care Health Plan
- Michael Heximer, CareChoices Network
- Gerry Hinkley, Pillsbury Winthrop Shaw Pittman LLP
- Robert Johnson, SI-BONE, Inc
- Veena Kumar, Dignity Health
- Arcelia Lopez, California Department of Veterans Affairs
- Regina Noonan, Borrego Community Health Foundation
- Vanessa Ridley, Santa Clara County Health & Hospital System
- Andrea Sun, University of California-San Francisco
- Elle Woods, Memorial Care Medical Group

COLORADO
- Carolyn Buppert, Law Office of Carolyn Buppert, PC
- Paul Burek, AP2 UniPath
- Pamela Hale, PK LTD
- David Hayden, Mind Springs Health
- Rosland McLeod, SCL Health
- Gayle Von Loh, Banner Health - North Colorado Medical Center
- Dawn Yancey, Rocky Mountain Cancer Centers

CONNECTICUT
- Moses Vargas, Connecticut Children

FLORIDA
- Tonya Barnes, University of Miami Hospital
- Desiray Co, Parrish Medical Center
- Cheryl Kerr, Jupiter Medical Center
- Mona Newton, First Coast Medical Center, Inc
- Christina Serra, University of Central Florida
- Sharon Westlake, Adventist Health System
- Andrea Zimmerman

GEORGIA
- Emily Smotherman, Childrens Healthcare of Atlanta

HAWAII
- Brittani Summers, Precision Toxicology

ILLINOIS
- James Doty, Land of Lincoln Health
- Grace Fan, Astellas LLC
- Cherry Grant, BlueCross BlueShield
- Maureen Hicks, Healthcare Information Services, LLC
- Melissa Knazze
- Mary Pidich, Select Rehabilitation, Inc
- Kindy Velez, University of Chicago Medicine

INDIANA
- Rob Matt, Hancock Regional Hospital
- Tracey Thompson, Eskenazi Health

IOWA
- Gary Botine, Mary Greeley Medical Center
- Liz Davidson, Leading Age Iowa
- Judi Erickson, Midwest Opportunities
- Todd Muckey, Bethany Lutheran Home
- Hope Sprague, G&G Living Centers, Inc
- Sara Tubbs, DAC, Inc

KANSAS
- Christopher Schneweis, Johnson County Government

KENTUCKY
- Trula Leach, Elizabethtown Hematology-Oncology

MARYLAND
- Hollie Seaton, Perdue Foods

MASSACHUSETTS
- Gerard Campbell, University of Massachusetts Medical School - Commonwealth Medicine
- Mike Kelliher, Behavioral Health Network, Inc

MICHIGAN
- Kay Fuller, RAC, Medical Device Regulatory Solutions LLC
- Jenice Hand, Detroit Medical Center
- Kristine Jackson, Blue Cross Blue Shield of Michigan
- Kelly Keenan, Spectrum Health Zeeland Community Hospital
- Larry Kubiak, Tenet Healthcare Corporation
- Karen Shastachuk, Detroit Medical Center

MINNESOTA
- Kimberly Akre, CliftonLarsonAllen LLP
- Mary Aylward, Essentia Health
- Joanne Groenewold, Medtronic Inc

MISSISSIPPI
- Stephen Jackson

MISSOURI
- Michelle Piranio, University of Missouri Health Care System
- Christina Randolph, Thompson Coburn LLP
- Wakaba Tessier, Husch Blackwell

NEBRASKA
- Jake Curtiss, Pharmaceutical Technologies, Inc

NEW JERSEY
- Caroline Ivanovski-Hauser, Bergen-Passaic Cataract Surgery and Laser Center
- Michael McCarthy, Cooper University Health Care

NEW YORK
- Andrea Ansorge, Hospital for Special Surgery
- Paul Burns, Slide Mountain LLC
- Kim Charland, Panacea Healthcare Solutions, Inc
- Cyprian Devine-Perez, New York University Medical Center
- Amethyst Jumbo, SCO Family of Services
- Heather Morgan, United Methodist Homes
- Tina Tryan, People Inc

NORTH CAROLINA
- Lisa Foster, Southern Regional AHEC
- Kathy Herring, Mountain Radiation Oncology, PA
- Meredith Mullins

OHIO
- Colleen Curran, Deloitte & Touche, LLP
- Anthony Lopez, Anesthesia Compliance Consultants
- Claire Turcotte, Bricker & Eckler LLP

OKLAHOMA
- Darlene Nolte, Craig General Hospital

OREGON
- Jeffrey Dover, ATRIO Health Plans
- Marilyn Tatro, Ensign Services, Inc

PENNSYLVANIA
- Stephanie Boyer, St. Luke's University Health Network
- Kelly Ditsche, Childrens Hospital of Philadelphia
- Laura Faulkner, CliftonLarsonAllen LLP
- Tara Howes, University of Pittsburgh Medical Center
- Erin Jack, Excela Health
- Camille Jescavage, TMG Health Inc
- Alexis Langella, Buchanan Ingersoll & Rooney PC
- Kathleen McGoldrick, AmeriHealth Caritas
- LeDice Murphy, Aetna Better Health Pennsylvania
- Lauren Parsons
- Paula Rowe, Children's Hospital of Philadelphia
- Cathlin Sullivan, Genesis HealthCare
- Jackie Viecelli, MedCare Equipment Company, LLC
- Terry Yandrich, Jefferson Hospital
- Jill Zimmerman, Penn Highlands DuBois

TENNESSEE
- Kim Boshers, Vanderbilt University Medical Center
- Ashley Flagg, Catholic Health Initiatives
- Tamar Myrick, TEAMHealth
- Andrew Shine, Catholic Health Initiatives/Memorial Hospital
- Suzette Stevens, HealthSpring

TEXAS
- Marc Billiot, HCA - The Woman's Hospital of Texas
- Cathie Bristo, Wilbarger General Hospital
- LaTonya Cole, Conifer Health Solution
- Cindy Hunter, TMF Health Quality Institute
- Jonathan Ishee, Vorys Sater Seymour and Pease, LLP
- Shane Jones, Wise Regional Health System
- Kathy Mahlow, Baylor Surgical Hospital at Las Colinas
- Juliette Morell, Texas Health Physician
- Stacy Pritt, UT Southwestern Medical Center
- Steven Whigham, McCreary, Veselka, Bragg & Allen, PC

UTAH
- Richard Rupert, TyphoonDATA

VIRGINIA
- Shannon Carillo, Apex Billing Solutions, Inc
- Susanne Pannes, Rotech Healthcare Inc
- Martha Scott, Amerigroup
- Beverly Smith, UnitedHealth Group

WASHINGTON
- Julio Galarza, UW Medicine Compliance
- Lisa Grosso, North Sound Mental Health Administration
- Kjersti Hagman, Group Health
- Larry Horne, Thurston-Mason Regional Support Network
- Laura Hunt
- Marcia Kelbon, Omeros Corporation
- Sue Lasicka, HealthPoint
- Stephani Lind, Othello Community Hospital
- Michelle Matt, HealthPoint
- Traci McCall, Lincoln Hospital District #3
- Ricardo Perez, Seattle Cancer Care Alliance
- LeAnne Sether, HealthPoint
- Tami Visser, Lummi Indian Business Council

WISCONSIN
- Beth Alvin, WEA Trust
- JuliAnna Meyer, Froedtert Hospital
- Colleen Patzer
- Breanna Suskey-Peyton, Medical College of Wisconsin
- Catherine Walker, Scion Dental

WASHINGTON DC
- Kathryn DeJesus, Medstar Washington Hospital Center
- David Matyas, Epstein Becker & Green PC
- Nikhil Mody, FTI Consulting
- Michael Paddock, Pillsbury Winthrop Shaw Pittman
- Asha Scielzo, Pillsbury Winthrop Shaw Pittman

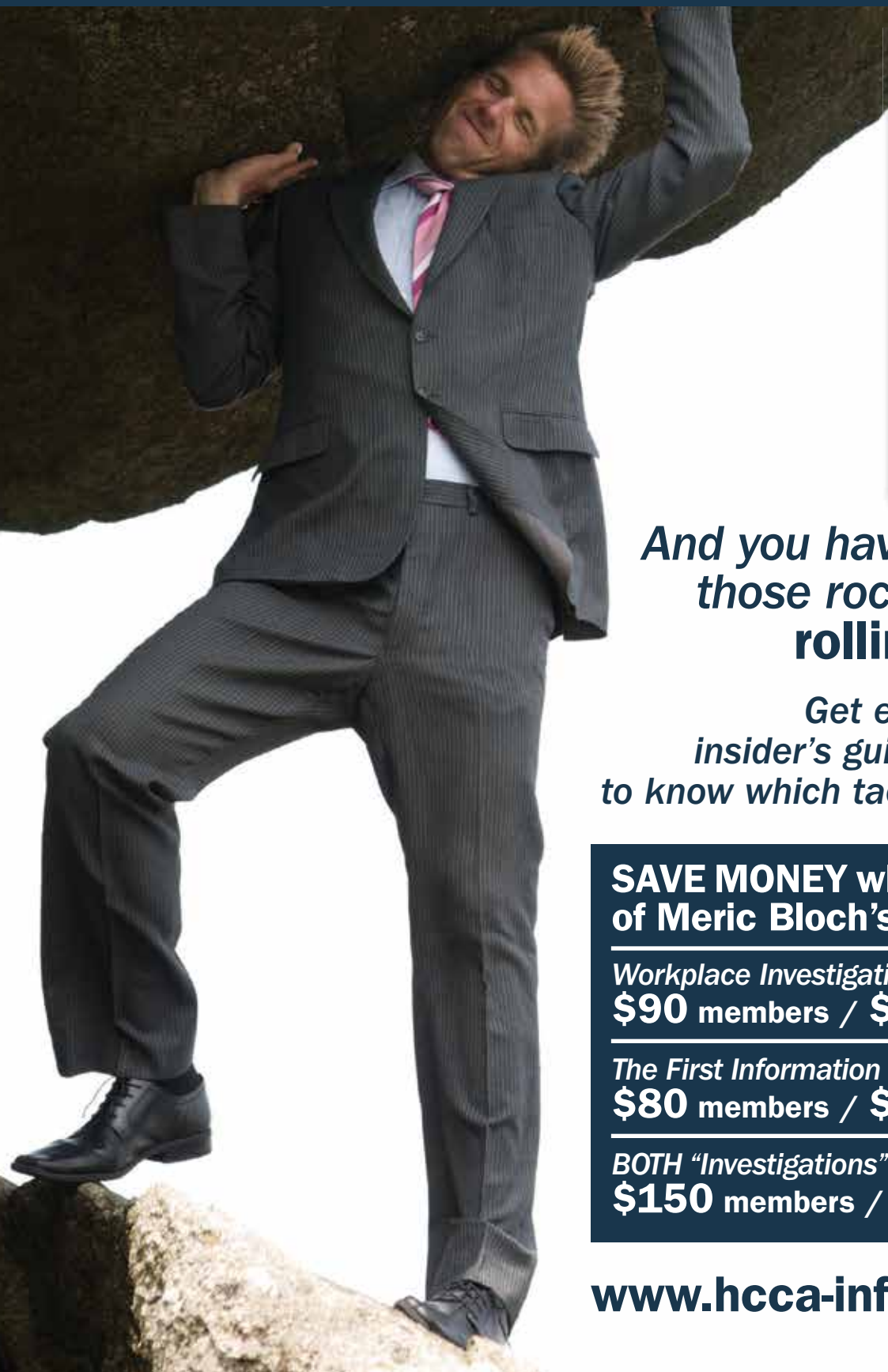
JOIN HCCA
ON SOCIAL MEDIA

www.hcca-info.org

HCCA's Corporate Members

Learn about the benefits of corporate membership at www.hcca-info.org/corporate

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



And you have to make sure those rocks don't end up **rolling over you…**

Get expert Meric Bloch's insider's guide to investigations to know which tactics will work best.

SAVE MONEY when you buy BOTH of Meric Bloch's books at once:

Workplace Investigations
$90 members / $100 non-members

The First Information Is Almost Always Wrong
$80 members / $90 non-members

BOTH "Investigations" books as a set
$150 members / $170 non-members

www.hcca-info.org/FirstInfo

Tear out this page and keep for reference, or share with a colleague. Visit www.hcca-info.org for more information.

Supervision of outpatient therapeutic services in the critical access hospital

Tomi Hagan (page 25)

- Critical access hospitals are now required to comply with the Supervision of Hospital Outpatient Therapeutic Services policy as a condition for Medicare payment.
- Direct supervision is required for all outpatient therapeutic services except for those designated for modified levels.
- Modified levels of supervision include general, personal, and the two-tiered non-surgical extended duration therapeutic service.
- Challenges facing critical access hospitals include identification of services, availability of qualified supervisory practitioners, mid-level provider restrictions, and limitations in the Emergency Department and rural health clinic.
- Steps to compliance include assessment of services provided, identification of supervisory practitioners, documentation, education, and monitoring.

Regulatory delays: Hurry up and wait

Karen Nelson (page 31)

- Regulatory delays can create challenges for healthcare organizations.
- New laws are subject to interpretation by governmental agencies and courts.
- The regulatory process allows for public participation and readjustment, giving healthcare organizations an opportunity for advocacy.
- Governmental agencies seek to balance the needs of healthcare organizations and other stakeholders.
- Regulatory delays can be managed successfully.

Be prepared for eDiscovery

Dean Boland (page 35)

- Litigation is inevitable and electronic data is the first front.
- Updating/auditing IT in preparation for litigation is necessary.
- eDiscovery is not a set-it-up-and-forget-it proposition.
- Inside counsel must understand technology sufficiently to manage eDiscovery.
- Different technology specialties have different functions; not all are eDiscovery capable.

Stark compliance: A focus on medical office building leases

Eugene A. (Tony) Fay (page 41)

- The Stark Law could be implicated if a hospital leases space to a referral source at rates below fair market value (FMV) or on terms that are not commercially reasonable.
- Medical office building (MOB) leases are complicated, and the FMV rental rate could vary on a suite-by-suite basis.
- Determining FMV requires a real estate appraiser with direct experience in MOB leases.
- The lease agreement or legal file should contain a copy of the fully executed lease agreement, along with a floor plan of the leased premises and the summary page from the FMV rental rate study.
- A compliance monitoring plan should be developed to monitor the accuracy and timeliness of rental payments.

How clinical integration lowers fraud and abuse risks

Alice G. Gosfield (page 47)

- Clinical integration can only begin with physicians working with each other.
- The standardization in clinical integration can lower false claims liabilities.
- Clinical integration requires that the collaborators adopt "value" as a value.
- The Stark regulations allow hospitals to offer free compliance training to staff members with continuing education credit.
- Hospitals that employ physicians will not succeed if they do not help their recruits to clinically integrate.

Maximizing research compliance reviews as part of your human research protections program

Emmelyn Kim (page 51)

- Employ targeted, risk-based compliance reviews to enhance program efficiency.
- Work with the Human Research Protection Program (HRPP) staff to maximize reviews.
- Standardize assessments, tools, and reports for consistency and ease of data analysis.
- Ensure transparency after the review process.
- Use metrics to streamline your compliance program and inform policy and education.

New CMS guidelines for acquiring a Medicare provider: Buyer beware

Kelly J. Skeat and Ari J. Markenson (page 54)

- Buyers face delays, surveys, and lost reimbursement under the new guidelines.
- Conducting due diligence in transactions is more important than ever.
- Representations, warranties, and indemnification provisions must be carefully negotiated.
- Purchase agreements must address who owns and controls Medicare records.
- The compliance team is integral to the entire transaction process.

The definition of "instrumentality" under the FCPA

Tom Fox (page 59)

- The Esquenazi decision is the first time a Court of Appeals discussed the definition of instrumentality under the FCPA.
- The Court developed a two-pronged test to determine if a state-owned enterprise is an instrumentality under the FCPA: the Control and Function tests.
- The Control test looks at how much control a government has over a state-owned enterprise.
- The Function test reviews how a state-owned entity functions in a country.
- The common test found in case law to determine if a state-owned enterprise is an "instrumentality" under the FCPA is actual control.

The final BAA deadline is September 22, 2014. Are you ready?

Tod Ferran (page 65)

- Business associates (BAs) include transcriptionists, pharmacies, and shredding companies.
- Satisfactory assurances demand BA patient data-handling processes be checked.
- Business associate agreements (BAAs) should include both covered entity and business associate obligations.
- Validation can be obtained in-house or through a trusted vendor.
- Updating BAAs provides opportunities to re-evaluate relationships and organizational security.

Compliance 101: The seven essential elements, Part 2: Designating a compliance officer and compliance committee

Adam K. Weinstein and Cindy Hart (page 68)

- The purpose of a compliance officer is to be neutral and free of bias.
- Every large organization needs a compliance committee.
- Key starting points will help guide you as a compliance officer.
- The compliance officer should participate in designating members of the compliance committee.
- Preparing for challenges associated with the role will ease the transition.

HCCA's Upcoming Events

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

September 2014

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
31	1 HCCA OFFICE CLOSED *Labor Day*	2	3	4 WEB CONFERENCE: *Risk-Based Monitoring: Not a One-Size-Fits-All Approach*	5	6
7	8 **Healthcare Privacy Basic Compliance Academy** San Francisco, CA	9 WEB CONFERENCE: *FY 2014: Hot Topics in Research Compliance*	10	11 CHPC Exam	12 **New England Regional Conference** Boston, MA	13
14	15	16	17	18	19 **Upper Midwest Regional Conference** Minneapolis, MN	20
21	22	23 WEB CONFERENCE: *Integrating PEPPER into Your SNF Compliance Program* *First Day of Autumn*	24	25 WEB CONFERENCE: *The Risk Analysis/ Risk Management Cycle: The Foundation for an Effective Security and Privacy Program* *Rosh Hashanah begins* *Navaratri begins*	26	27
28	29 **Midwest Regional Conference** Overland Park, KS **Basic Compliance Academy** Nashville, TN	30	1	2 CHC Exam	3	4

October 2014

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
28	29 **Midwest Regional Conference** Overland Park, KS **Basic Compliance Academy** Nashville, TN	30	1	2 CHC Exam	3 *Yom Kippur begins*	4 *Eid al-Adha*
5	6 **North Central Regional Conference** Indianapolis, IN	7	8	9 WEB CONFERENCE: *HIPAA Privacy & Security Risk Analysis: Real World Methods for Compliance*	10 **East Central Regional Conference** Pittsburgh, PA	11
12 **Clinical Practice Compliance Conference** Philadelphia, PA	13 *Columbus Day*	14 WEB CONFERENCE: *Auditor Secrets: How to Prepare for Top HIPAA Compliance and Data Security Threats*	15	16 **Hawaii Regional Conference** Honolulu, HI	17	18
19	20 **Basic Compliance Academy** Las Vegas, NV	21	22	23 CHC Exam *Diwali*	24 **Mountain Regional Conference** Denver, CO *Muharram begins*	25
26	27 **Basic Compliance Academy** Chicago, IL	28	29	30 CHC Exam	31 *Halloween*	1

Dates and locations are subject to change.

Clinical Practice Compliance Conference

October 12–14 • Philadelphia, PA

Basic Compliance Academies

September 29–October 2 • Nashville, TN — **SOLD OUT**

October 20–23 • Las Vegas, NV — **SOLD OUT**

October 27–30 • Chicago, IL — **SOLD OUT**

November 17–20 • Orlando, FL — **SOLD OUT**

December 1–4 • San Diego, CA — **LIMITED SEATS**

Research Basic Compliance Academies

November 3–6 • Orlando, FL

Healthcare Privacy Basic Compliance Academies

September 8–11 • San Francisco, CA

November 3–6 • Orlando, FL

Regional Conferences

New England • September 12 • Boston, MA

Upper Midwest • September 19 • Minneapolis, MN

Midwest • September 29 • Overland Park, KS

North Central • October 6 • Indianapolis, IN

East Central • October 10 • Pittsburgh, PA

Hawaii • October 16–17 • Honolulu, HI

Mountain • October 24 • Denver, CO

Mid Central • November 7 • Louisville, KY

Desert Southwest • November 14 • Phoenix, AZ

South Central • November 21 • Nashville, TN

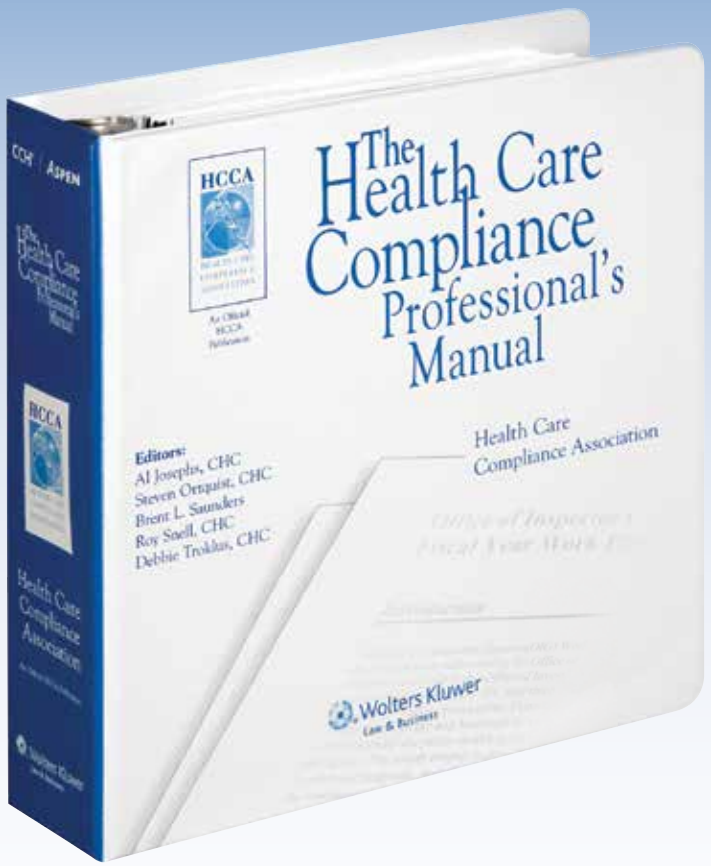
Upper West Coast • December 5 • San Francisco, CA

Gulf Coast • December 12 • Houston, TX

HCCA

HEALTH CARE COMPLIANCE ASSOCIATION

The Health Care Compliance Professional's Manual



SUBSCRIPTION SERVICE INCLUDED WITH PERIODIC UPDATES

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

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

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

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

MEMBER PRICE: $399
NON-MEMBER PRICE: $439

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

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

Wolters Kluwer
Law & Business

Start planning now for

HCCA's 2015 Conferences

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

Learn more at www.hcca-info.org

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

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

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 • Chicago, IL

November 2–5 • Orlando, FL

Research Basic Compliance Academies

March 2–5 • San Diego, CA

November 2–5 • Orlando, FL

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

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.