HCCA HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

May 2015

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

From the courtroom to Compliance — one lawyer's journey and the lessons learned

an interview with Tracy Carlson Ivers
Compliance and Legal Analyst, Masonicare

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NEW *from HCCA in 2015*

Register by August 18

SAVE $175

Healthcare Enforcement Compliance Institute

October 25–28, 2015 | Washington Hilton | Washington DC

General Session speakers announced

Michael Horowitz, Inspector General, United States Department of Justice

Cynthia Schnedar, Director, Office of Compliance

Greg Demske, Chief Counsel to the Inspector General, HHS-OIG

Jocelyn Samuels, Director, U.S. Department of Health and Human Services Office for Civil Rights

Learn more at hcca-info.org

Questions? taci.tolzman@corporatecompliance.org

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HEALTH CARE COMPLIANCE ASSOCIATION

by Roy Snell, CHC, CCEP-F

Thank you

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*

We have just passed the 10,000 member mark as we near our 20th anniversary. These milestones cause reflection. Why are we where we are? There are a number of reasons, starting with the Board leadership and a tremendous staff.

Snell

However, all that effort is for naught if the people in our profession were not as generous as they are. Our success is directly related to the support of those who have contributed articles, spoken at conferences, contributed to the discussion on social media, etc. That is what has attracted people to our organization. That is what keeps people coming back. That is why the organization is respected by people outside the organization. We pride ourselves on our quality of expertise and content that you have provided. The Certified in Healthcare Compliance credential is respected because volunteers have put it together. The leadership and staff of the organization thank you. Attendees of conferences, readers of the magazine, and the people who hold a credential thank you.

I am often asked, "How can I get involved?" Here are some of the ideas I can think of:

- Submit multiple ideas for presenting at multiple conferences
- Write an article for *Compliance Today*
- Contribute blog posts to *The Compliance and Ethics Blog*
- Write for *Ethikos*
- Send in news for *TWCC*, the weekly e-news magazine, to *HCCAservice@hcca-info.org*
- Write for *The Health Care Compliance Professional's Manual*
- Contribute audit tools to *Health Care Auditing & Monitoring Tools*
- Contribute to our social media, through HCCA*net*, Twitter, LinkedIn, Instagram, etc.
- Propose a local enforcement speaker for a local HCCA conference
- When switching jobs, send in something to *margaret.dragon@coporatecompliance.org* for "People on the move" in *Compliance Today*
- Post documents on HCCA*net*

> Our success is directly related to the support of those who have contributed articles, spoken at conferences, contributed to the discussion on social media, etc. That is what has attracted people to our organization. That is what keeps people coming back.

There are many other ways to get involved. If all else fails, call or email the office and ask to speak to someone about these or other ideas. We can be reached at 952-988-0141 or *HCCAservice@hcca-info.org*.

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

> Resource consolidation and ROI are going to motivate compliance officers and senior leadership teams to measure performance and outcomes differently.

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Compliance TODAY

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VOLUME 17, ISSUE 5

Former company officer earns half-million dollar whistleblower award

The Securities and Exchange Commission (SEC) has recently announced "a whistleblower award payout between $475,000 and $575,000 to a former company officer who reported original, high-quality information about a securities fraud that resulted in an SEC enforcement action with sanctions exceeding $1 million."

According to the SEC press release, "Officers, directors, trustees, or partners who learn about a fraud through another employee reporting the misconduct generally aren't eligible for an award under the SEC's whistleblower program. However, there is an exception to this exclusion that makes an officer eligible if he or she reports the information to the SEC more than 120 days after other responsible compliance personnel possessed the information and failed to adequately address the issue. This is the first SEC whistleblower award to an officer under these circumstances.

"'Corporate officers have front-row seats overseeing the activities of their companies, and this particular officer should be commended for stepping up to report a securities law violation when it became apparent that the company's internal compliance system was not functioning well enough to address it,' said Andrew Ceresney, Director of the SEC's Division of Enforcement."

For more: *http://1.usa.gov/1GV6J5e*

Survey reveals shortfalls in healthcare security & compliance policy and major mobile vulnerabilities

A recent survey conducted by DataMotion,™ an experienced email encryption and health information service provider (HISP), reveal a significant amount of security risk occurring within organizations.

According to the DataMotion press release, "While companies in all industries increasingly have put security and compliance policies in place—nearly 90 percent of all respondents affirming that in 2014 (compared to 81 percent in 2013)—the growth is largely from healthcare entities. More than 97 percent from the industry report their organizations as having policies in place, compared to 90.4 percent in 2013. However, challenges remain for healthcare when it comes to implementing these, ranging from low employee comprehension to policy violations. Additionally, a lack of encryption, risks in mobile device usage and low awareness of Direct Secure Messaging (Direct) pose serious issues for the highly regulated industry."

DataMotion reported it "polled more than 780 IT and business decision-makers across the U.S. and Canada. In particular, the survey focused on individuals who routinely work with sensitive data and compliance regulations in a variety of industries including healthcare, financial services, education and government. More than 300 respondents were from healthcare."

For complete survey results (registration required): *http://bit.ly/1AwktMC*

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

Regulatory news

Joint Commission awards first Memory Care Certification

The Joint Commission's Nursing Care Center Accreditation Program recently announced in a press release "that Chaparral House, a nonprofit skilled nursing facility in Berkeley, California, is the first skilled nursing facility in the United States to be awarded the organization's Memory Care Certification.

"The Joint Commission began offering Memory Care Certification in July 2014 to recognize nursing homes that provide memory care services for patients and residents with dementia and other cognitive impairments. The certification was developed with feedback from respected industry experts in memory care, and builds upon new accreditation requirements addressing memory care services that also took effect at that same time for all currently accredited nursing homes and those seeking accreditation."

For more: *http://bit.ly/18Tc6Df*

CMS delays final rule on Reporting and Returning of Overpayments

On February 18, 2015, *McKnight's Long Term Care News* reported that the Centers for Medicare and Medicaid Services "made official its plan to postpone implementation of a new rule on collecting hundreds of millions of dollars in overpayments until Feb. 16, 2016—but providers remain on the hook for returning the money before then."

According to the notice in the Federal Register (FR), "This document announces the extension of the timeline for publication of the 'Medicare Program; Reporting and Returning of Overpayments' final rule."

For complete FR notice: *http://1.usa.gov/1DsS9Rk*

CMS publishes final rule on Right of Appeal for Medicare Secondary Payer Determinations Relating to Liability Insurance

The final rule was published in the February 27, 2015 Federal Register: "This final rule implements provisions of the Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act) which require us to provide a right of appeal and an appeal process for liability insurance (including self-insurance), no-fault insurance, and workers' compensation laws or plans when Medicare pursues a Medicare Secondary Payer (MSP) recovery claim directly from the liability insurance (including self-insurance), no-fault insurance, or workers' compensation law or plan."

For more: *http://bit.ly/19s72gr*

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

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

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Nov 30–Dec 3 • San Diego, CA

Learn more and register at
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HCCA *conference news*

Research Compliance Conference

May 31–June 3, 2015 | Austin, TX

www.hcca-info.org/research

Join us in Austin for the primary networking and learning event for compliance and ethics professionals within Research Compliance. Don't miss this opportunity to help increase the effectiveness of your institution's research compliance program by gathering with your peers to discuss emerging risks and issues, share best practices, and build valuable relationships.

The program will cover a wide range of research compliance hot topics, including the following general sessions:

- Federal Enforcement Priorities for Research Compliance
- Compliance Implications for Cutting Edge Research
- Research Year in Review
- The Top 10 Human Research Protection Compliance Risks

More than 20 breakout sessions will be offered beginning Sunday, May 31 through Wednesday, June 3. Timely topics will include:

- Billing and compliance concerns
- Clinical trial disclosure requirements
- FDA warning letters
- Enterprise research risk
- and many more!

By registering as an attendee for the Research Compliance Conference, you'll gain complimentary access to SCCE's Higher Education Compliance Conference. The parallel schedule gives you the freedom to attend sessions at either conference—two for the price of one.

At the conclusion of the conference, the Certified in Healthcare Research Compliance (CHRC)® exam will be administered. Attendees of the conference have the opportunity to earn sufficient continuing education units (CEU) to meet this requirement for taking the certification exam.

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

HCCA *website news*

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

Top pages last month

Home Page | Job Board | Events | Add CEUs | National Conferences

Number of website visits last month

58,008

Past conference handouts

Miss a session at the last conference you went to, or did you simply misplace the slides? Come to the HCCA website. After each conference, we put available slide-shows up for attendees to view. Just go to *Resources > HCCA Resources > Conference Handouts*.

Each conference is listed by the conference name or type of conference (Regional). Once you click on the conference you're looking for, the past conferences will be organized with the most recent at the top. Grab what you missed and then see what was discussed in past conferences.

Video of the month

What is the best way to deal with the press when you have bad news to share?

See this video and others that discuss dealing with the press at: *http://bit.ly/1MFftNq*

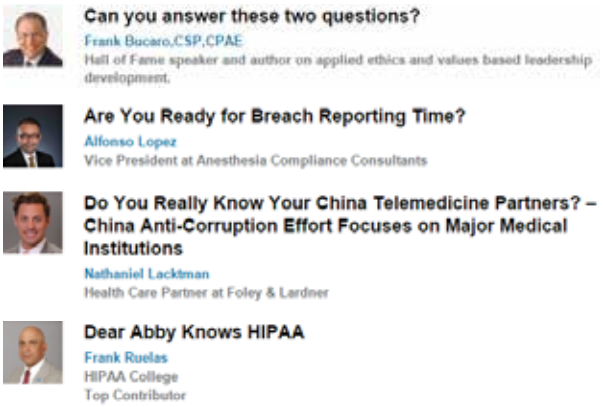
Find the latest HCCA website updates online ▶ www.hcca-info.org

HCCA *social media news*

Contact Stephanie Gallagher at 952-567-6212 or email her at stephanie.gallagher@corporatecompliance.org with any questions about HCCA social media.

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

Join us on LinkedIn—a business-oriented network with more than 240 million active users. With more than 20,000 members, our LinkedIn group fosters more than 75 new discussion posts every week. Some recent highlights:



Pinterest — *www.pinterest.com/theHCCA*

Check out our Pinterest boards for *HIPAA*, *ICD-10*, *ACA*, *Compliance Videos*, and using *Technology & Social Media* in healthcare, as well as map-boards for our major conferences (highlighting local restaurants, sights, and things to do in each of our conference cities). Our "infographics of the month" and much more can all be found on our Pinterest boards!

The C&E Blog — *www.complianceandethics.org*

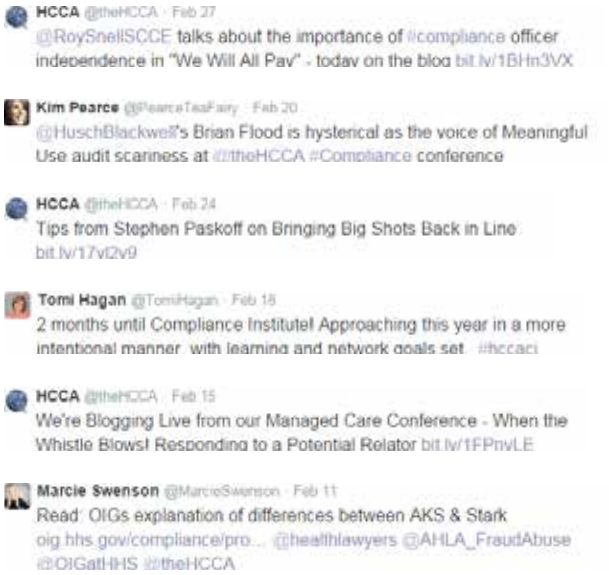
Stop by our Compliance & Ethics Blog to check out discussions about hot topics and breaking news in compliance & ethics. Be sure to subscribe to receive alerts when new content is added! Two recent posts:

Live from HCCA's Webinar: A Practical Guide to Using Encryption for Reducing HIPAA Data Breach Risk

Live from Managed Care - Compliance Executive Communications: What do Business Leaders Really Want to Know?

Twitter — *www.twitter.com/theHCCA*

Join 11,000+ others and follow HCCA for breaking news and insights. Some recent favorite tweets:



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

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

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

PEOPLE *on the* MOVE

▶ New Perspective Senior Living in Eden Prairie, MN has named **Lore Brownson** Senior Vice President of Quality Services and Chief Compliance Officer.

▶ **Cara Merski** has been appointed Chief Compliance Officer and Director of Internal Audit at Tufts Medical Center in Boston.

▶ Accretive Health in Chicago recently announced that **Corey Perman** has joined its leadership team as the new Chief Compliance Officer.

▶ **Beckie Robertson**, RHIT, CHPC, CHPS, was recently promoted to Privacy and Security Officer at Cookeville Regional Medical Center in Cookeville, TN.

▶ **Alicia Shickle**, CHC, CPC, CPCO, CPPM, has recently joined RR Health Strategies (RRHS) in Uniondale, NY as the Director of Coding and Compliance.

▶ **Susan M. Strickland**, MS, DHEd, has been appointed Clinical Trials Coverage Analyst, Research and Clinical Trial Administration at Rush University Medical Center in Chicago.

▶ TeamHealth Holdings Inc., a provider of outsourced physician staffing solutions for hospitals based in Knoxville, TN, announced the appointment of **Matthew Tormey** as the organization's Chief Compliance Officer.

▶ Jersey Shore Hospital, in Jersey Shore, PA, recently announced it has named **Colleen Yost** the hospital's Compliance Officer.

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

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

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

HCCS ONLINE COMPLIANCE COURSES

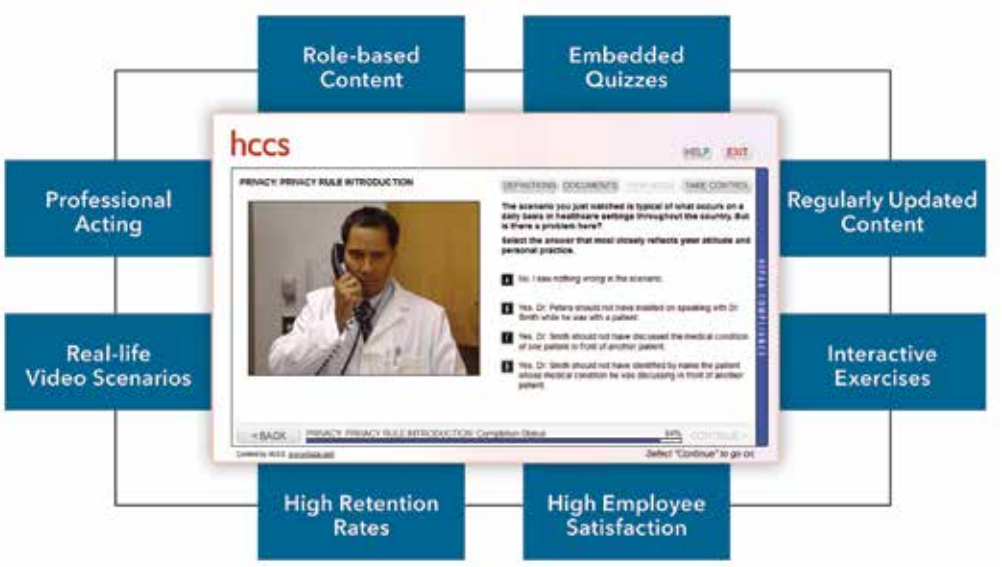
General Compliance Suite

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.



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Tracy Carlson Ivers, ESQ.
Compliance and Legal Analyst
Masonicare
Wallingford, CT

(pictured with Stacy Allen, Masonicare's Director of Corporate Compliance)

an interview by Lori J. Strauss, RN, MSA, CHC, CHPC, CCEP, CHRC

Meet Tracy Carlson Ivers

*This interview with **Tracy Carlson Ivers** (Tivers@Masonicare.org) was conducted by **Lori J. Strauss** (ljs6n@virginia.edu), Chief Corporate Compliance & Privacy Officer at the University of Virginia Health System in Charlottesville, VA.*

LS: Thank you, Tracy, for your willingness to tell us about yourself, what led you to the Compliance field, and the valuable lessons you've learned along the way. Your undergraduate degree is in exercise physiology, a clinical role that is quite different from a typical non-clinical compliance role. Tell us about Masonicare and what led to you become their Legal and Compliance Analyst?

TI: Although I've been a practicing attorney for almost 20 years, I took a few years off to take care of my children. When I returned to the workforce, I took a position as a consultant in the fraud and abuse division of a managed care company. My job was reviewing audits and negotiating overpayments with network providers. I really knew nothing about healthcare when I started that position.

Even though my degrees were in exercise physiology and law, neither had prepared me for my new "compliance enforcement" position. I wanted to understand the healthcare industry better and be effective in my role. So, after doing some research, I decided to enroll in a medical coding course. I was working very closely with our coders and figured this would be a good place to start. Later that year, I took the CPC [Certified Professional Coder] exam and, well, the rest is history. Prior to taking that medical coding course, I never imagined that my healthcare career would be in Compliance.

About a year later, Masonicare was looking for a legal and compliance analyst. I knew the position would expose me to the provider side of healthcare and would be a great learning opportunity. I was interviewed and offered the position.

LS: Can you tell us about Masonicare and the types of services they provide?

TI: Masonicare is one of the leading providers of healthcare and retirement living communities for seniors in the state of Connecticut. Although we have satellite offices across the entire state, our main campus is located in Wallingford, CT. The organization provides home health, hospice, skilled nursing, acute care, dementia, Alzheimer's care, outpatient, assisted and independent living, residential care, primary care, and psychiatric and behavioral health services. It's a very exciting place to work.

LS: You obtained your law degree shortly after completing your undergraduate degree. Can you tell us what motivated you to become a lawyer and about your law school experience?

TI: I became a lawyer because I wanted to help people solve problems. I also felt that a law degree would give me the tools I needed to do something great someday. (I'm still not sure what this great thing is yet.) So, I attended law school at night and worked two jobs to put myself through school. As I look back now, I'm not sure how I did it, but I made it work. I was a clerk at the New Haven Superior Court during the day and spent weekends (and most evenings, when I wasn't in class) catering parties. The experience taught me a great deal about time management and how to deal with people. I also became a very good cook and event planner!

LS: What was your experience at the courthouse like?

IT: At first, very intimidating! I had to manage a judge and a courtroom. It was "baptism by fire"! I loved it! It was fascinating! I coordinated voir dire (i.e., the questioning of prospective jurors by a judge and attorneys for jury trials), participated in trials, managed jurors, facilitated evidentiary hearings, and sat through pre- and post-trial conferences. I learned to research legal issues and analyze case law. Because I worked with the same judge for so long, he was more like a friend and mentor. He quizzed me on legal arguments, case law, evidentiary issues, and trial tactics. We also did the daily crossword puzzle together. When I think back on that time, I still laugh. Every so often, out of nowhere, in the middle of a trial, my judge would call a recess and call me into chambers, comment on proceedings, and ask, "Carlson, did you get the answer to 13 across? It's been driving me crazy all morning." I learned the rules of evidence (which are not as easy as they look) and about the realities of doing trial work. Law school, of course, taught me how to think like a lawyer, but my job as a clerk taught me how to be a good litigator.

Law school, of course, taught me how to think like a lawyer, but my job as a clerk taught me how to be a good litigator.

LS: In what area(s) of the law did you specialize?

TI: I became a litigator and eventually specialized in criminal defense and personal injury law.

LS: How did working for various law firms, including your own, assist you in your compliance role? What are some of the significant differences?

TI: I had mostly worked at small law firms, so the transition to the corporate setting was a culture shock. All the same, my role in Compliance is still very much the same: I help people solve problems. I analyze issues, problem-solve, and anticipate problems, similar to when I was a litigator. The experience also helped me become a better communicator. You have to realize, I was working with people from all walks of life—from the judges to the lawyers, to court staff and jurors—and let's not forget about the defendants and their families. I've dealt with some pretty tough and colorful characters over the course of my career. I think a good compliance professional should be adept at mingling in different circles. My legal career helped me fine tune these skills.

One of the biggest differences I see in Compliance is that there is a great opportunity to deal with issues proactively. As a litigator, I was called in to help only *after* the damage had been done. In Compliance, the goal is to prophylactically spot, educate, and mitigate legal, reputational, and financial harm before the client is in trouble.

LS: When you moved into your current compliance role in 2010, what did you think you knew about compliance after years as an attorney, that you found not to be the case?

TI: I never imagined how different healthcare and compliance would be from the other areas of law I had practiced in. I knew I would need time to learn about my organization, however, I didn't anticipate the complexities of healthcare. Healthcare is *very* complicated! Aside from the alphabet soup of acronyms, there are state and federal regulations, conditions of participation, regulatory trends, licensing, certificate of needs, Stark, anti-kickback, privacy and security, reimbursement, and billing practices to learn. I am very grateful to those who mentored me through the learning process—and, trust me, there have been many! Masonicare's Director of Corporate Compliance, Stacy Allen, has been one of my most trusted corporate advisors since I joined the organization five years ago. She has always made it a priority to meet with me on a weekly basis to discuss projects, regulatory changes, operational changes, vision for the department, concerns, and professional goals. She is incredibly organized, has a memory like no one I have ever met (with the patience to match), and she has worked in Compliance for a very long time. She personifies the expression "team player" and has been largely responsible for teaching me about the infrastructure of the organization and the basics of compliance. With her guidance, I've become much more comfortable with the subject matter and have grown in my compliance role. We have become a strong team and continue to meet on a weekly basis. I hadn't experienced anything quite like this in my career as a litigator.

I never imagined how different healthcare and compliance would be from the other areas of law I had practiced in. …I didn't anticipate the complexities of healthcare.

LS: More recently you became a Certified in Healthcare Compliance professional

through the Compliance Certification Board. Why did you seek the CHC certification?

TI: Having entered the Compliance field later in my career, I felt I needed to learn the subject matter quickly. Most of my friends had already moved into partnership roles with their firms or sat in leadership positions with their companies. I took a career "time out" to raise my family, and while I have no regrets about my decision, it was time to get my career back on track. By then, I knew that I wanted to build my career around the area of compliance. I also knew that HCCA/SCCE led the country in compliance education and training. So I attended their Compliance Academy in 2013. When I completed the Academy, I took the exam and I passed. Halleluiah!

LS: What professional benefits do you see in having your CHC and as a member of the Health Care Compliance Association?

TI: Having my CHC gives me a certain level of credibility among my peers, colleagues, and stakeholders. In this day and age, it is rare to see a compliance position that doesn't require a CHC certification. My certification and membership give me access to networking events and to the most current compliance information, sample policies, webinars, trends, and research in the area of compliance. When I participate in an HCCA/SCCE sponsored event or call one of my colleagues who I know through the association, the information I'm getting is accurate and up-to-date.

LS: Why is networking important for compliance professionals?

TI: Healthcare rules and regulations are constantly evolving and, realistically, there's too much information for any *one* person to know. Today's teachers are tomorrow's students. We have to support, educate, and help each other out whenever possible. What do you do when that unusual compliance issue crops up on your desk that you have no idea how to deal with? Let's just say, it's a great sense of a comfort to know you have a network of experts across the country you can call on to help walk you through the issue and potential solutions.

You also never know who you're going meet or where an opportunity could lead you. I listened to Dan Levinson, the Inspector General, speak at a conference last year about the future of healthcare. During his presentation, he urged the audience to provide feedback and comment on healthcare issues facing the country. His request was sincere, and he stayed after the presentation to answer questions. I spoke with him briefly. Although I doubt he recalls our discussion, I do. I won't lie; it was pretty cool to have a conversation (albeit a brief one) with the Inspector General. Networking opportunities like these are rare. Capitalize on them when you can.

Healthcare rules and regulations are constantly evolving and, realistically, there's too much information for any *one* person to know.

LS: What training strategies have you seen effectively used to educate board members on their oversight responsibilities for compliance programs?

TI: Although I'm not directly involved in Masonicare's board training, I do participate in training as a member of the Rushford Board of Directors (a Hartford HealthCare Partner).

It's been interesting to experience compliance training from the other side of the table. It's my first year as a director for Rushford, but I was genuinely impressed by their whole training process. The training was scheduled outside of the regular board meeting, and it was held at a different location. We were served breakfast and lunch, and time was set aside for attendees to socialize before, during, and after the event. The hospital CEO addressed key hospital issues with the board and then—and I loved this part—he called in prominent, high-profile speakers from outside of the hospital system to talk about the big picture in healthcare, board responsibilities, quality initiatives, and industry compliance concerns. The CEO closed his remarks with the hospital's mission, vision, and value statement. The meeting was brilliantly orchestrated. But, more importantly, it was on point, and it was engaging, informative, entertaining, and effective.

As a general matter of compliance, I expect quality issues and reporting requirements will continue to ramp up.

LS: Where do you see the major compliance risks in senior healthcare and retirement living communities today, and why do you believe these are compliance risk areas?

TI: I spend a good deal of my day reviewing state and federal updates and reading through professional publications and healthcare bulletins. I participate in webinars and conferences on a regular basis. These are the compliance trends I've seen through these sources.

As a general matter of compliance, I expect quality issues and reporting requirements will continue to ramp up. Resource consolidation and ROI [return on investment] are going to motivate compliance officers and senior leadership teams to measure performance and outcomes differently. Third-party risk management deficiencies, prosecutions for grossly deficient patient care, and issues stemming from strategic alliances will continue to gain momentum.

In home health, documentation, demand billing, timely responsiveness to ADRs [Additional Documentation Requests], and criminal background checks are hot spots.

Skilled nursing facilities (SNFs) need to watch high rate hospitalizations, questionable Part B billing patterns, issues concerning ABNs [Advanced Beneficiary Notices], and criminal background checks. Although MDS [Minimum Data Sets] and RUGs [Resource Utilization Groups] are not specifically referenced in the Work Plan, I think these are going create major risks for SNFs over the next few years.

As for hospice, accuracy of claims for the level of care in assisted living facilities and general inpatient claims will continue to create risk.

LS: When compliance professionals are involved in reviewing healthcare-related contracts, such as those for skilled nursing, physician, home health, or radiology services, what do you suggest should be key areas of focus?

TI: I suggest they start with the following question: "What are the goals of the parties?" Sometimes agreements can be restructured to meet the goals of the parties more effectively. They should also be sure to include any regulatory language, mandatory contract provisions, and applicable conditions of participation. Beware of automatic renewals and

cancellation timeframes. These can easily slip through the cracks. When in doubt, ask your legal advisors to review the contract.

LS: When you conduct compliance training and education for physicians and staff, what strategies do you use to engage your audience?

TI: In short, make it interesting. Tailor presentations to fit the personality of the group you'll be training. Incorporate humor, stories, games, and prizes into training activities. Experiment with new ideas. I'm always eager to try out new training strategies. Keep sessions short and simple. Understand your audience and what their compliance risk areas are. For example, physician vs. housekeeping: Poor physician documentation creates payback implications. Unsanitary hospital conditions can shut down facilities. People need to clearly understand their compliance responsibilities.

LS: Can you tell us few things about yourself that people would be surprised to know?

TI: Certainly.

- I have a dirt bike.
- I'm a ski junkie, bumps and woods!
- I've taken classes at the Culinary Institute of America.
- I'm planning to run a half marathon at the Great Wall of China in the spring.
- I'm a living kidney donor.

LS: In closing, with the ever-changing healthcare environment today, where do you see the Compliance profession in 10 years?

TI: I see larger Compliance departments, bigger budgets, reformed healthcare systems and, with any luck, healthier patients!

LS: Thank you, Tracy for sharing your extensive background and valuable experiences with us.

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

Adieu, Adios, Addio

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This one-page column was a concept I created that Margaret Dragon, HCCA's Director of Communications, so eloquently titled Exhale. The purpose and intent of the column was to offer a perspective, regulatory guidance, and an occasional sanity check for compliance officers and associated professionals. Over the past few years, I correlated movies, songs, quotes, and real-life stories with compliance analogies.

DeGroot

Dr. Bob Ossoff, a profound otolaryngologist and compliance professional with Vanderbilt University, and I have delivered numerous presentations on stress, with a particular emphasis on work-life balance. I considered those presentations an extension of this column. We conversed with the audience, on many occasions, about the need to unplug from the electronic world, the effort required to step back, and the ability to let go and strive for work–life balance. Many of us in this field find work-life balance exceptionally challenging. We tend to accept multiple assignments, projects, and initiatives with a "can do" attitude. We are committed. Often this is true in our personal life as well, whether it is coaching soccer, serving on a board of directors for a non-profit, or working for our favorite charity. Conversely, many equate the measure of success by the number of committees and boards served. We are all aware of the danger in focusing on high numbers that do not always equate to high quality or quality that is sustainable.

Parallel to the art of saying "no" is knowing when to step back or step away. This is an artful strategy used in military combat and in the game of chess. As compliance professionals, we practice the skill regularly, knowing when we are truly analyzing compliance issues or engaging to fix an operational issue.

Many of us in this field find work–life balance exceptionally challenging. We tend to accept multiple assignments, projects, and initiatives with a "can do" attitude. …We are all aware of the danger in focusing on high numbers that do not always equate to high quality or quality that is sustainable.

In response to this column, many of you followed up with emails and anecdotal stories that provided quite a few laughs, yet with incredible insight. While I am not leaving the profession nor will I cease writing, I simply need to step away from writing monthly. More importantly, the readers will be privy to a new style of writing and thought-provoking articles by Cathy Boerner. Cathy will provide an insight and perspective that you will enjoy.

Thank you for all you have given me!
Auf Wiedersehen.

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Law & Business

by Janice Anderson, Esq. and Sara Iams, Esq.

The Two-Midnight Rule: Past, present, and future

» The Two-Midnight Rule, effective October 1, 2013, provides guidelines for making Medicare inpatient admission decisions.

» An inpatient admission is "generally appropriate" if the admitting practitioner expects the patient to require a stay that crosses at least two midnights and admits the patient based upon that expectation.

» The two-midnight benchmark and the two-midnight presumption are the medical review policies used by MACs and RACs to evaluate compliance.

» Compliance officers need to use lessons learned from the Probe & Educate audit period to prepare for RAC audits as of May 1, 2015.

» Compliance officers must stay abreast of changes to Two-Midnight Rule policies, including pending case law and proposed legislation, which may further delay enforcement of this controversial rule.

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Anderson

Iams

In an effort to simplify its hospital admission guidelines, the Centers for Medicare & Medicaid Services (CMS) introduced the so-called Two-Midnight Rule in the FY 2014 Inpatient Prospective Payment System (IPPS) final rule.[1] Since its introduction, aspects of the Two-Midnight Rule have been repeatedly delayed and "clarified," making it difficult for hospitals and their compliance teams to keep up with its status, to manage the Medicare Administrative Contractor (MAC) Probe & Educate program, and to prepare for Recovery Audit Contractor (RAC) or other enforcement. This article will provide an overview of the Two-Midnight Rule, a discussion of its current status, and tips to prepare for the expiration of the RAC enforcement moratorium on April 30, 2015.

History of the Two-Midnight Rule

Prior to FY 2014, CMS counseled hospitals to follow a "24-hour" benchmark to determine whether an inpatient admission was appropriate. Specifically, CMS guidance called for hospitals to designate a patient as an "inpatient if formally admitted…with the expectation that he or she will remain at least overnight," but also acknowledged that the decision to admit "is a complex medical judgment which can be made only after the physician has considered a number of factors…."[2] (Please note that this historic admission policy, although superseded by the Two-Midnight Rule, still appears in the Benefit Policy Manual as of January 1, 2015.)

Over time, this guidance proved problematic for a number of reasons. First, according to CMS, the application of the policy varied widely among hospitals, causing beneficiaries with identical clinical characteristics to be assigned a different patient status (inpatient or outpatient)—and to incur a different cost—depending on the hospital. Second, beginning in 2011, RAC auditors began to review short-stay inpatient admissions and increasingly alleged that, although in many cases the patient may have received

medically necessary services, the patient should have been cared for as an outpatient. These RAC audits highlighted the ambiguity of the Medicare admission criteria and the inadequacy of CMS Part B rebilling policies following Part A denials. In addition, in response to the short-stay denials, hospitals increasingly placed patients in outpatient observation status, often resulting in higher out-of-pocket costs for the beneficiary.

To resolve the issues created by its historic guidance and to standardize hospital admissions for Medicare beneficiaries, CMS adopted the Two-Midnight Rule, effective October 1, 2013. The Two-Midnight Rule provides that an inpatient admission is "generally appropriate" under Part A if the admitting practitioner "expects the patient to require a stay that crosses at least 2 midnights" and admits the patient to the hospital based upon that expectation. Conversely, if the admitting practitioner does not expect the patient to stay for two midnights, then inpatient care would be generally inappropriate. To make this determination, admitting practitioners are expected to consider such factors as patient history, comorbidities, severity of signs and symptoms, current medical needs, and the risk of an adverse event. All relevant factors must be documented in the medical record. For purposes of making the initial two-midnight determination, the admitting practitioner may start the clock at the time the patient receives his/her first outpatient service. All time spent receiving observation services, treatment in the Emergency Department, or other services in outpatient treatment areas may be considered in the two-midnight calculation. Time spent in the waiting room or receiving preliminary triage services (e.g., vital signs) may not be considered.

CMS informed its contractors regarding the application of the Two-Midnight Rule through two separate, but related, policies: the two-midnight presumption and the two-midnight benchmark. Under the presumption, CMS instructs MACs and RACs to presume that inpatient stays are reasonable and necessary—and therefore payable under Part A—if they cross two midnights following the formal patient admission order. Absent evidence of systemic gaming by the hospital, such stays should not be the focus of MAC and RAC medical reviews. If a practitioner admits the beneficiary, but the inpatient stay lasts only 0-1 midnight following the formal patient admission order, CMS and the review contractors will instead apply the two-midnight benchmark. The benchmark requires reviewers to evaluate whether, at the time of the admission order, it was reasonable for the admitting practitioner to expect the beneficiary to require medically necessary services for at least two midnights, taking into account all time spent receiving outpatient services. If the review contractor finds the admission expectation to be reasonable and the medical record supports that decision, Part A payment will be considered appropriate.

CMS informed its contractors regarding the application of the Two-Midnight Rule through two separate, but related, policies: the two-midnight presumption and the two-midnight benchmark.

Several limited exceptions to the Two-Midnight Rule exist. Specifically, CMS and the review contractors will consider Part A inpatient payment appropriate, even though the length of stay may be expected to be shorter than two midnights:

- for procedures on the "inpatient only" list, in which cases, length of stay is irrelevant;
- in "rare and unusual circumstances" in which a two-midnight stay is not expected by the admitting practitioner, but inpatient status is nonetheless deemed necessary; and
- in unforeseen circumstances that lead to a short stay, such as death, transfer, or patient departure against medical advice.

Enforcement: Moving from Probe & Educate to full-scale RAC audits

The Two-Midnight Rule was not well-received by the provider community. It was criticized as an effort to usurp the clinical judgment of admitting practitioners and, even though it was intended to clarify CMS's admission policies, it seemed only to muddy the waters. In response to this industry feedback, CMS announced the Probe & Educate program, a focused pre-payment audit program designed to:

- ensure provider understanding of the Two-Midnight Rule,
- offer provider-specific education, and
- correct improper claims as necessary.

The Probe & Educate audits began in November 2013 and encompass claims with dates of admission between October 1, 2013, and April 30, 2015. Within this time period, and using sample sizes of 10 claims (small hospitals) and 25 claims (large hospitals), MACs are auditing inpatient claims spanning 0–1 midnight after formal patient admission. MACs will deny claims found to be out of compliance with the Two-Midnight Rule and, consistent with the goal of the Probe & Educate program, provide hospitals with feedback regarding the reason(s) for any denials. In addition, based on relatively low error-rate thresholds (i.e., more than one error in a sample of 10 draws "moderate to significant" concern from CMS), hospitals may be subject to additional Probe & Educate audits with increasing claim volumes.

To date, RACs have had no role in Two-Midnight Rule enforcement. CMS prohibited RACs from conducting pre- or post-payment "patient status" claim reviews of claims with dates of admission during the Probe & Educate period. This has allowed hospitals to avoid the scrutiny of contingency-fee driven RACs and to engage with MACs on a less adversarial basis. But the RAC enforcement moratorium ended May 1, 2015, and although RACs are unlikely to take up auditing immediately—they are prohibited from looking backward in their audits—hospital compliance teams nonetheless need to be prepared for the additional scrutiny.

As CMS transitions from MAC Probe & Educate to the possibility of full-scale RAC audits, keep in mind the following tips:

- It was likely a shock to the (compliance) system to go from adversarial interactions with MACs/RACs to cooperative and education-based interactions under the Probe & Educate program. Get ready to flip the switch again. Interactions with RACs are inherently more adversarial, and compliance teams need to be ready not just to explain how they comply with the Two-Midnight Rule, but to *defend* their compliance as well.
- Hospitals have been frustrated by the level of subjectivity in the Probe & Educate reviews. Evaluating compliance with the two-midnight benchmark ultimately depends on clinical judgment, and the clinical basis for the admission can be subject to debate. The best way to combat the subjectivity is to have comprehensive documentation in the medical record. Requiring the admitting practitioner to attest explicitly to Two-Midnight Rule compliance is one option (although it is *not* mandated by CMS), but ultimately, the depth and

descriptiveness of the clinical support will short-circuit the MACs' arguments. Training physicians and other admitting practitioners on the scope of the required documentation is essential.

- Remember that meeting admission criteria, including Interqual or Milliman criteria, is no longer sufficient support for an inpatient admission. Despite the longstanding use of these criteria, CMS and the contractors will expect to see support in the medical record to justify the expectation that the patient's stay would cross two midnights.
- CMS and a number of MACs have published lists of the most common errors found during the Probe & Educate audits. Even if a hospital performs well on its initial Probe & Educate audit, compliance teams can and should still use these lists to identify shortcomings and to improve processes internally.
- One silver lining of the Probe & Educate program is the rare opportunity to develop relationships with MAC personnel in a non-adversarial context. To the extent you have developed a good working relationship with the MAC, maintain it. It will only serve the hospital and the entire compliance team well to have a close contact at the MAC for Two-Midnight Rule issues or any other issue that may arise in the future.

Looking ahead

Lest the industry get too comfortable with the Two-Midnight Rule, an ongoing court case and recently proposed federal legislation may result in further changes to the inpatient admission policy. Fortunately for hospitals, the case and the legislation are driven by the provider industry, so any changes are likely to be in the hospitals' favor.

In the case, in which competing motions for summary judgment are still pending, numerous hospitals along with the American Hospital Association are challenging the 0.2% rate cut imposed by CMS in connection with the Two-Midnight Rule.[3] The rate cut is based upon CMS's assumption that it would be required to pay hospitals an additional $220 million annually because of the Two-Midnight Rule. The hospitals, by contrast, estimate the new policy will lead to a $200 million *reduction* in annual payments. If the hospitals are victorious, the Two-Midnight Rule itself would not change, but it would call into question the assumptions made by CMS in cutting rates and may offer a basis for further challenge.

In addition, as of the date this publication went to print, Congress continues to debate the Medicare Access and CHIP Reauthorization Act of 2015, which would extend the RAC enforcement moratorium for an additional five months through September 30, 2015. Compliance officers will need to keep a close eye on this legislation to determine if and when the RAC audits will begin.

Conclusion

The only thing constant in the implementation of the Two-Midnight Rule has been change. Without question, compliance officers have played a key role thus far in managing the changes, training workforce members, and understanding the implications for hospital operations. In 2015, compliance officers will need to double-down on these efforts to prepare for RAC audits and to stay abreast of the changes that are almost certain to come.

1. 78 Fed. Reg. 50496, 50944-50952. August 19, 2013. Available at http://bit.ly/1DskdEA
2. Medicare Benefit Policy Manual, Chapter 1, § 10.
3. *Shands Jacksonville Medical Center et al. v. Sylvia Mathews Burwell et al.*, Case No. CIV-14-263-EGS Summary Judgment filed September 15, 2014 in District Court for the District of Columbia.

by Kim C. Stanger

Keys to EMTALA compliance

» Violations of EMTALA may result in significant fines and penalties for hospitals and physicians. Serious violations may result in termination of the hospital's Medicare provider agreement.

» EMTALA applies to all hospitals that participate in Medicare and their affiliated physicians; however, EMTALA requirements differ depending on the type of hospital.

» Understanding when EMTALA applies is crucial to avoiding fines and penalties.

» Hospitals that violate EMTALA are not generally required to report themselves, but they should take steps to mitigate their liability if a violation is discovered.

» A provider is unlikely to face a significant EMTALA penalty if it does what is best for the patient and documents its actions.

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Violations of the Emergency Medical Treatment and Active Labor Act, also known as EMTALA (42 USC 1935dd), may result in significant fines and penalties for hospitals and physicians. Physicians who violate EMTALA may be fined up to $50,000 per violation. Hospitals that violate EMTALA may be fined up to $50,000 per violation depending on their number of beds. In addition, hospitals may be sued by those who have been damaged by the hospital's violation, including injured patients or other medical facilities that provided care in the wake of a hospital's failure to do so. Serious violations may result in termination of the hospital's Medicare provider agreement.

Stanger

EMTALA requirements

EMTALA applies to all hospitals that participate in Medicare and their affiliated physicians; however, EMTALA requirements differ depending on the type of hospital. If a hospital has a dedicated Emergency Department and a person comes to the hospital seeking emergency care, the hospital must provide an appropriate medical screening examination. A "dedicated" Emergency Department includes a licensed emergency room or department; a department that is held out to the public as a place that provides emergency care without requiring a prescheduled appointment (e.g., an Urgent Care center, labor or delivery unit, or mental health unit); or a department in which at least one-third of its outpatient visits for emergency care during the prior year were provided without prescheduled appointments. If the exam reveals an emergency medical condition, the hospital must provide either stabilizing treatment or an appropriate transfer of the patient to another facility. Participating hospitals with specialized capabilities (including specialty hospitals without a dedicated Emergency Department) must accept the transfer of an emergency patient. Hospitals must fulfill their EMTALA obligations, even if the patient cannot pay.[1]

Complying with EMTALA

The following summarizes key EMTALA compliance issues as well as tips for avoiding or minimizing EMTALA liability.[2]

Know when EMTALA applies

EMTALA is generally triggered when a person seeking emergency care comes to the hospital, including the hospital's main campus and hospital-owned and operated buildings within 250 yards of the hospital. EMTALA also likely applies to a hospital's off-campus Urgent Care centers or similar facilities that operate as a department of the hospital if patients receive emergency care at the facility without prescheduled appointments. EMTALA does *not* apply to persons who: (1) have already been admitted as inpatients, or (2) have already begun to receive outpatient services. Also, EMTALA does not apply to persons who present to the Emergency Department for prescheduled tests or preventive care, such as flu shots or immunizations. In such situations, hospitals should ensure that the documentation supports the conclusion that EMTALA does not apply.

Beware ambulances

EMTALA applies if a person is in an ambulance owned and operated by the hospital, even if it has not arrived at the hospital. EMTALA also prohibits hospitals from diverting any inbound ambulance unless the hospital is on diversionary status (i.e., it lacks the staff or facilities to accept additional emergency patients). Hospitals should clearly document when they are on diversionary status and the basis for such. If the hospital is not on diversionary status, it may discuss with ambulance personnel whether the person's condition requires specialized care available at another facility, but the hospital should make it clear and document that it is not diverting the ambulance and that it will provide care within its capability if the person is brought to the hospital. Even if the hospital is on diversionary status, EMTALA applies if the person is brought to the hospital.

Conduct and document an appropriate medical screening examination

If a person presents at the hospital for emergency care, the hospital must conduct an appropriate medical screening exam that is reasonably calculated to identify an emergency medical condition. An "emergency medical condition" is generally "a medical condition manifesting itself by acute symptoms of sufficient severity… such that the absence of immediate medical attention could reasonably be expected to… plac[e] the health of the individual… in serious jeopardy."[3]

> EMTALA is generally triggered when a person seeking emergency care comes to the hospital…

The scope of the exam depends on the person's presenting symptoms and the hospital's capabilities. It may range from simple questioning sufficient to confirm clearly non-emergent conditions, to performance of ancillary tests or specialty services for complex or serious matters. The medical record should reflect ongoing monitoring appropriate to the person's symptoms until it is determined whether the person has an emergency medical condition. If an appropriate exam concludes that there is no emergency medical condition, then the hospital's EMTALA obligation ends. On the other hand, if the exam identifies an emergency medical condition, then the hospital is obligated to provide stabilizing treatment or an appropriate transfer. Accordingly, it is critical that the records document the performance of an appropriate exam, as well as the conclusions of the exam.

Use qualified personnel to conduct the examination

The medical screening exam must be performed by persons who have been designated as qualified to perform appropriate screening exams ("qualified medical personnel") in a document approved by the hospital's governing body. Different categories of providers may be authorized to perform exams for different types of patients. For example, a nurse or nurse midwife may be designated as a qualified medical person to rule out labor, if consistent with state scope-of-practice laws.

Provide and document stabilizing treatment

If the medical screening exam reveals a potential emergency medical condition, the hospital must provide either stabilizing treatment within its capability and capacity (including ancillary services and on-call specialists available to the hospital) or an appropriate transfer to another facility. A person is deemed stabilized if "no material deterioration of the condition is likely… to result from or occur during transfer… or, with respect [to a woman in labor], that the woman has delivered the child and the placenta."[4]

According to CMS, a person is deemed "stable" for discharge if: (1) the emergency medical condition that caused the individual to present to the hospital is resolved even though the underlying medical condition may persist, and (2) "the individual has reached the point where his/her continued care… could be reasonably performed as an outpatient or later as an inpatient, provided the individual is given a plan for appropriate follow-up care…."[5]

The hospital's EMTALA obligations end when the person is stabilized or admitted in good faith as an inpatient. On the other hand, if the person is not stabilized, the hospital's EMTALA obligations continue until the person is stabilized, admitted as an inpatient, or appropriately transferred. It is therefore vital to document that an emergency patient is "stable" before they are discharged; otherwise, the hospital must continue to provide care or conduct and document an appropriate transfer.

Obtain patient consent or physician certification to transfer or discharge an unstable patient

A hospital may not discharge or transfer an unstable patient unless either: (1) the person requests the discharge or transfer after being informed of his/her EMTALA rights; or (2) a physician certifies in writing that the benefits of discharge or transfer outweigh the risks. The physician's certification must be express and state the reasons for the transfer. The certification must be made by a physician, not a mid-level provider, nurse, or other practitioner. If the physician is not present, a qualified medical person may sign the certification, but only after consulting with the physician and the physician must countersign. Of course, EMTALA would not require these steps if the person's emergency medical condition had ended or the patient was stabilized, but it is prudent to obtain the certification for all transfers in case CMS questions whether the patient was stabilized.

It is therefore vital to document that an emergency patient is "stable" before they are discharged; otherwise, the hospital must continue to provide care or conduct and document an appropriate transfer.

Provide and document an appropriate transfer

When transferring an unstable patient, the hospital must: (1) provide treatment to minimize the risks during transfer; (2) ensure the receiving facility has agreed to receive the transfer; (3) send relevant medical records to the receiving facility; and (4) use qualified personnel and equipment to effect the transfer. Transfers by private vehicle are not prohibited, but they are suspect. If the patient insists on transfer by car, the hospital should document the patient's informed decision.

Document a patient's refusal of care

EMTALA does not require care contrary to the wishes of a competent patient or their authorized representative. If the patient refuses care otherwise required by EMTALA, the statute requires that the hospital document the refusal in writing. If possible, the hospital should obtain the patient's written and signed request or refusal for care. The documentation should identify the treatment offered; confirm that the risks, benefits, and the hospital's EMTALA obligations were explained to the patient; and document the patient's informed refusal or request for alternative care.

Do not delay or discourage care

EMTALA prevents hospitals from delaying the required care while it obtains information about payment. Providers may engage in reasonable registration processes, including asking about insurance, as long as it does not delay care, but hospitals may not seek preauthorization before initiating care or discourage patients from receiving appropriate care.

Maintain required signs, logs, lists, and policies

EMTALA requires hospitals to post signs explaining patients' EMTALA rights in Emergency Departments and similar locations. They must maintain a log of persons who came to the Emergency Department seeking assistance, and document whether the person was treated, admitted, transferred, or discharged. The log is often the first place surveyors go when reviewing EMTALA compliance; it behooves hospitals to periodically review the log to ensure that it is being properly maintained and reflects compliant practices.

Hospitals must maintain a list of providers who are on call for emergency services. Hospitals have a great deal of flexibility in how they manage their on-call list, but they should ensure that providers comply with their on-call duties to minimize the hospital's liability if the provider fails to respond. Among other things, hospitals that transfer a patient because of an on-call physician's failure to respond must notify the receiving facility of the name of the physician. Finally, hospitals should implement written EMTALA policies and periodically train personnel concerning their EMTALA obligations. Having written policies and documented training will both help avoid EMTALA violations and mitigate sanctions if a violation occurs.

Receive transfers if you have specialized capabilities

The foregoing requirements generally apply to hospitals with dedicated Emergency Departments; however, all participating hospitals must accept transfers of emergency patients if the hospital has specialized capabilities. Failure to do so is an EMTALA violation. A hospital may refuse to accept the transfer if: (1) it lacks specialized capabilities (i.e., the transferring hospital can provide the same level of care as the receiving hospital); and (2) if the patient was admitted as an inpatient at the transferring facility. Hospitals seeking to transfer an emergency patient may want to avoid admitting the patient before the transfer.

Respond promptly to potential violations

If a potential EMTALA violation occurs, respond immediately. Hospitals that have received an improper transfer must report the violation to the appropriate state or federal agencies. Hospitals that violate EMTALA are not generally required to report themselves, but they should take steps to mitigate their liability if a violation is discovered. Among other things, they should immediately investigate and document the facts while the matter is still relatively fresh in witnesses' minds, including key facts concerning the care provided and patient's status (e.g., whether the emergency condition was resolved or the patient was stabilized). They should correct or supplement documentation through appropriate medical record entries. If warranted, they should take corrective action against providers or employees who have violated policies, modify policies and procedures, and/or train personnel to avoid recurrences. Prompt corrective action may help avoid EMTALA penalties.

Do what is best for the patient

Finally and most importantly, EMTALA is about proper patient care. A provider is unlikely to face a significant EMTALA penalty if it: (1) does what is best for the patient, and (2) documents its actions. In the vast majority of EMTALA cases I have defended, I am convinced that the provider rendered appropriate patient care. The problem occurred because the provider failed to document an appropriate exam, stabilizing treatment, an appropriate transfer, or the patient's status. Doing what is best for the patient and documenting the basis for its actions will protect against EMTALA violations as well as malpractice claims.

1. Centers for Medicare & Medicaid Services (CMS): Medicare Program, Emergency Medical Treatment and Labor Act (EMTALA): Applicability to Hospital Inpatients and Hospitals With Specialized Capabilities. 42 CFR 489.24(a-g). February 2, 2012. Available at http://1.usa.gov/1xk622v
2. CMS: State Operations Manual, Appendix V, EMTALA Interpretive Guidelines for 489.24(a)(i). Available at http://go.cms.gov/1DCXN3m
3. 42 CFR 489.24(b), definition of "emergency medical condition."
4. 42 CFR 489.24(a)(ii) and (d), definition of "stabilized."
5. *Ibid., Ref #2:* Interpretive Guidelines at 489.24(d)(1)(i).

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by Erica Lindsay, PharmD., MBA, Esq.

Drug diversion in healthcare facilities, Part 1: Identify and prevent

» Drug diversion is the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber.

» One out of 10 nurses may be dependent on controlled substances.

» Compliance has an important role on the multidisciplinary team when conducting a drug diversion investigation.

» Policies should be established within the Compliance department on how to handle drug diversion investigations and should be applied consistently.

» Being proactive through education, competencies, and anonymous reporting can lead to a dramatic decrease in drug diversion within your facility.

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Drug diversion is the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber. This may include "deflection of prescription drugs" from medical sources into the illegal market. Drug diversion can lead to addiction, overdoses, and death. When the healthcare worker's addiction is supported by drug diversion it can become a multiple-victim crime that impacts patients, healthcare workers, and employers. Healthcare workers may also be involved with diversion for recreational purposes, relief of addictions, monetary gain, self-medication for pain or sleep, or other illicit activities.[1]

Lindsay

The scope of the problem

The more common reasons that lead to drug diversion include personal use, sale, and illicit use. Anyone with access to drugs can become a diverter, from the physician to the custodian. Among healthcare providers, it is estimated that 15% of pharmacists, 10% of nurses, and 8% of physicians are challenged with alcohol and/or drug dependency.[2]

According to the Bureau of Labor Statistics May 2013 report, there are 287,420 pharmacists in the U.S., which means there could be 43,113 potential substance abusers. The report shows 2,661,890 nurses employed in the U.S., so an estimated 266,189 nurses may be substance abusers or dependent on controlled substances.[3]

In a 1999 report, nurses were surveyed anonymously about drug abuse, and 20% admitted to misusing at least one prescription drug. Easy access was highly correlated with drug misuse. Nurses reported to use: opioids 60%, tranquilizers 40%, sedatives 11%, amphetamines 3.5%, and inhalants 1.9%.[4]

Of the top 17 abused prescriptions in 2013, 16 of the drugs (94%) are classified as Schedule II, III, or IV medications including Ritalin, Oxycodone, Ativan, Vicodin, and Percocet.[5]

Examples

Many providers are victims of drug abuse and divert drugs to maintain their habit. At a facility in Tennessee, a physician was abusing narcotic pain relievers, up to 100 tablets a day of Percocet, Vicodin, etc. There were no complaints from patients or staff, even though the physician demonstrated behavioral changes, including dressing poorly, rounding at abnormal hours, and not handling administrative duties. The physician's father intervened and got the physician help. Since then, the physician has returned to practice successfully while remaining drug free.[6]

Mayo Clinic reported the following examples[7] where drug diversion was discovered at their facilities:

- A procedural sedation nurse assigned to administer opioids and sedatives to patients during colonoscopy was found to have a secret pocket sewn inside her uniform top, into which she dropped syringes of the potent opioid fentanyl and substituted them with syringes containing saline solution.
- A radiology technician who was positive for hepatitis C diverted unused fentanyl syringes intended for administration to patients, causing five patients to be infected with hepatitis C virus.
- A night custodian revealed that while rummaging through sharps waste containers, he had been withdrawing and consolidating the miniscule vestiges remaining in fentanyl vials, which he later used to support his addiction.

An instance where diversion of a non-narcotic for personal use was seen when a nurse was discovered to divert furosemide from the automatic dispensing cabinet (ADC), because she had an eating disorder and took furosemide to assist with weight loss. The facility reported the nurse to the police and the state board of nursing for theft. The action became a permanent part of the nurse's professional record.[8] All diversion should be handled consistently, regardless of drug type.

Someone who diverts drugs usually targets oral or injectable forms of brand name medications with the highest street value. The top diverted drugs for economic gain include Humira, Enbrel, Remicade, and Copaxone.

Someone who diverts drugs usually targets oral or injectable forms of brand name medications with the highest street value. The top diverted drugs for economic gain include Humira, Enbrel, Remicade, and Copaxone. These drugs were included in the top 10 drugs with quarterly sales over $1 billion in the U.S.

In August 2012, *The Miami Herald* reported that a pharmacy technician at the University of Miami Sylvester Comprehensive Cancer Center, stole non-narcotic medications, including Neulasta and Aloxi, over a 3-year period. The technician would steal four Neulasta doses at a time, at a cost of $2,600 per dose. While the pharmacy's focus was primarily toward narcotics, the lack of monitoring for high-cost medications led to the University of Miami losing more than $14 million.[9]

Other generic medications are highly valuable as well, including ketamine, midazolam, oxycodone, and hydrocodone. On October 6, 2014, the Drug Enforcement Administration (DEA) rescheduled hydrocodone combination products from Schedule III to Schedule II,

which may lead to increased diversion due to the lack of refills. Prior to the schedule change, hydrocodone combination products could be refilled five times in a 6-month period.

An example of illicit use was reported when a nurse supervisor diverted and accumulated liquid morphine waste over a period of time and administered the lethal dose to her husband. The long-term care facility management company confirmed that the morphine had not been properly disposed of or destroyed. The son filed a civil wrongful death suit against the nursing home, arguing management's failure to implement and maintain an adequate system of record keeping of controlled substances was in violation of state and federal requirements, thus becoming a substantial factor in causing the death of his father. The suit also named the director of nursing at the facility as a defendant, alleging that she had failed to exercise ordinary care in supervising the activities of the nurse/wife.[10]

The common thread between these cases is the lack of controls for prescription drugs within the high-risk areas of a healthcare facility, including pharmacy storage, administration by staff, and disposal. These high-risk areas should be the focus of implementation and maintenance of control of all prescription drugs. Any drug can be abused or provide economic gain; therefore, selective monitoring of drugs by schedule type will not be as effective.

Availability of pharmacy services

According to a national survey conducted in 2012 by ASHP, 30% of hospitals today offer 24-hour inpatient pharmacy services. In hospitals with 400+ beds, 95% of Pharmacy departments are open around the clock. Of the 70% of the hospitals that do not provide 24-hour pharmacy services, there is a higher risk for drug diversion due to the lack of monitoring and supervision while the pharmacy is closed.

Other patient care facilities that may not have an onsite pharmacy include: adult day care centers, alcohol/drug rehabilitation centers, assisted living communities, home health agencies, hospice, skilled nursing facilities, physician offices, and senior centers.

If the facility does not have pharmacy services onsite, policies and procedures must be established that detail record keeping, proper destruction, and waste disposal to prevent controlled substance diversion. Nursing administration and staff are primarily responsible for drug distribution to patients in the absence of pharmacy. A third party (i.e. hospital administrator or pharmacy consultant) should conduct periodic and random audits to allow diversion to be identified and resolved quickly.

In addition, there should be policies and procedures for handling controlled substances established and updated regularly. Policies and procedures should address:

- Ordering controlled substances for pharmacy or facility with DEA Form 222 and Controlled Substance Ordering System (CSOS);
- Reconciliation of drugs from wholesaler;
- Storage and auditing of drugs in automated controlled drug cabinets (e.g., Pyxis, Accudose, Omnicell);
- Distributing drugs, including controls, throughout the facility (e.g., operating rooms, outpatient facilities, patient care areas);
- Pharmacy compounding records; and
- Documentation of waste.

Helpful hints on identifying potential drug diversion include:

- Inconsistent or incorrect charting;
- Offers to medicate other nurses' patients on a regular basis;
- Displays inconsistent work quality with times of high and low efficiency;
- Obtains larger dose of narcotics when order dose is unavailable, then documents the remaining amount wasted;

- Requests to care for specific patients;
- Patient reveals consistent pain scale patterns or complaint that narcotics are not having the desired effect; and
- Prior medications dispensed to patients immediately prior to discharge.

Using reports

Perform ongoing surveillance through constant monitoring of the following reports: ADC activity, anesthesia flow, operating room (OR) waste, abnormal usage, and transaction. This is a sample of reports that can give valuable information on users and usage of medications throughout the hospital. Scheduled and random audits of these and other reports can allow administration to identify potential drug diversion in a proactive manner.[11]

A more comprehensive approach includes a system for prevention and detection of drug diversion. Create an emergency signal (e.g., Code N) to be used to notify administration of a possible diversion issue. Once diversion is detected, an investigation should be pursued involving Compliance, Pharmacy, and nursing managers and directors. Upon verification, if a healthcare worker is accused of diversion, the established policy should be implemented without discrimination.

Staff education is also a key to being proactive in preventing drug diversion. Educating staff during orientation, periodically throughout the year, and annually is an effective way to expose staff to the rules and regulations of proper handling of prescriptions drugs within the facility.

Finally, incorporating a drug reporting line to the current compliance hotline empowers staff to report possible diversion issues anonymously.

Conclusion

Prescription medications are a crucial aspect in providing patient care within a healthcare facility. Nurses, physicians, pharmacists, and other auxiliary staff can handle drugs on a regular basis. Failure to handle and distribute all medications, especially controlled substances, can lead to a felony, DEA investigation, and disciplinary action from the professional boards (e.g., Boards of Nursing, Pharmacy, Medicine).

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by David Hoffman, JD, FCPP

Pressure ulcer risk assessments

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I have spent much of my career focused on pressure ulcers, since avoidable pressure ulcers have served as the basis for successful government enforcement activities. I believe that compliance officers in hospitals and nursing homes must be cognizant of the need for nursing staff to use their judgment in determining a patient's risk for developing pressure ulcers. Concluding that a patient is at mild risk or not at risk at all, despite having an actual pressure ulcer, is an indicator that nurses may be focusing on the questions on the often-used Braden Scale[1] without using their skills to make accurate and appropriate risk assessments. Facilities that use wound care policies and procedures based upon the Braden Scale score may find an absence or a delay in the implementation of these procedures, if the Braden Scale score is calculated inappropriately or if the assessment of the patient is not taken into consideration in determining an individual's specific risk for the development of pressure ulcers. The following interventions should be considered:

Hoffman

- Conduct audits on current patients throughout the facility with staff nurses by reviewing patients' current Braden Scale scores, their current clinical condition, and the interventions in place. Is there a discrepancy between what the Braden Scale score predicts and the measures put into place? Is there a discrepancy between what measures are in place and the policies and procedures for pressure ulcer prevention or treatment?
- Does the Braden Scale score dictate the implementation of specific policies in terms of support surfaces (beds), dietary consultations, and topical treatments? Is the staff aware of what Braden Scale score places a patient at high risk?
- Are there sufficient numbers of support surfaces in-house or available by contract to meet the needs of the patients? Is there a process in place that assures relative easy access to appropriate mattresses and beds?
- Do house officers, hospitalists, and attending physicians read and act upon the recommendations of the dietitian, the wound care team, and others involved in pressure ulcer treatment and prevention? Do physicians defer to nursing for all wound assessments as well as recommendations for care? Who is ultimately responsible for the coordination of wound treatment plans?
- Perform an audit of patients who developed Stage II, III, IV, unstageable, and suspected deep tissue injury (SDTI) wounds during the course of their hospitalization or nursing home stay. Did the patients' Braden Scale scores predict these wounds? If not, is there an opportunity to improve staff education to ensure understanding of the process of determining a Braden Scale score as well as the application of nursing judgment to fully appreciate those patients at risk?

The accurate reporting of hospital and nursing home-acquired pressure ulcers and effective pressure ulcer prevention and treatment protocols are important quality and compliance issues that must be incorporated into a facility's effective compliance program.

1. Braden Scale for Predicting Pressure Sore Risk. Available at http://www.in.gov/isdh/files/Braden_Scale.pdf

by Wade Miller, JD, CHC; Kimyatta McClary, JD, CHC; and Amy Bailey, CHC, CPC, CPC-H, CPC-I, CCS-P

Recent corporate integrity agreements: Best practices for compliance

» The compliance obligations outlined in corporate integrity agreements (CIAs) can give providers some insight as to what regulators view as best practices in the healthcare industry.

» The standard CIA negotiated by the OIG generally includes provisions pertaining to the seven elements of an effective compliance program.

» CIAs are also a resource as to what might be required of specific providers in particular industries or regarding certain compliance risks.

» A review of recent CIAs for industry best practices should be included in a provider's regular evaluation of its compliance program.

» Implementation and oversight of CIAs require significant personnel and financial resources.

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The Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS) often conditions settlement of federal healthcare program investigations arising under the civil False Claims Act (FCA) on the provider entering a corporate integrity agreement (CIA). Providers or entities agree to adhere to heightened compliance obligations outlined in a CIA, and in exchange, the OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other federal healthcare programs. There are two types of CIAs, traditional CIAs and Quality of Care CIAs. This article is focused on the correlation between compliance programs and traditional CIAs, but providers are encouraged to also review the Quality of Care CIAs to minimize compliance and false claims risk due to patient care issues. CIAs are generally expensive to implement and require providers to complete a significant number of requirements within a short timeframe. CIAs include certain general components pertaining to the seven elements of an effective compliance program and also include additional compliance initiatives designed to help prevent against the type of activity that was the subject of the investigation. The compliance obligations outlined in CIAs can give providers insight as to what the OIG views as best practices in the healthcare industry. Compliance professionals should review the terms of CIAs entered into by providers in their particular healthcare field and consider if updates to their existing compliance programs are warranted.[1]

The OIG has defined the mission of its CIAs as follows:

> CIAs have many common elements, but each one addresses the specific facts at issue and often attempts to accommodate and recognize many of the elements of preexisting


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voluntary compliance programs. A comprehensive CIA typically lasts five years and includes requirements to:

- Hire a compliance officer/appoint a compliance committee;
- Develop written standards and policies;
- Implement a comprehensive employee training program;
- Retain an independent review organization to conduct annual reviews;
- Establish a confidential disclosure program;
- Restrict employment of ineligible persons (someone currently ineligible to participate in the Federal healthcare programs or Federal procurement or nonprocurement programs);
- Report overpayments, reportable events, and ongoing investigations/legal proceedings; and
- Provide an implementation report and annual reports to the OIG on the status of the entity's compliance activities.[2]

The rise in enforcement of the federal healthcare laws makes it more important than ever for healthcare providers to evaluate and improve their internal compliance programs. As a part of that evaluation process, providers should stay abreast of the terms of recent CIAs negotiated by the OIG.

This article highlights recent CIAs, discusses best practices that healthcare providers can glean from CIAs, and those practices which they can implement in order to ultimately avoid violations of the healthcare fraud and abuse laws.

CIAs and best practices for compliance

The healthcare industry's standards for an effective compliance program are modeled on the seven elements of an effective compliance program provided in Chapter 8 of the Federal Sentencing Guidelines.[3] These elements include:

1. A written code of conduct and policies and procedures
2. Organizational oversight (compliance officer and compliance committee)
3. Training and Education
4. Auditing and Monitoring
5. Consistent discipline among employees and enforcement of policies and procedures
6. Investigating systematic concerns and problems in the organization
7. Open communication and reporting concerns (i.e., anonymous hotline for complaints)

The OIG has stated that although there is no "one size fits all" compliance program, these seven elements can be customized to fit the needs and fiscal responsibilities of any given healthcare entity and that every effective compliance program begins with a formal commitment to these seven elements.

A review of the basic structure of recent CIAs provides guidance as to how OIG envisions these essential elements in practice.

Written code of conduct and policies and procedures

Codes of conduct and policies and procedures must contain "commitment to full compliance with all Federal healthcare program requirements," discussion of how all relevant personnel must comply with these laws, and the requirement to report suspected violations to the compliance officer.

Organizational oversight

A standard CIA requires a provider's compliance officer to report directly to the board of directors and not to the company's general counsel, as a means of ensuring transparency and awareness throughout the corporate structure. Recent CIAs have required personal attestations of compliance by the compliance

officer and other governing employees. Beyond internal oversight by the board, executives, and compliance officer, CIAs also require the engagement of an Independent Review Organization (IRO) to review the provider's progress in implementing the requirements of the CIA and to document the provider's overall compliance with federal healthcare laws.

Training and Education

The OIG requires both general and specific training for relevant personnel under a CIA. General training relates to CIA requirements and reviews the compliance program, including the code of conduct. Specific training involves the discussion of federal healthcare program requirements and provider-specific policies and procedures that relate to federal healthcare program requirements, as well as a discussion of the personal obligations of personnel to follow federal requirements, the legal sanctions for failing to do so, and examples of non-compliance. CIAs also require board member training and certification that each relevant employee has completed their required training sessions. Careful consideration should be given in defining the term "relevant" personnel. Organizations should consider extending the training and education requirements to include all contract physicians, coders, and billers.

The OIG requires both general and specific training for relevant personnel under a CIA.

Auditing and Monitoring

CIAs often require companies to hire an IRO to review and report on the company's compliance efforts and progress in implementing all facets of the CIA on an annual or more frequent basis. These reviews are typically conducted through a sampling and analysis of documentation and claims to ensure medical necessity, coding, and reimbursement accuracy. The outline of the IRO audits can provide guidance to other companies as to how they may want to consider structuring their audits in a particular risk area. CIAs also require a full systems review, related to errors that result in a net overpayment error rate of at least 5%, to determine the cause of the error and identify appropriate corrective action.

Consistent discipline and enforcement

These agreements require strict screening of employees and those it conducts business with to ensure that no "ineligible person" (i.e., an individual or entity currently excluded from participation in federal healthcare programs) is improperly engaging in an excluded activity related to federal healthcare programs. All providers, regardless of whether subject to CIA, should be conducting similar screening.

Investigating systematic concerns and problems

Many CIAs require providers to develop compliance risk evaluation and mitigation procedures that allow a provider to determine any systematic concerns in their operations before they lead to compliance violations. These procedures are meant to result in a system that collects information from internal compliance audits, items submitted to the provider's disclosure program, and IRO reviews and then monitors for any risks and potential violations stemming from the risk areas named in those sources. This risk evaluation program is meant to be overseen by the Compliance department or an independent consultant, with the results overseen by the compliance officer

and reviewed by the provider's IRO. CIAs also require a full systems review related to errors resulting in a net overpayment error rate of more than 5% to determine the cause of the error and identify appropriate corrective action.

Open communication and reporting concerns

Providers must explicitly state in their codes of conduct that all individuals have a right to use the Compliance department's disclosure program and that the provider is committed to non-retaliation and to maintaining confidentiality and anonymity with respect to such disclosures (non-retaliation is now often referred to as the "8th element" of an effective compliance program). The Compliance department is also required to maintain a disclosure log, which "shall include a record and summary of each disclosure received (whether anonymous or not), the status of respective internal reviews, and any corrective action taken in response to internal reviews."

CIAs are a rich resource for providers because they demonstrate how the OIG envisions a provider should implement the seven elements into a compliance program and effectively mitigate compliance risks in day-to-day operations.

Providers must explicitly state… that all individuals have a right to use the Compliance department's disclosure program and that the provider is committed to "non-retaliation"…

Best practices derived from CIAs and recent enforcement

A review of recent government enforcement activity and the CIAs negotiated by the OIG can also serve as an additional resource for best practice for compliance regarding what the OIG might require beyond the seven essential elements for a particular industry or regarding particular compliance risks. For example, recent CIAs negotiated by the OIG have included specific compliance practices for pharmaceutical companies, home health, and hospitals, as well as compliance measures related to pharmaceutical promotional practices, coding and claim processing, referrals, and physician agreements. Providers should consider implementing these specific compliance practices, in addition to the seven essential elements, to avoid criminal and civil liability under the healthcare fraud and abuse laws.

Parkland Health and Hospital

The Parkland system entered into a CIA[4] on May 24, 2013 as part of its settlement to resolve allegations related to improper claims submission to both Medicare and Texas Medicaid, including upcoding of evaluation and management services (E/M), lack of medical necessity, and inadequate supervision of residents and medical students. Parkland's CIA requires the hospital to establish a compliance committee, appoint a chief quality officer, use a patient care and quality dashboard, and engage an outside compliance expert to assist the board with their duties. The hospital was required to develop policies and procedures related to patient care, documentation, and claims submission, as well as to provide significant training to all staff and employees. The compliance and quality committees must meet with the board on a quarterly basis. The CIA also requires an

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Best practice takeaway: The Parkland CIA supports the need to develop strong policies and procedures related to patient care, documentation, coding, and billing. It emphasizes the importance of education and training on code of conduct, policies and procedures, and proper patient care to all levels of administrative and clinical staff. It also stresses the need for effective auditing and monitoring of clinical documentation as well as claims accuracy. The Parkland CIA requirement to appoint an outside compliance expert to assist the hospital and board in its duties is unique and suggests that if providers do not have in-house healthcare compliance experts, partnering with outside experts is advised.

Johnson & Johnson

Johnson & Johnson entered into a CIA[5] on October 31, 2013 as part of its settlement to resolve allegations related to its prescription drugs Risperdal, Invega, and Natrecor. Johnson & Johnson was accused of promoting these drugs for uses unapproved by the Food and Drug Administration (FDA) and of paying kickbacks to physicians and the nation's largest pharmacy specializing in dispensing prescription drugs to nursing home patients. Johnson & Johnson's CIA requires the company to "change its executive compensation program to permit the company to recoup annual bonuses and other long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct", which includes both currently employed executives and executives who have left the company.[6] The CIA also requires Johnson & Johnson to modify its policies and procedures to discuss appropriate ways to conduct promotional and product-related functions with third parties to maintain compliance, including a discussion of the types of materials and information that may be distributed by Johnson & Johnson sales representatives and how those representatives can and cannot discuss non-FDA approved ("off-label") uses of Johnson & Johnson products. The CIA requires Johnson & Johnson sales representatives to refer questions about off-label uses of government-reimbursed products to the "relevant medical affairs" or "medical information & services department" rather than fielding the questions themselves.

Best practice takeaway: The Johnson & Johnson CIA suggests that pharmaceutical policies and procedures should include instruction to sales personnel on the appropriate ways to conduct promotional and product-related functions with third parties to maintain compliance. OIG has indicated that policies and procedures should feature a discussion of the types of materials and information that may be distributed by sales representatives and how those representatives can and cannot discuss off-label uses. The Johnson & Johnson CIA also indicates that industry best practice is to have sales representatives refer all questions they receive about off-label uses of government-reimbursed products to their company's Medical Affairs or Medical Information & Services departments, rather than fielding the questions themselves.

Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.

Endo entered into a CIA[7] on February 21, 2014 to resolve allegations that it marketed the prescription drug Lidoderm for uses unapproved by the FDA. Endo's CIA includes compliance measures such as "making publicly available the results of certain clinical trials and requiring an annual review and certification of its compliance efforts by the Chief Executive Officer of its parent company, Endo Health Solutions."[8] The CIA also places significant restrictions and disclosure requirements on "third-party educational activity," which are defined in the CIA as "professional education

for [healthcare providers] intended to be independent of Endo's control or influence and that are conducted by a third party and supported by Endo including continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences."

Endo is required to post summary information on its company website about medical education grants and charitable contributions made by Endo—including the number and total value of those grants and contributions in each calendar year. Endo is also required to ensure that all of its consultants are contractually obligated to fully comply with the disclosure requirements of the CIA. Finally, the CIA requires that Endo contractually obligate all authors of biomedical manuscripts affiliated with Endo to fully comply with the International Committee of Medical Journal Editors criteria regarding authorship and disclosure of their relationship with Endo and to disclose any potential conflict of interests that may bias their work.

> … it is important for pharmaceutical companies to closely monitor the provider education programs that they sponsor.

Best practice takeaway: As discussed in the Endo CIAs, it is important for pharmaceutical companies to closely monitor the provider education programs that they sponsor. OIG has sent the message that pharmaceutical companies should be reviewing, tracking, and evaluating their funding of third-party educational activities to ensure that funding decisions are "based on objective criteria such as qualifications of the requestor, the quality of the Third Party Educational Activity program, and pre-established educational goals" of the company. Integrating this kind of funding review and tracking system into a corporate compliance program can help mitigate overall risk.

Halifax Hospital Medical Center and Halifax Staffing Inc.

Halifax entered into a CIA[9] on March 10, 2014 and agreed to pay an $85 million settlement to resolve allegations that it violated the FCA by submitting Medicare claims that violated the Stark Law. Specifically, it was alleged that Halifax executed contracts with oncologists that provided an incentive bonus for the value of the prescription drugs and tests that the oncologists ordered and were later billed to Medicare. Halifax's CIA requires it to "undertake substantial internal compliance reforms and to submit its federal healthcare program claims to independent review for the next five years."[10]

The CIA also contains a discussion of how to conduct "arrangements training" to instruct personnel on how to conduct themselves in arrangements that potentially implicate the Stark Law or the Anti-Kickback Statute (AKS). Halifax was instructed to discuss the Stark Law and the AKS; review Halifax's policies regarding referrals and the tracking of referrals; review the personal obligations of each individual involved in the "development, approval, management or review" of the company's physician and contract agreements; and review the legal sanctions and examples of violations of the AKS and Stark Law. The arrangements training is required under the CIA to occur for at least two hours annually and must be given to new hires before they are involved with any physician agreement or contract.

Best practice takeaway: The CIA entered into by Halifax contains helpful guidance related to agreements with physicians who may be potential sources for referrals.

Providers should train personnel to understand the relevant federal healthcare statutes implicated by physician agreements and other contract arrangements (Stark and AKS), review the company policies regarding physician agreements and contract arrangements, implement a system for tracking such arrangements, and discuss the personal obligations of each individual involved in the "development, approval, management or review" of the provider's contract agreements. Providers should consider implementing or enhancing their training on the legal sanctions related to federal healthcare fraud and abuse laws, give examples of violations of the AKS and Stark Law, and ensure this training is given to new hires before they are involved in negotiating or approving arrangements with potential referral sources. Mirroring these training practices would be a strong step toward maintaining Stark and AKS compliance.

Amedisys Inc.

Amedisys entered into a CIA[11] on April 22, 2014 as part of a settlement to resolve allegations that it violated the FCA by submitting false home healthcare billings to Medicare for ineligible patients and nursing and therapy services. Amedisys was also accused of maintaining improper financial relationships with referring physicians in violation of the AKS and the Stark Law.[12] The company's CIA requires the implementation of an Internal Risk Evaluation and Mitigation Program (REM Program) that identifies the material Medicare risk areas for Amedisys' home health services, outlines all "risk mitigation activities" that Amedisys will engage in, and requires Amedisys to create a system that monitors and tracks these mitigation activities that it implements to avoid Medicare compliance issues. The REM Program also requires the filing of an annual REM Program Review, which is conducted by an IRO.

The Amedisys CIA also outlines important training requirements for any "relevant covered person" under the agreement. Beyond general compliance training, the CIA also includes specific training requirements related to coding, reimbursement, and billing for services related to federal healthcare programs. The provisions of the CIA mandate that relevant personnel receive training in federal healthcare program requirements regarding the accurate coding and submission of home health claims; the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; the legal sanctions for violations of these federal programs; a review of all applicable policies, procedures, statutes, and regulations; and examples of proper and improper claims submission practices. The mandates of the Amedisys CIA require this specific training of relevant personnel to occur annually for an additional hour per session.

Best practice takeaway: As seen in the Amedisys CIA, OIG has placed an emphasis on the training of personnel who are involved with coding and claim processing. Healthcare providers should review their orientation and training materials to ensure that they address these issues and that this training is reaching all personnel involved with coding and claims processing.

DaVita Healthcare Partners, Inc.

DaVita entered into a CIA[13] in October of 2014 as part of a settlement to resolve allegations that it violated the FCA by paying kickbacks to induce the referral of patients to its dialysis clinics across the country. DaVita's CIA requires it to "unwind some of its business arrangements and restructure others, and includes the appointment of an Independent Monitor to prospectively review DaVita's arrangements with nephrologists and other healthcare providers for compliance with the Anti-Kickback Statute."[14] Under the CIA, DaVita must develop

a process for documenting the selection of healthcare providers with whom it enters into joint venture arrangements and other covered business arrangements. This process must include selection criteria that relates to the providers' ability to perform the functions of the arrangement and not on the providers' ability to provide referrals to DaVita.

DaVita must also create a centralized tracking system for all existing or new covered business arrangements with healthcare providers that tracks: remuneration between parties, investments made by parties, and estimated return of investment for parties for all partial acquisitions and partial divestiture arrangements. The system must also track the services provided under these arrangements; the use of leased spaces and medical equipment; and establish a system of review, approval, and enforcement that ensures compliance with the CIA and the AKS in all covered business arrangements. Finally, DaVita's CIA also requires it to send notice to all joint venture partners and medical directors notifying them that they (and their colleagues) are free to refer patients to non-joint venture facilities, that DaVita will not enforce any "patient-related non-disparagement or non-solicitation clauses," and that DaVita will not enforce the investment non-compete provisions found in its joint venture clinics formed by partial divestitures.

Best practice takeaway: Joint ventures and other agreements between a healthcare provider and physicians who refer patients to that provider create potential compliance issues. The DaVita CIA offers guidance on how to avoid these issues. As suggested by the Halifax CIA, providers should consider creating (or enhancing) a system that documents the selection of healthcare providers with whom it enters into joint venture arrangements and other business arrangements. Selection criteria for these business arrangements should relate to the providers' ability to perform the functions of the arrangement and not on the providers' ability to provide referrals. Providers should also track all existing or new business arrangements with healthcare providers, investments made by parties, and estimated return of investment for parties for all partial acquisitions and partial divestiture arrangements. It is also important to track the services provided under these arrangements and the use of leased spaces and medical equipment.

Dignity Health

Dignity Health entered into a CIA[15] in October of 2014 as part of a settlement to resolve allegations that it improperly overcharged the Medicare and Tricare programs for inpatient services that could have been rendered on an outpatient basis. The CIA designates a significant number of roles as "certifying employees" and requires that each member in one of the designated roles certify on an annual basis that they have received training and understand the compliance requirements that pertain to them, and that the department is in compliance with federal healthcare program requirements and the terms of the CIA. Employees required to provide this annual certification include the president, chief financial officer, chief executive officer, chief operating officer, and chief medical officer. The CIA also requires the performance of a system-wide, annual risk assessment, as well as an annual review conducted by an IRO of at least 100 claims.

Best practice takeaway: The Dignity Health CIA reinforces the importance of a commitment to compliance by all employees at every level within the organization. Compliance education and training should be provided to all employees and employees should be required to demonstrate an understanding of the compliance requirements and how those requirements apply to them on a day-to-day basis.

Conclusion

The risks of criminal and civil liability are significant for healthcare providers who fail to regularly evaluate their compliance program. Additionally, the cost of implementing a CIA and engaging an IRO are significant financial expenses. As a part of any provider's regular compliance evaluation, in addition to reviewing the federal healthcare laws and regulations for changes or updates, providers should also review the terms of recent CIAs negotiated by the OIG in order to ascertain the OIG's perspective of current industry best practices for an effective compliance program and their ability to meet the government's expectations.

The authors are grateful to Matthew Lawson (matt.lawson@alston.com), an Associate in Alston & Bird LLP's Litigation & Trial Practice Group in Atlanta, for his assistance in researching this article.

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

"Takeoff"

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"Your safety is important to us! If you haven't already done so, fasten your seat belt and hold on! Please review your job duties. If you do not wish to perform the functions described in your job duties, please ask your supervisor for a reassignment. At this time, your supervisor requests that your cell phone be turned on 24 hours a day, so they can get in touch with you.

Willenberg

"This is a non-smoking job, but drinking heavily may make you feel better. Both are not permitted while on the job, but you may feel the need to partake of them while on personal time. Tampering with, disabling, or destroying policies and procedures is prohibited by law, so plan accordingly.

"While you are at work, you may want to wear your bulletproof seat belt. Insert your head into a vice and tighten by doing your job. To release the stress of you job, breathe deeply. We suggest that you keep your bulletproof seat belt always fastened, as you may experience frequent turbulence.

"There are several emergency exits available to you during conflict. The forward one is when you decide to just walk away. The aft one is when you realize things have gone awry. There is also one over each wing, which is when you feel like jumping out the window. Please take a few moments to locate your nearest exit, keeping in mind that the closet exit may be in your car every evening. In the event of an evacuation, your job is equipped with an inflatable slide, which may be used as a life raft. In the event of added pressure, imagine that an oxygen mask appears in front of you. To start the flow of oxygen, pull the mask towards you. Place it firmly over your nose and mouth and breathe normally. The oxygen mask will not inflate, but you will feel better, and it will muffle the screaming. If you are dealing with a stressful situation, secure your mask before assisting others.

There are several emergency exits available to you during conflict. The forward one is when you decide to just walk away. The aft one is when you realize things have gone awry. There is also one over each wing, which is when you feel like jumping out the window.

"Keep in mind that a life vest is located under your desk. When you feel you need it, put it around your neck and pull firmly on the red cord. This is only advised when you are at your wit's end. If you have any questions, please don't hesitate to ask one of your Principal Investigators; they will certainly wish you an enjoyable journey. Thank you, and have and good flight!"

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by Winston Y. Chan and Emily C. Aldridge

Healthcare providers' False Claims Act self-disclosure "discount"

» The government has introduced incentives to healthcare providers that voluntarily disclose potential False Claims Act violations.

» It remains unclear whether there is any discernible financial "discount" to self-disclosing entities.

» Although the OIG states that self-disclosers may not face treble damages, it has not offered any indication of what multiplier it uses.

» The government generally does not impose certification of compliance agreements (CCAs) and corporate integrity agreements (CIAs) in self-disclosure cases.

» This alone may be a sufficient predictable benefit to warrant self-disclosure for healthcare providers.

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In recent years, the government has introduced incentives to entities that self-disclose potential False Claims Act (FCA) violations to the government. This can be particularly attractive to healthcare providers, which are often the focus of government FCA investigations and prosecutions. It remains unclear, however, whether there is any discernible financial "discount" to those that voluntarily disclose FCA violations. The Updated Self-Disclosure Protocol of 2013, published by the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS), promises that participants may not face the treble damages that they might otherwise be required to pay, but neither the OIG nor federal prosecutors offer information that can be used to peg what multiplier they actually tend to use. However, it is apparent that the government generally has imposed certification of compliance agreements (CCAs) and corporate integrity agreements (CIAs) in only a handful of self-disclosure cases, and this alone may be a sufficient predictable benefit to warrant self-disclosure for many healthcare providers, given the burden and associated expense of such agreements.

Chan

Aldridge

The current guidelines

The False Claims Act, (31 U.S.C. §§ 3729-33), enacted in 1863, provides that any person who knowingly submits false claims to the government is liable for the government's damages, increased by a multiplier, plus an added penalty for each false claim. The statute has been amended a number of times, raising penalties to their present levels: a treble damages multiplier (raised from double damages) and a penalty of $5,500 to $11,000, depending on the type of claim. The statute imposes liability for those who knowingly submit a false claim to the government, those who improperly avoid the payment of money to the government, and

those who conspire to violate the FCA. The statute requires that guilty parties have knowledge of the falsity of their actions—defined as "actual knowledge," "deliberate ignorance of the truth," and "reckless disregard for the truth or falsity of the information."

Enforcement agencies are allowed to discount penalties for parties who voluntarily disclose their wrongdoing to the government. The question before us specifically focuses on the nature of this discount in the healthcare context, and whether recent government statements and settlement trends can help hospitals and other providers predict the savings they might earn from self-disclosure.

The answer to this question becomes increasingly important as the federal government turns up the heat on its FCA enforcement. In 2014 alone, it recovered a record $5.69 billion in settlements and judgments under the FCA and related legislation. It was the first time the government recovered more than $5 billion in cases under the FCA and brought total recoveries from January 2009 to the end of Fiscal Year 2014 to $22.75 billion, which a press release characterized as "more than half the recoveries since Congress amended the False Claims Act 28 years ago to strengthen the statute and increase the incentives for whistleblowers to file suit."[1]

Enforcement agencies are allowed to discount penalties for parties who voluntarily disclose their wrongdoing to the government.

Part of the explanation for this rise in enforcement activity may be the FCA's *qui tam* provisions, which invite whistleblowers or relators to sue on the government's behalf with the potential of collecting up to 30% of the monies recovered. In 2014, whistleblowers initiated more than 700 FCA cases, exceeding 700 for the second year in a row. Recoveries in *qui tam* cases during FY 2014 totaled nearly $3 billion, with whistleblowers receiving $435 million. If federal action were not enough, the 2005 Federal Deficit Reduction Act (DRA), [42 U.S.C. § 1396(h)], included incentives designed to encourage states to adopt false claims act laws of their own and collect an additional 10% of any federal Medicaid funds recovered through a state action.

However, another explanation is the government's prioritization of pursuing FCA claims in specific industries where the impact of the fraud is acute and the cost recovery is therefore greatest as well—for example, healthcare. These claims typically involve fraud alleged against federal healthcare programs such as Medicare, Medicaid, and TRICARE federal health coverage for the armed services. Since January 2009, the Department of Justice (DOJ) has recovered $14.5 billion in federal healthcare fraud. In 2014 alone, it recovered $2.3 billion, marking the fifth straight year that the DOJ has recovered more than $2 billion in cases involving false claims against federal healthcare programs. To coordinate this effort, the government relies not only on the Civil Division of the DOJ, but also the OIG. In May 2009, HHS and the DOJ created the Health Care Fraud Prevention and Enforcement Action Team (HEAT) to coordinate these efforts. The government has also launched a public-private partnership to allow an insider perspective to inform best practices and offer insight into where to direct investigations most effectively.

The False Claims Act operates with particular force in the healthcare industry because it operates alongside additional anti-fraud

legislation that targets specific prohibitions. The Social Security Act authorizes the Secretary of HHS to pursue civil monetary penalties (CMPs) under separate authority, and many of these duties have been delegated to the OIG. Many of these CMPs are enumerated in the Civil Monetary Penalties Law (CMPL) (prohibiting false claims for federal healthcare funds), the Anti-Kickback Statute (prohibiting offering or seeking remuneration for patient referrals), and the Stark Law (prohibiting physician self-referrals). Each of these carries the same treble damages and per-violation penalties. Depending on their conduct, healthcare providers can face potential liability under a number of these statutes, as well as the FCA, for a single transaction or occurrence.

Parties under FCA scrutiny face not only triple damages and per-violation fines, but also non-monetary sanctions like CIAs and CCAs, whereby they must promise to implement enhanced and expensive safeguards.

Self-reporting guidelines and specific recommendations

Both the OIG and CMS have published recommended self-disclosure protocols (SDPs)—guidelines for healthcare companies and providers to self-report potential fraud in return for leniency. The two independent processes are described below.

The OIG self-disclosure protocols

The OIG has published SDPs since 1998. When a healthcare provider self-discloses potentially fraudulent conduct, the OIG alleges it takes the self-disclosure and the provider's level of cooperation into account when deciding on settlement terms. From the time of the OIG's original Provider Self-Disclosure Protocol in 1998 to its update in April 2013, the SDP reporting mechanisms resulted in more than 800 settlements totaling $280 million.[2]

On April 17, 2013, the OIG officially updated its SDP, comprehensively incorporating ad hoc changes that had been announced in earlier years and responding to feedback it had solicited from the healthcare industry. The 2013 SDP highlights three particular rewards that disclosing parties can expect to receive in exchange for their cooperation:

- A presumption against requiring disclosing parties to sign CIAs, promising specific prophylactic compliance efforts, in exchange for their continued participation in federal programs;
- The reduction of damages to a lower multiplier, at minimum 1.5 times the single damages, to be determined on a case-by-case basis; and
- A promise that timely disclosure to the OIG will not require duplicate submissions to CMS and other authorities, and disclosing parties will not be required to return overpayments until a settlement has been agreed upon.

Additionally, the OIG streamlined its internal processes to reduce the time for which a case is pending to 12 months. The updated SDP reiterates that the OIG demands minimum settlement levels: $50,000 for Anti-Kickback Statute violations and $10,000 for all other violations.

For a submission to satisfy the OIG's SDP, a disclosing party must take several steps:

1. Acknowledge the conduct is a potential violation by explicitly identifying the specific laws at issue.
2. Take corrective action and end the potential conduct at issue within 90 days of submission to the SDP.
3. Perform an initial investigation and damages audit within three months of acceptance by the OIG.
4. A proper disclosure includes: (a) complete information on the healthcare provider;

(b) an organizational chart, if the entity is owned or part of a network or system; (c) identification of the party's designated representative handling the claim; (d) a statement describing all relevant details of the conduct at issue; (e) the federal healthcare programs affected; (f) an estimate of the damages derived using SDP estimation methodology; (g) a description of the disclosing party's corrective action; (h) a statement regarding whether the disclosing party knows of any concurrent or pending investigation or action taken by the government in this matter, even by another department or enforcement agency; (i) the name of the party authorized to enter into a settlement agreement; and (j) certification of the truth of all disclosed information.

The guidelines also include specific methodology for estimating damages for false billing claims, claims involving the hiring of a person or entity excluded from federal programs, and claims involving allegations under the Anti-Kickback or Stark Statute.

Significantly, this process tolls the statute of limitations on related criminal or regulatory action that could result from the same behavior—meaning that while the disclosure review takes place, the statute of limitations on government prosecution is paused and cannot run out.

…while the disclosure review takes place, the statute of limitations on government prosecution is paused and cannot run out.

CMS self-disclosure protocols

The OIG's SDP process does not allow for violations of the Stark Law that do not also contain a colorable kickback allegation. In other words, if physician self-referral is the only allegation leveled at the party, they cannot avail themselves of the favorable self-disclosure remedies available through the OIG's office.

For this reason, the Affordable Care Act, enacted on March 23, 2010, empowered the Centers for Medicare & Medicaid Services (CMS) to develop its own protocol for handling self-referred disclosures of potential Stark Law violations.[3] The Self-Referral Disclosure Protocol (SRDP) is similar in many ways to the OIG's process. CMS will engage the OIG and DOJ as needed to ensure the disclosing party's review is comprehensive and that the government's response is coordinated. Furthermore, the elements of an appropriate disclosure are nearly identical, with few material differences. CMS is explicit about the five factors under consideration in its review:

- The nature of the allegedly violating behavior;
- The timeliness of the disclosure;
- The party's cooperation during review;
- The risk of litigation; and
- The financial position of the disclosing party.

However, the SRDP differs from the OIG's process in that it is not a settlement itself, but instead results in an Advisory Opinion of recommendations for CMS penalties. This opinion may be the basis for a settlement, but CMS is not bound by its determination, and the disclosing party can appeal its decision. As a result, the CMS process may be more discretionary and, therefore, more flexible than the OIG's. There is no discussion of minimum penalties or multipliers of damages, which could indicate that the CMS has more authority to downwardly depart from precedent. On the other hand, it could indicate that the system has potential to

be more punitive. For example, there are several mentions of CCAs that suggest that CMS still relies on using those as sanctions, even against voluntary disclosures. Disclosing parties should consider these possible outcomes when choosing whether to commit to the OIG or CMS self-disclosure avenue.

Self-disclosure from the government's point of view

It is difficult to find truly revelatory statements from policymakers regarding self-disclosure and healthcare providers. One might expect the Attorney General or the Secretary of HHS to indicate more clearly the penalty discount that parties can expect from voluntary disclosure, much like occurs in the context of antitrust violations.

Here, we highlight two types of statements. The first are statements made by policymakers and analysts discussing the voluntary disclosure protocols and anti-fraud measures more generally. The second are statements made by policy and law enforcement officials in the context of publicized settlements. The latter are particularly important, as they reveal the careful efforts by many to signal to other healthcare providers what the standards of the government's settlement review may be.

Policymakers' comments

The OIG Provider Self-Disclosure Protocol, most recently updated in April 2013, describes four primary benefits of self-disclosure. First, there is "a presumption against requiring integrity agreement obligations in exchange for a release of OIG's permissive exclusion authorities in resolving an SDP matter."[4] Second, the government will use "a lower multiplier on single damages than would normally be required" in a government-initiated investigation. Ultimately, however, the OIG generally requires a minimum multiplier of 1.5 times the single damages and has the discretion to choose the exact multiplier. Third, the OIG suggests that use of the SDP "may mitigate potential exposure under section 1128J(d) of the Social Security Act, 42 U.S.C. 1320a-7k(d)," which requires the reporting and returning of overpayments 60 days after the date on which the overpayment was identified. Fourth and finally, the OIG offers the somewhat vague promise that it will commit to working with entities using the SDP, and that it expects SDP cases to be resolved in fewer than 12 months.

The government has made few other public statements encouraging self-disclosure of FCA violations in the recent past, but in 2012, Acting Assistant Attorney General Stuart F. Delery said this at the American Bar Association's Ninth National Institute on the Civil False Claims Act and Qui Tam Enforcement:

> Most defendants in FCA matters have come to recognize that there is an enormous benefit to be gained by avoiding what will likely be costly and protracted discovery, trial, and the mandatory treble damages and penalties that will be assessed if the government prevails. The more thorough and effective the job defense counsel do investigating the case and presenting their clients' views of the applicable facts and law, the more likely it is that we will find these defenses persuasive, and the more credit your clients will get from the federal government in negotiated resolutions. And, I might add, because disclosure and cooperation show a sincere interest in cleaning house—and ensuring a culture of doing the right thing—they can help companies demonstrate the necessary responsibility to continue participating in government programs and contracts. There are legal requirements, policies, and practices in place that encourage businesses to combat

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> fraud on their own. For example, as many of you may know, under the False Claims Act, self-disclosure of violations can mean a reduction in potential damages—either in litigation or during settlement. So, a decision to come in promptly and work with the government to resolve any liability that may arise from past wrongdoing is more than the right litigation decision. It is a good economic decision.[5]

Settlement-related comments

By and large, prosecutors and policymakers have been reluctant to discuss the formulae by which they determine damages and penalties for FCA violations, voluntary disclosure or otherwise. However, the public statements related to some of the higher profile settlements of this kind reveal how careful the government is to signal that it values early action, cooperation, and good faith. Voluntary self-disclosure that fails to meet any of these criteria may be viewed less favorably and be subject to harsher penalties and consequences than it might have otherwise.

For example, in October of last year, the United States Attorney's Office for the Northern District of New York stated in a press release regarding the resolution of False Claims Act liability:

> Due in large part to Lourdes's decision to self-disclose these issues and its cooperation throughout the government's investigation, the hospital was required to pay far less than the treble damages and penalties that the United States is authorized to seek under the False Claims Act.... United States Attorney [Richard S.] Hartunian said: 'Today's settlement is an excellent example of how voluntary self-disclosure benefits both the integrity of healthcare programs and providers who discover and report evidence of improper billing in their organization. Lourdes should be commended for the manner in which it handled the disclosure.'[6]

A 2014 press release regarding a FCA settlement in the Northern District of Ohio included a quote that Inspector General Daniel R. Levinson was "pleased that Memorial [Hospital] stepped forward to disclose these improper financial relationships and is working to avoid future occurrences."[7]

Similarly, in a 2013 settlement press release out of the District of Utah, Derrick L. Jackson, Special Agent in Charge at the U.S. Department of Health and Human Services, Office of Inspector General in Atlanta, encouraged self-disclosure and stated:

> This case is an excellent example of collaboration between the healthcare community and the law enforcement community coming together to serve the American taxpayer. When this hospital realized it had received inappropriate Medicare payments, it brought the matter to the attention of the U.S. Attorney's Office and refunded the money to the Medicare Trust Fund. We certainly hope that other healthcare providers will do the same when they realize they have been overpaid.[8]

Another 2013 press release "applaud[ed] Intermountain [Healthcare] for recognizing their liability and coming forward to self-disclose these violations."[9]

The Middle District of Tennessee was especially effusive in a 2012 press release, in which U.S. Attorney Jerry E. Martin stated:

> Maury Regional is to be commended for the manner in which the hospital handled the disclosure of these billing issues once the issues came to light through the hospital's compliance program. After notifying

this office that the billing issues had been discovered, Maury Regional outlined its plan to determine the scope of these issues, followed through on that plan, and worked closely with us to bring this matter to resolution. Self-disclosure by providers is critical to the protection of the integrity of the federal healthcare system and this office is committed to bringing voluntary disclosures to resolution as quickly and as efficiently as is reasonably possible.[10]

Another official continued, "Maury Regional was transparent in their disclosure to the government and ultimately saved the taxpayers the cost associated with a federal investigation. OIG and the United States Attorney's Office will continue to work with healthcare providers to return substantial dollars back to Medicare."

Trends evident in recent FCA self-disclosure settlements

Government press releases may point to cases that the government thinks are particularly illustrative of the kinds of settlement process they hope to encourage with the SDP. For example, the case involving Maury Regional Hospital in Tennessee was, by insiders' accounts, amicable, cooperative, and efficient for all parties involved. The fact that the government and private parties worked together so effectively prompted this case to become a model case-study for the procedure by others. The case was also the first time a healthcare company in Tennessee self-reported violations to the False Claims Act, and its publicity may have been a result of law enforcement hoping to encourage others to follow suit.

The government has been incredibly consistent across these cases. In nearly every case, it was careful to signal that the financial penalties, no matter how large the number, were tailored more narrowly in recognition of the disclosing party's cooperation. It was particularly voluble on this count where the dollar figure imposed was in the millions.[11]

The government has been incredibly consistent across these cases. In nearly every case, it was careful to signal that the financial penalties, no matter how large the number, were tailored more narrowly in recognition of the disclosing party's cooperation.

The government has also been clear in its intention not to impose soft penalties, such as CIAs, CCAs, or other compliance measures on self-disclosing parties. CIAs typically last three to five years and require the healthcare provider to institute a corporate integrity program, which could include employee training, annual audits reported to the OIG, and new written compliance policies. In only a very few self-disclosure cases has the OIG asked the party to sign a CIA or CCA. This relieves the healthcare provider of the costs of fulfilling such agreements, which can range from tens of thousands of dollars to cover the cost of auditors to many millions of dollars, depending on the extent of the CIA.

Case study: A repeat player

Healthcare providers that have experienced settlement after both self-disclosure and after

a government-initiated investigation demonstrate potential differences in treatment, the key of which is the imposition of a CIA or CCA in the absence of self-disclosure.

In May 2000, Community Health Systems (CHS) agreed to pay $31 million to resolve allegations that it submitted false claims for reimbursement to Medicare, Medicaid, and TRICARE. CHS had disclosed four years of "upcoding" (i.e., the improper assignment of diagnostic codes to hospital inpatient discharges for the purpose of increasing reimbursement amounts) at its hospitals after the government informed CHS that it was investigating several of CHS's hospitals. In the press release announcing the settlement, Department of Health and Human Services Inspector General June Brown Gibbs remarked, "This case is a good example of the value of compliance programs and provider self-disclosure. Through its voluntary compliance program, Community Health Systems identified a Medicare billing abuse and then self-disclosed the problem to the government."[12] The settlement included a corporate compliance agreement, but as Gibbs stated, "Because of the self-disclosure, we have significantly modified the company's obligations under the corporate compliance agreement that is part of the settlement."

In August 2014, CHS again settled False Claims Act allegations with the government. This time, CHS had not participated in self-disclosure. Instead, a government investigation initiated by several *qui tam* lawsuits revealed that "from 2005 through 2010, CHS [allegedly] engaged in a deliberate corporate-driven scheme to increase inpatient admissions" of Medicare, Medicaid, and TRICARE program beneficiaries who were admitted through the Emergency Department for medically unnecessary care. In addition, Laredo Medical Center, a CHS hospital, was alleged to have submitted false claims to Medicare from 2005 through 2010 for inpatient medical procedures that should have been performed more cheaply as outpatient procedures, and to have violated the Stark Law. CHS paid $89.15 million to resolve the inpatient scheme allegations and $9 million to resolve the Laredo Medical Center allegations. It was the largest FCA settlement in the history of the Middle District of Tennessee. The press release was sternly worded and offered such admonitions as, "Put simply, these types of fraudulent practices will not be tolerated and the investigation and resolution of such claims will continue to be a high priority of this office." It continued, "Health care providers should make treatment decisions based on patients' medical needs, not profit margins. We will not allow this type of misconduct to compromise the integrity of our health care system."[13]

Moreover, the terms of the settlement required CHS to enter into a "a rigorous multi-year Corporate Integrity Agreement" with the OIG under which it is required to retain independent review organizations to review the accuracy of the company's claims for inpatient services furnished to federal healthcare program beneficiaries for five years.[14]

CHS's example could therefore demonstrate at least a few benefits to self-disclosure. The differences between these two settlements are stark. It is true that the facts of the alleged false claims differ. At a minimum, the 2014 alleged violations took place over six years as compared to four, and the alleged illegal acts were not the same. Both sets of violations, however, involved the same company, the same law, the same federal healthcare programs, and, for the most part, behavior that took place throughout the chain. The principal difference between the settlements is that the first involved self-disclosed violations and the second did not, so they are worth comparing. Although the difference between the settlements is huge—$67 million—the key measure

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of a settlement is the discount the government applied to a provider's actual damages to reach a settlement amount. Because the government does not disclose those figures, however, it is impossible to compare the discount percentage between self-disclosure settlements and settlements of government-initiated investigations.

Nevertheless, CHS appears to have benefitted greatly from its self-disclosure. First, the tones of the two press releases could not be more unlike. The 2000 press release is mostly free of chastisement of the company, touts the value of self-disclosure, and is spare on detail. The 2014 press release, on the other hand, explains the company's wrongdoing and the harsh terms of the settlement in detail, quoting no less than five government officials. If the press releases are any indication of the tone of the two investigations, CHS likely had an easier time during the first investigation. Second and more importantly for our purposes, CHS's obligations under the terms of its first CIA were "significantly modified" and likely less costly and inconvenient.

Although the 2000 CIA is not available publicly, the 2014 CIA is, and the obligations contained in the CIA's 60 pages are onerous. For five years, CHS must, among other duties, maintain a compliance program; develop and distribute a written code of conduct and policies and procedures, to be updated annually; provide various trainings to employees; create procedures to ensure that new arrangements with physicians do not violate the Anti-Kickback Statute or the Stark Law; hire an independent auditor to perform numerous reviews; maintain a disclosure program for employee whistleblowers; and report any possible overpayments and FCA violations to the OIG.[15] These are fairly common in other non-self-disclosure cases. It seems likely that CHS could have avoided at least some of these burdensome obligations through self-disclosure.

Conclusion

Although the government has announced that it is predisposed to apply only the 1.5 times damages multiplier (as opposed to treble damages) to self-disclosing healthcare providers, it has not released any information that would allow parties to predict the penalties they will have to pay. Although it is impossible to determine whether the government gives any financial "discount" to self-disclosing healthcare providers, there does appear to be a "discount" for CIAs and CCAs usually imposed during FCA settlements. Self-disclosing parties can expect the potential for lesser collateral obligations, thus reducing the ultimate cost of settlement.

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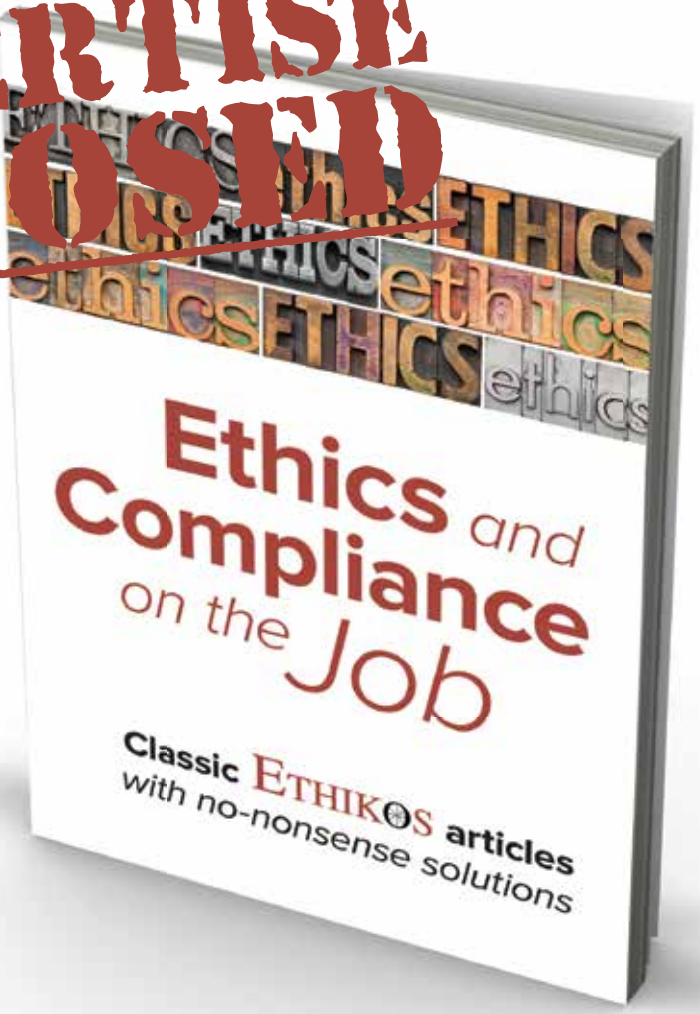

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HEALTH CARE COMPLIANCE ASSOCIATION

by Faye Hager, BSN, RN

Embedding financial compliance for clinical trials

» Financial compliance for clinical trials begins long before site initiation.
» Financial compliance affects multiple study documents.
» CMS provides several online resources related to research billing compliance.
» Subject Financial Tracking ensures the appropriate billing route is maintained.
» Systems may be hard-wired to support research billing compliance.

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There was a time when one of my greatest financial concerns related to clinical trials was to ensure that our institution recouped the research costs detailed in the study budget. Although fully recovering research costs is important to the financial health of the institution, being aware and compliant to research billing regulations is critical to establishing and maintaining a compliance culture in the facility. To this end, the Center for Medicare & Medicaid Services (CMS) has published their clinical trial policy to provide guidance to institutions that conduct research billing procedures.[1] Many private payers are independent and are not tied to the Medicare policies, but there seems to be a shift towards accepting Medicare's policies as the gold-standard. This article will only address the Medicare guidelines.

Hager

Our Research department does not as yet have an electronic research data management system to assist us with the various documents that pertain to clinical trial management. Multiple personnel manage contracts, budgets, and regulatory documents, such as the Informed Consent. This situation demands good communication among colleagues to ensure that the documents are consistent and compliant with the CMS regulations set forth for clinical trials.

The steady flow of new studies to be reviewed is an additional challenge. Last year, 54% of our clinical research studies were new. Of those, more than half were initiated in the last quarter of the year. Although our personnel are pretty good communicators, I found it challenging to be confident that I had covered all the elements that needed my review. With studies coming at a frantic pace, I wanted to have a greater certainty that I would be able to intercede with necessary changes prior to the execution of the contract or the submission of the Informed Consent to the Institutional Review Board. To facilitate consistent oversight, I created a Financial Study Startup Packet (FSSP). The packet is a compilation of several sheets that contain the critical elements for financial compliance review. They must all be completed before a study is ready to be fully executed. When a new study is sent to my desk to review, I use an FSSP folder, consisting of the following sheets, to guide my review. **(To download examples of all seven sheets, visit** *http://bit.ly/ct-2015-05-hager***.)**

Sheet 1: Action Items Checklist

This list was created using input from all personnel responsible for each section of study

Sheet 1: Action Items Checklist

Study Name			
ACTION ITEMS - Contracts	**COMPLETED**	**DATE**	**NOTES**
Site Questionnaire - CRC	☐		
Confidential Disclosure Agreement	☐		
Request Protocol & CRF	☐		
Define Study Acronym	☐		
Clinical Trial Agreement	☐		
Summary - Executive	☐		
Fully Exec Contract - received	☐		
ACTION ITEMS - Fiscal	**COMPLETED**	**DATE**	**NOTES**
Study Category Determination	☐		
Document Harmony: ICF, budget, CTA	☐		
Study Cost Analysis	☐		
Medicare Cost Coverage Analysis	☐		
Study Startup Reimbursement Grid	☐		
Principal Investigator Payment form	☐		
Executive Budget Summary	☐		
Financial Tracking Form	☐		
ACTION ITEMS - Regulatory	**COMPLETED**	**DATE**	**NOTES**
Informed Consent Draft	☐		
IRB Prep	☐		
IRB Doc	☐		
Investigator Doc	☐		
Sponsor Doc	☐		
Conflict of Interest Doc	☐		
IRB Submit	☐		
Schedule Site Initiation Visit	☐		
Delegation Of Responsibilities Form	☐		
Site Training Checklist	☐		
ACTION ITEM - Administrative	**COMPLETED**	**DATE**	**NOTES**
Database	☐		
Contract Cover Sheet	☐		
Contract Database	☐		
Email (contract)	☐		
Epic (If required)	☐		
Clinical Trial Number	☐		
Screening & Enrollment Sheets	☐		
(If Declined - Table Docs)	☐		
ACTION ITEM - CRC	**COMPLETED**	**DATE**	**NOTES**
Assign CRC	☐		
CRC Cost Estimate –(crc)	☐		
Alert Team Email	☐		

startup. The list contains the necessary actions required in the process from the initial study site questionnaire through to the study site initiation visit. Various research staff may enter and update information as tasks are completed.

TIP: Place the Action Items Checklist on a shared drive for easy, ready access. This saves time, because study personnel may reference the list to check the status of study startup activities, rather than requiring the time to place a call, send an email, or walk to another office.

Sheet 2: Study Category Determination

When an institution conducts a variety of research studies, decision-makers may become overwhelmed without a means to consistently review so many variables. This sheet was created to provide a consistent process for assessing the "billability" of a study. This is very important, because if a study has procedures that will be billed to Medicare, the patient claim must include the appropriate research billing codes (secondary diagnosis code V70.7, Condition Code 30, the eight-digit clinicaltrial.gov number, and a modifier of Q0 or Q1).

The studies typically fall into one of three categories. The simplest of our studies consist of chart reviews for quality. These studies do not include any healthcare services in their protocols. The entire study cost is geared around personnel time to retrospectively review the charts. That cost is entirely borne by the sponsor.

Occasionally we have sponsors, or investigators, who wish to conduct post-FDA-approval marketing studies. These studies collect data for outcome measures. This category of study does not require the addition of research billing codes, because the research activity is merely data collection.

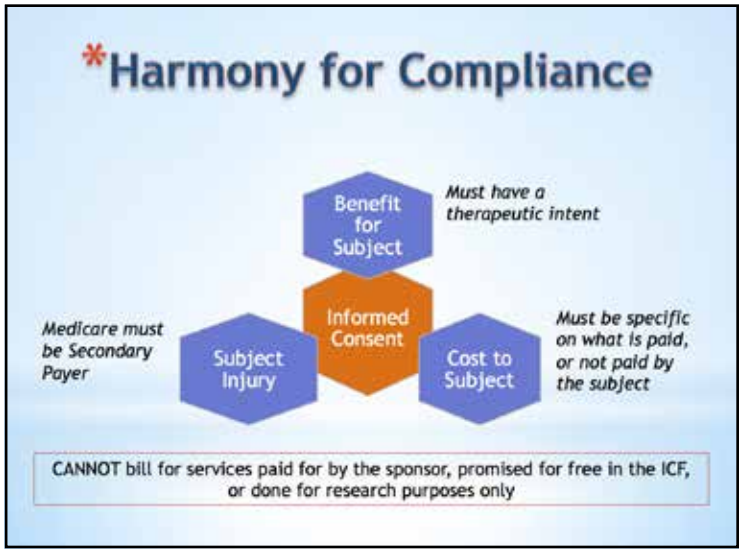
Other studies include an investigational item/service. The research agent in those studies has not yet been FDA approved. The study may be funded by the National Institute of Health (NIH) or by a cancer consortium that supports National Cancer Institute (NCI) studies. The CMS clinical trial policy can guide

your institution for what constitutes a "qualified clinical trial." Each institution must incorporate the principles of that policy into their own written research financial policies. Medicare has provided a helpful resource, "Mandatory Reporting of National Clinical Trial (NCT) Identifier Numbers on Medicare Claims - Qs & As."[2] This sheet provides me with a tool that guides me in the complex decision-making matrix. I can simply and consistently review the billable status of the various studies that come across my desk. Once the category is determined, all billing processes are set up to comply.

TIP: Our institution uses Epic software systems for our electronic medical records (EMR). We worked with the Epic technicians to build an internal process to "flag" research accounts that will direct a subject's research claim to the Research Office. The flag is the name of the research study. At the time the procedure is scheduled, the registrar will enter the study name into a flag field. Additionally a second flag is utilized which will state, "Bill all services to research." We refer to these as the research billing flags.

TIP: The secondary diagnosis code of V70.7 is entered on all research-related claims. This code signifies that an item or service was provided for a patient who is participating in a research study. The presence of the V70.7 code will place the claim into a work queue for our office to review. If the claim goes to Medicare, the research billing codes and modifiers are entered. If the claim is paid by the sponsor, the billing flags are placed into the Epic system to send the claim to the Research Office for sponsor payment.

Sheet 3: Harmony for Compliance



Sheet 3: Harmony for Compliance

This sheet provides a guide to remind me to check the budget, Informed Consent, and Clinical Trial Agreement for self-consistent statements related to the research finances of the study. Of particular concern are the sections that relate to the following:

- **Cost to subject**: Here, I want to ensure that the language in the Informed Consent matches the language in the Clinical Trial Agreement as well as in the study budget. I also want to ensure that a third-party payer will not be billed for anything that the sponsor has stated will be provided free to the subject. I look for clear statements as to what the subject would, or would not, be required to cover. Finally, I look to ensure that the amount the Informed Consent states as an honorarium to the subject for his/her involvement matches the sponsor's budget.
- **Benefit for subject:** The CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) lists the requirements that must be met for Medicare to provide coverage of the study routine costs.[3] One of those requirements is that the study must have a therapeutic intent. If the study does not have a

therapeutic intent, Medicare cannot be billed and the study sponsor must bear the entire cost of the study.

TIP: In research, it is difficult to know if the study will bring a benefit, or not, to the subject. Our template language is: "Your participation in this research study may or may not be a benefit to you."

- **Subject injury:** I work with the sponsor to achieve acceptable and consistent compliance verbiage. I must exercise caution when the Clinical Trial Agreement and the Informed Consent state something along the lines of, "If an injury or illness occurs which is directly linked to your study participation, the sponsor will pay if your insurance denies coverage." Once a sponsor makes a payment, such payments can be considered to be payments made by liability insurance. Carefully review the injury language to ensure that you comply with the Medicare as Secondary Payer regulation.[4]

Sheet 4: Study Startup Grid

This sheet is used to remind me to capture the often hidden and forgotten costs for a study start. The sponsor may request support in the development of the protocol or clinical trial agreement. The sponsor may communicate with an Imaging department with requests for phantom images to be conducted to provide quality review of our imaging capabilities. Because these departments do not include our study personnel, we may overlook capturing that information. The Study Startup Grid sheet provides me with template prompts to check with other departments for any costs that have occurred prior to the start of the study. The grid also provides me with a consistent calculation for arriving at a startup funding request.

TIP: Be sure that you include the institution's benefits and overhead when you enter in the study personnel wage for the cost calculation.

Sheet 5: Study Cost and Cost Coverage Analysis

This is a complex worksheet and addresses multiple needs. One need is to ensure that the sponsor adequately covers our expenses to participate in the study. When I review the protocol, I pull out every procedure that has a cost associated with it. I enter in the amount the sponsor is proposing to pay for the study visit. The sheet is used to then calculate the sponsor funding and compare it to the institutional expenses. I continue to negotiate the budget with the sponsor until I have arrived at full coverage for our participation.

As the sheet is populated, a Medicare Cost Analysis is simultaneously carried out. Every line item must be reviewed for appropriate billing. If the National Coverage

Activity	Role	Time	Wage	Sub-total
Protocol:				
Development	PI		*enter in hourly wage*	
Review	PI		*enter in hourly wage*	
Review	CRC		*enter in hourly wage*	
CTA :				
Development	Contracts		*enter in hourly wage*	
Review	Contracts		*enter in hourly wage*	
Budget:				
Development	Contracts		*enter in hourly wage*	
Review	Contracts		*enter in hourly wage*	
CMS compliance review	Contracts		*enter in hourly wage*	
Regulatory Documents:				
Preparation & Submission	Regulatory		*enter in hourly wage*	
Secondary responses F/U	Regulatory		*enter in hourly wage*	
Informed Consent	Regulatory		*enter in hourly wage*	
Protocol	Regulatory		*enter in hourly wage*	
Training:				
Study team	CRC		*enter in hourly wage*	
Patient Care team	CRC		*enter in hourly wage*	
Additional Needs:				
Phantom images				
calibration of equipment				
webinar attendance				
software				
hardware				

Sheet 4: Study Startup Grid

Sheet 6: Subject Financial Tracking

visit	activity	DOS	hrs	
1	enrollment			
	informed consent			sponsor provides coverage
	medical hx			sponsor provides coverage
	surgical hx			sponsor provides coverage
	demographics			sponsor provides coverage
CODES	Physical w vital signs			to insurance-use billing codes
	life-style advice			sponsor provides coverage
CODES	HGA1C (83036)			to insurance-use billing codes
	CRC fees		6	sponsor provides coverage
	PI admin		1	sponsor provides coverage
	PI oversight			sponsor provides coverage
	subject			sponsor provides coverage
2	randomization			
FLAGS	office visit			USE RESEARCH FLAGS
	inclusion/exclusion			sponsor provides coverage
	randomization			sponsor provides coverage
	concomitant meds			sponsor provides coverage
FLAGS	ECG (93005)			USE RESEARCH FLAGS
FLAGS	ECG read (93010)			USE RESEARCH FLAGS
FLAGS	CBC w Diff (85025)			USE RESEARCH FLAGS
	study med dispensed			sponsor provides coverage
	SAE's			sponsor provides coverage
	CRC fees		6	sponsor provides coverage
	PI admin		1	sponsor provides coverage
	PI oversight			sponsor provides coverage
	subject			sponsor provides coverage
3	week 1 follow up			
FLAGS	office visit			USE RESEARCH FLAGS
	adverse events/SAE's			sponsor provides coverage
	study med review			sponsor provides coverage
	CRC fees		1	sponsor provides coverage
	PI admin		0.5	sponsor provides coverage
	PI oversight			sponsor provides coverage
	subject			sponsor provides coverage

Determination does not indicate that the line item is billable to Medicare, then the sponsor must provide funding for that item.

Sheet 6: Subject Financial Tracking

This sheet is generated from the larger Study Cost and Cost Coverage Analysis sheet. Line items from the full cost/coverage analysis that do not contain a payment process are deleted. The remaining list provides a tracking sheet for the study billable items/services. The column at the left helps the coordinator recall how to route the bill for that particular item/service. A financial tracking sheet is created for every subject in every study.

TIP: Each coordinator is provided with a tracking sheet for each study subject. The coordinator is responsible to alert the Research Finance Office of all study billable procedures. The staff can then enter the Epic system to review that the item/service has an accurate billing route.

Sheet 7: Principal Investigator (PI) Payment Authorization

This sheet directs our office where to send the PI research payments. The Principal Investigator may select to have the payment sent to his/her practice or to his/her residence. If the practice is to receive the payment, the office address and tax ID number are also required. If the payment is to be sent to the residence, the address and the PI's Social Security number is required.

TIP: When a check is issued to the Principal Investigator, the check is accompanied by a form letter to inform the PI what the payment is for: the study name, the subject number, and study visit. This will assist the PI in his/her own tracking of research payments.

Conclusion

Using the Financial Study Startup Packet has enabled me to conduct a more consistent and thorough review of the various documents that must not only be compliant as a stand-alone entity, but must also be in harmony with each other.

1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Routine Costs in Clinical Trials, Section 310.1. Publication Number 100-3, version 2. Available at http://go.cms.gov/1bcdnHi
2. CMS: "Mandatory Reporting of National Clinical Trial (NCT) Identifier Numbers on Medicare Claims – Qs & As." Available at http://go.cms.gov/1EqHUL7
3. *Ibid*, Ref #1.
4. 42 CFR 411.32 Available at http://bit.ly/18TkYJ4

by Bill Wong, DC, CHC, CHPC, CCS, CPC and Tomi Hagan, MSN, RN, CHC

Compliance issues in telemedicine

» Telemedicine is expected to experience continued growth in the healthcare industry.

» Compliance professionals should understand the complex regulatory requirements for the provision of telemedicine.

» The responsibilities of the distant and originating site should be clearly defined.

» Risks and pitfalls include reimbursement issues, fraud and abuse, credentialing and privileging, informed consent, continuity of care, and privacy/security.

» Compliance professionals should take a proactive approach in mitigating compliance risk by adhering to accepted standards.

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Imagine a world where a medical provider walks in his office, clicks on his computer, and checks his schedule of patients. Then, instead of getting up and walking to the room where his patients would normally be, he clicks on the name and instantly, the patient appears on the computer screen. The provider begins his evaluation and management office visit. This patient encounter may seem normal, but this interaction is actually taking place hundreds of miles away. This encounter is part of a new wave of medicine called telemedicine.

The field of Telemedicine has exploded tremendously over the last few years. This newfound endorsement by healthcare leaders is largely influenced by the shift in payment by healthcare payers, including Medicare and Medicaid. Under the Patient Protection and Affordable Care Act (PPACA), financial and payment incentives are given to healthcare providers who produce better outcomes while reducing cost. Moving from a "fee for service" model in which healthcare providers are paid for in-person visits to an outcome-driven care model, telemedicine is estimated to grow at a rate of 14% from 2011–2018 and to exceed $32.5 billion by 2018 as an industry.[1] For this reason, many hospitals and large group practices are building infrastructures that can accommodate these changes, while remaining in compliance with the complex rules and regulations that come with providing this service.

Wong

Hagan

Telemedicine/Telehealth definitions

Compliance professionals should understand the meaning of the various terms used to describe telemedicine, including:

- **Telemedicine** is defined by American Telemedicine Association (ATA) as "the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools and other forms of telecommunications technology."[2]
- **Telehealth** (or telemonitoring) is defined by The Centers for Medicare & Medicaid Services (CMS) as: "the use of telecommunications

and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance. Telehealth includes such technologies as telephones, facsimile machines, electronic mail systems, and remote patient monitoring devices which are used to collect and transmit data for monitoring and interpretation."[3]

The specific definitions may vary by state and organization; however, most are consistent in attributing the term telemedicine specifically to patient care, as a subset within telehealth, which refers to overall access to health information and not necessarily the provision of direct patient care.

Compliance professionals should also have an understanding of the definitions and responsibilities of the sites involved in the provision of telemedicine, including:

- **Distant site** refers to the site at which the physician or other licensed practitioner delivering the service is located at the time the service is provided via telecommunications system. Distant site practitioners, including physicians, nurse practitioners, physician assistants, nurse midwives, clinical nurse specialists, clinical psychologists, clinical social workers, and registered dietitian/nutritional professionals may be eligible for Medicare payment.
- **Originating site** refers to the location of the Medicare patient at the time the service being furnished occurs via a telecommunications system. The originating site is only eligible for Medicare payment if the originating site is located in a rural health professional shortage area or in a county outside of a metropolitan statistical area. Those originating sites authorized by law are: physician offices, hospitals, critical access hospitals, rural health clinics, federally qualified health centers, hospital-based renal dialysis units, skilled nursing facilities, and community mental health centers.
- **Asynchronous or "store and forward"** refers to the transfer of data from one site to another through the use of a camera or similar device that records (stores) an image that is sent (forwarded) via telecommunication to another site for consultation. Asynchronous or "store and forward" applications would not be considered telemedicine and are only permitted in federal demonstration programs conducted in Alaska and Hawaii.

Telemedicine and telehealth compliance

Because telemedicine touches on many aspects of healthcare, such as payment and reimbursement, fraud and abuse, credentialing and privileging, privacy, informed consent, documentation, and regulatory compliance, the compliance officer must have a broad understanding of this service. Potential risks and pitfalls include but are not limited to the following.

Reimbursement

Medicare and Medicaid Reimbursement still is limited and generally requires face-to-face, simultaneous interaction between a patient and provider. Exceptions are made to certain eligible facilities located in a rural area with a shortage of healthcare professionals. The final rule published on November 13, 2014 does significantly expand Medicare reimbursement for telehealth services, particularly in the area of chronic care management.[4] With the barrage of regulations from the federal level (Medicare), state level (Medicaid), and private payers, the compliance officer will need to keep abreast of these reimbursement requirements and restrictions that may affect the billing practices of the organization. The ATA maintains

a list of legislation regarding telemedicine by each state.[5] Careful examination of all applicable regulations is necessary to ensure the submission of compliant claims.

Fraud and abuse
Business arrangements between healthcare entities, equipment leases, and/or use of products owned by a provider should be scrutinized. These arrangements should be structured in a manner that does not violate federal fraud and abuse laws, including the Anti-Kickback Statute and Stark Law.

Credentialing
Hospitals must ensure that telemedicine providers of the distant hospital are appropriately privileged and legally licensed to provide services to the originating hospitals' patients. CMS does allow the distant site to rely on the credentialing and privileging decision of the distant site hospital or information provided by other telemedicine entities when determining privileges for distant site providers; however, certain conditions must be met, including a written agreement. Consideration should be given to the distant site's ability to evaluate the quality of care provided by the distant site provider and accessibility to peer review information.

Hospitals must ensure that telemedicine providers of the distant hospital are appropriately privileged and legally licensed to provide services to the originating hospitals' patients.

Informed consent
Patients should be made fully aware of and consent to the potential benefits and risks associated with telemedicine, including delays that could result from substandard or failure of telecommunication equipment. Proof of informed consent should be documented in the patient record.

Maintaining continuity of care
Documentation of telemedicine encounters should be included in the medical record of the patient. Appropriate documentation would ensure an accurate and complete patient history. A plan should be in place for data management, including maintenance of the patient's medical record and liability for any security breach or unauthorized disclosures. State law must be considered when determining if data from the telemedicine encounter, including recordings, should be included in the patient's medical record. Special circumstances, including telemental health, may apply.

Privacy, security, and patient confidentiality
Healthcare providers in telemedicine have the same obligation and responsibility as face-to-face providers to safeguard the patient's protected health information (PHI) and electronic protected health information (ePhI) as outlined in the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act. Technical safeguards must be in place to protect against third-party interference or unsecure transmissions. In addition, all devices used in the telemedicine encounter should have up-to-date security software. Current unencrypted platforms, such as Skype, Facetime, or Google Talk, are not HIPAA compliant and thus are not allowed.

Mitigation of compliance risk

Knowing these areas of risk, what can a compliance officer do to mitigate these factors? The Federation of State Medical Boards adopted the Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.[6] Although state medical boards are not required to adopt the policy, they are likely to use it for guidance. The policy does not address reimbursement, but does provide guidelines regarding the provision of care via telemedicine.

The ATA has made a series of practice guidelines available on their website, including the Core Operational Guidelines for Telehealth Services Involving Provider-Patient Interactions, along with guidelines for telemedicine specialties, including dermatology, mental health, pathology, primary, urgent, and intensive care.[7]

Conclusion

As hospitals begin their adoption of telemedicine, it is important that the compliance officer keeps abreast of the rapidly changing regulatory requirements of this exciting area of healthcare. By being proactive in mitigating risk, the compliance officer can create a successful and rewarding implementation of telemedicine.

1. Practical Patient Care: "Confidence Grows in Telemedicine." November 10, 2012. Available at http://bit.ly/1EVNCHN
2. American Telemedicine Association: "What is Telemedicine?" 2012. Available at http://bit.ly/1xsqyZo
3. Centers for Medicare and Medicaid Services: Telehealth. January 2014. Available at http://go.cms.gov/1EkmbSr
4. Centers for Medicare and Medicaid Services, Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Date for the Center for Medicare and Medicaid Innovation Models, & Other Revisions to Part B for CY 2015. 79 Federal Register, 67598, November 13, 2014. Available at: http://1.usa.gov/1EkmgFQ
5. American Telemedicine Association: 2014 State Telemedicine Legislation Tracking. December 18, 2014. Available at: http://bit.ly/18yhbku
6. Federation of State Medical Boards: Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine. April 26, 2014. Available at: http://bit.ly/1MFmzBq
7. American Telemedicine Association: Telemedicine Practice Guidelines. Available at: http://bit.ly/1CmuLYz

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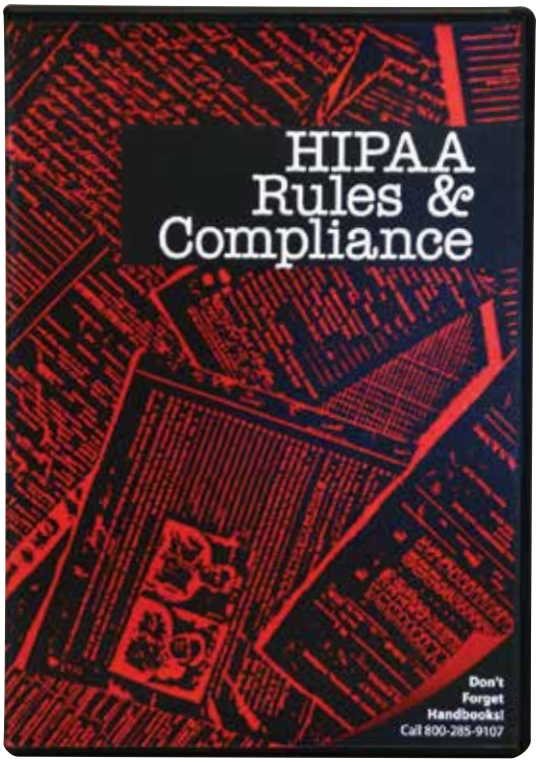
The Health Insurance Portability and Accountability Act (HIPAA) has undergone several modifications since its enactment in 1996, from the Genetic Information Nondiscrimination Act (2010) to the HITECH Act. Recently, the Department of Health and Human Services issued the HIPAA Omnibus Rule to revise,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



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by Linda L. Vila, JD, CHC

Live compliance education and training: Five essential components

» Live compliance training can be more effective than computerized training, if key imperatives are met.
» A highly seasoned and exceptionally skilled instructor is the key to sustainable, live compliance training.
» The relevance, importance, and necessity of training must be clearly articulated at the onset of the training.
» Global and topic-specific learning goals and objectives should be expressly stated, prior to and during the training, respectively.
» As time is often limited for training sessions, experiential learning modalities, although extremely effective, may be impractical to implement.

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With the growth in popularity of Internet-based healthcare compliance training, live training has been, to a considerable extent, cast aside as an outdated modality and replaced with computerized education. Although a technological approach does have its benefits, it does not possess the sustainable impact and notable outcomes that in-person training has on the workforce.


Vila

The advantages to computer-based compliance training include flexibility of scheduling, self-paced learning, easy record-keeping, consistent content, ability to train a large number of individuals in a short period of time, and the lack of necessity to train live instructors to provide the training.[1] Further, an online training system can readily track employee comprehension of the information presented, as well as update the content as laws, rules, and regulations change.[2] In most cases, modules are equipped with tools that measure participant understanding and ease of documentation; this is of significant value to healthcare organizations as the Office of the Inspector General calls for organizations to not only evidence that the workforce is trained, but that its members grasp the concepts presented.[3] Effective compliance education is a key component to an effective compliance program.[4]

Computerized compliance training, however, can be exceedingly expensive and, thus, prohibitive for organizations with limited resources. It can be problematic where members have limited access to computers, either at work or home, and the organization does not have the ability to provide access to computer terminals for everyone. In addition, not all individuals are computer literate and some may be intimidated by the notion, much less the action, of e-learning. Surprisingly, this is not an unusual occurrence. The electronic environment does not promote a high level of comfort for all users, and the lack of human interaction, coupled with the inability of workforce members to ask questions or initiate discussions and obtain instant responses and feedback to issues raised, can be detrimental to the pedagogical process.

Key components

A live compliance education and training program, structured and developed properly for intended audiences can have a tremendous, positive influence on an organization's compliance program as well as its culture. The live presentation approach can be effected in various ways but, to realize benefits far greater than those which online training can produce, it must encompass five key components, several of which incorporate concepts of adult learning theories.

The instructor

The first and most pivotal component is an experienced and skilled instructor. The instructor must be viewed as a credible and trustworthy source and possess the requisite credentials, qualifications, and knowledge worthy of attention. Although a background in healthcare compliance is helpful, a background as a healthcare professional, either from within the organization or as an external consultant, is essential, and the ability to deliver the training material with fluency from familiarity and with authority is key. A healthcare lawyer with compliance expertise fills these shoes quite well. The instructor should be well-versed in using case studies as a vehicle for connecting the discipline-based knowledge with practical situations; this derivative of storytelling is an effective tool for adult learners.[5] A superior training experience will be provided by an instructor who is enthusiastic about the educational material, engaging with the workforce members, and approachable.

Relevant information

Second, it is essential that the instructor begin each training session by explaining and emphasizing the relevance, importance, and necessity of the information that will be presented. A key imperative for workforce members is to know the "why" behind the "what" they are being asked to learn, and subsequently practice, so making a strong case in this regard is critical to prepare learners. Failing to create this learning nexus can hinder an individual's receptiveness and appreciation for the material and result in an indifferent "So what?" which will derail the training from the start.[6]

Goals and objectives

Third, the instructor must present clearly defined learning goals and objectives that not only address the big picture of the training but the specific topics that are presented throughout the training. Learners are always interested in knowing exactly what must be absorbed and where the presentation must capture their complete attention and engagement; thus, spelling out the tenets that are most important or identifying the material that is especially essential is both valuable and effective. Articulated learning objectives, both global and narrow, also help keep the instructor on message and move the learning experience to its stated purpose.

Experience

The fourth element to an unmatched, live educational encounter is to use the experiences of the workforce trainees during the training, because some of the richest resources for learning reside in the trainees themselves. The instructor should tap into this treasure trove of knowledge through the use of experiential techniques: group discussions, simulation exercises, and problem-solving activities which correlate the trainees' experiences with the information being presented. Workforce members who are active participants in learning absorb, understand, and remember information better than passive participants.[7] It must be noted that while an experiential teaching methodology is extremely beneficial, it has its downside: It is enormously time-consuming to execute. Training sessions must be scheduled

for a finite period of time so that organization operations are not significantly disrupted and departments are not deprived of their workforce members indefinitely. Opening the door to substantial trainee participation can result in sessions running way too long, a backlogging of sessions (if training is scheduled back to back), a loss in momentum of the session, and loss of trainees' attention. If this approach is used, the instructor must be extraordinarily well-versed in its execution.

Evaluation

Last, evaluating the effectiveness of the education should be performed throughout each training session, as opposed to at the end of the session or days after the session was delivered. Interspersing test questions after material has been presented allows for trainees to gauge whether they understood the concepts put forth and, most importantly, ask questions if they did not. Failure to provide the correct answer to a question posed can promote misunderstanding or confusion of an issue that is paramount to fostering a compliant and lawful organization.

Conclusion

There are many aspects and considerations to live compliance training which may indeed be challenging to undertake, particularly obtaining an excellent instructor and scheduling, coordinating, and tracking education sessions and attendant workforce members, respectively, in a large healthcare organization. These logistical issues, however, are minimal compared to the camaraderie that develops and a sustainable culture of cooperation that results from individuals who experience the training process together as they strive to conduct business with the highest legal and ethical standards.

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2. Donnetta Horseman: "Compliance training enhances N.C. health system." *Health Management Technology,* 2013; vol.34. no.4, pp. 16. Available at http://bit.ly/1DB49jS
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by Safa Ansari, JD and Lisa Shuman, MPA, CHC

Effective auditing and monitoring for small group physician practices

» Implement proactive auditing and monitoring measures to decrease vulnerability to fraud and abuse.
» Assign responsibility for auditing and monitoring functions to one or more employees.
» Integrate monitoring activities into daily operations of management and staff.
» Develop a consistent and ongoing method for auditing and monitoring.
» Conduct periodic internal or external compliance program audits.

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Gravely ill patients seeking urgent medical attention have often missed repeated opportunities to engage in preventative care—care that could have put them on a path towards health instead of illness. Likewise, in today's regulatory climate, implementing a compliance program can be like practicing preventative medicine for small group physician practices. Proactively ensuring compliance program effectiveness by employing auditing and monitoring mechanisms will lead to a much healthier small group physician practice in comparison to one that functions only reactively to detected compliance violations after the fact.

Small group physician practices must engage in preventative compliance measures especially since they, like many other healthcare providers, may eventually have to demonstrate their compliance activities to the Centers for Medicare & Medicaid Services (CMS) as a condition of participation in federally funded programs. The Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010. Section 6410 of the PPACA mandates compliance programs for all healthcare providers that participate in federal healthcare programs. Section 6401 of PPACA also mandates that CMS define the core elements of this required compliance program.[1] However, to date, CMS has not issued the pertinent regulations. In the absence of regulatory requirements, small group physician practices may look to the U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG) Compliance Program for Individual and Small Group Physician Practices.[2] This voluntary OIG compliance guidance is the current framework by which small group physician practices can comply with Section 6401 of PPACA to institute and enforce an effective compliance program.


Ansari


Shuman

Benefits of auditing and monitoring

Internal auditing and monitoring is an essential component of a compliance program. Physician practices of all sizes may gain various benefits by

implementing auditing and monitoring compliance measures. The OIG guidance states that all healthcare providers have a "duty to reasonably ensure" that claims submitted to Medicare and other federal healthcare programs are truthful and accurate. Employing auditing and monitoring measures ensures proper payment of claims and guards against violations of federal laws that govern physician self-referrals and impermissible kickbacks. Auditing and monitoring can also increase documentation accuracy by encouraging a culture of compliance within the practice. This commitment to accurate documentation and to compliance, generally, will enhance patient care, minimize billing mistakes, help streamline business operations, reduce audit risk by the OIG or CMS, and help the practice avoid entering into a corporate integrity agreement (CIA) with the OIG. Furthermore, implementing consistent auditing and monitoring practices can evidence good faith efforts toward implementation of an effective compliance program, if an investigation occurs. Proactive auditing and monitoring can help lower fines, penalties, and additional expenses in case of a settlement and/or CIA.

Many small group physician practices have not yet implemented auditing and monitoring compliance measures, despite the many benefits. This tends to be due to the various difficulties small group physician practices face in developing and maintaining an effect compliance program. For example, small physician practices often have limited financial and personnel resources, and this is coupled with demanding time constraints, or even limited compliance knowledge and experience. These factors can and should be taken into consideration when developing the compliance program, including a practice's auditing and monitoring measures. The OIG voluntary guidance states that there is no "one size fits all" compliance program for all small group practices, and that each practice should develop an individualized program based on the practice's needs and resources.

Small physician practices should ask themselves various questions when developing an effective auditing and monitoring program:

1. How can the practice assess its risk areas for non-compliance?
2. Does the practice have a tight budget that does not allow for yearly independent auditing by experts to assess risk areas and ongoing monitoring efforts?
3. Is there an accountable individual within the practice structure who is tasked with effectively managing auditing and monitoring efforts?
4. Can the practice afford to hire staff or compensate existing employees to oversee compliance program implementation and/or ongoing internal monitoring tasks?
5. Are there mechanisms to document potential compliance violations and to take corrective action in response to auditing and monitoring findings?

The OIG guidance notes that an audit is an excellent method by which a physician practice can identify problem areas and focus on the specific risks related to those issues. The guidance notes two types of audit reviews to evaluate problem areas: (1) a standards and procedures review; and (2) a claims submissions review. First, practices should review standards and procedures to ensure they are effective and align with current government regulations. Second, practices should review bills and medical records for compliance with applicable coding, billing, and documentation requirements. The physician practice can decide whether to review claims retrospectively as an audit or concurrently with the claims submission as a monitoring effort. A claims submission review will identify areas within the claims development and submission process that may fall out of compliance, or necessitate further education and training (see Table 1).

Table 1: Monitoring High Risk Areas

Claims Development and Submissions	Assessment Questions
Coding and Billing	**Does the practice:** ▶ Employ or have access to a certified coder who is responsible for reviewing claims? ▶ Maintain written and current policies and procedures for conducting claims reviews?
Medical Necessity/ Documentation	**Does the practice:** ▶ Have adequate processes to review medical records for medical necessity and proper documentation? ▶ Ensure physician orders are completed correctly? (e.g., signed and dated within the appropriate timeframe)
Denials	**Does the practice:** ▶ Maintain current standards and procedures for handling denials? ▶ Maintain a log of all current and past denials? ▶ Have a process to analyze denials to determine common patterns?
Credit Balances/ Refunds	**Does the practice:** ▶ Maintain current standards and procedures for handling credit balances? ▶ Assign an individual(s) the responsibility of tracking and handling credit balances? ▶ Maintain a refund and/or disclosure procedure to correct overpayments to ensure identified overpayments are repaid within 60 days?
Record Retention	**Does the practice:** ▶ Maintain current standards and procedures regarding the creation, distribution, retention, and destruction of documents? ▶ Retain key compliance documents? (e.g., educational activities, internal investigations and intern audit results) ▶ Secure medical records against loss, destruction, unauthorized access or reproduction, corruption, or damage?

Baseline audits

Initially, practices can conduct a baseline audit to outline the operational standards of the practice and identify risk areas for non-compliance. As part of the baseline audit, the practice may interview employees about their daily processes and procedures in order to determine internal risks. Practices may also consider the OIG Work Plan and OIG Fraud Alerts to determine potential risk. In conducting a baseline audit, physician groups must determine the scope of the audit. The OIG recommends that physician practices review claims submitted and paid during the 3-month period following training and education. The OIG guidance notes that there is not a set formula as to how many medical records the practice should review, but states that a basic guide is five or more records per federal payer, or five to ten medical records per physician. In addition to serving as a starting point for compliance program efforts, a baseline audit can also serve as a benchmark for future audits, allowing the practice to evidence compliance efforts by showing increases or decreases in denial rates, error rates, overpayments, etc.

The compliance officer or compliance professional should be involved in conducting the baseline audit. Small physician practices may face resource constraints that make it unfeasible to

Table 2: Internal Auditing of the Compliance Program

Compliance Element	Assessment Questions
Auditing and Monitoring	**Does the practice:** ▶ Have procedures for auditing and monitoring? ▶ Assign responsibility for auditing and monitoring? ▶ Monitor high-risk areas? ▶ Conduct periodic (at least yearly) claims review audits and compliance program audits?
Policies and Procedures	**Does the practice:** ▶ Maintain a Code of Conduct? ▶ Disseminate the Code of Conduct to all employees? ▶ Require employees to sign an attestation that they have received, read, and understand the Code of Conduct? ▶ Maintain a core set of policies and procedures? (e.g., non-retaliation, sanction screening, education and training, etc.) ▶ Have a process to monitor that all policies and procedures are current and complete, approved by the appropriate compliance personnel/committee, consistently formatted, and contain correct effective and revision dates?
Compliance officer/ Compliance professional	**Does the practice:** ▶ Assign a compliance officer or compliance professional(s) with written job description to oversee the compliance program.
Training and Education	**Does the practice:** ▶ Conduct one hour of general compliance training on the operation and importance of the compliance program, the repercussions for violating standards and procedures, and other key risk areas upon hire, and annually thereafter? ▶ Conduct specialized training? (e.g., billing, marketing, etc.) ▶ Maintain a record of employees who have completed the trainings?
Responding to detected offenses	**Does the practice:** ▶ Have a process to investigate detected violations? ▶ Track investigations to completion? ▶ Have a process for developing corrective action plans? ▶ Have a process for refunding overpayments that is in compliance with current federal regulations?
Open lines of communication	**Does the practice:** ▶ Have an open door policy? ▶ Have a method to report compliance concerns anonymously? (e.g., hotline or drop box) ▶ Have a process for following through on all complaints to resolution? ▶ Maintain a tracking log of all compliance complaints received and the investigation?
Enforcement/ Sanction screening	**Does the practice:** ▶ Screen all employees and contractors prior to hire, on a periodic basis, and at least quarterly thereafter against the OIG List of Excluded Individuals/Entities, the General Services Administration's System for Award Management sanction list, and state exclusion lists?

task a single individual with the management of all compliance functions. In this situation, the practice may designate more than one employee with auditing and monitoring responsibility. Operational managers or a practice administrator (depending on practice size) should be responsible for ongoing monitoring activities in their department or job function. For example, the billing manager can be responsible for monitoring claims development and submissions.

Ongoing monitoring

Table 1 provides a basic framework by which small group physician practices may begin to assess and monitor high-risk areas pertinent to their practice. It serves as a template that can be expanded.

Additional high-risk areas that can be included in this table are the Anti-Kickback Statute, Stark Law, conflict of interest, marketing, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In addition to monitoring high-risk areas, practices should monitor elements of the compliance program, such as compliance-related complaints, hotline calls, monthly or quarterly sanction screening, and policies and procedures. Managers are responsible for ongoing monitoring, and the compliance officer or compliance professional is responsible for overseeing monitoring activities. Auditing and monitoring reports should also be communicated to the compliance officer, the executive compliance committee, and/or the board, if applicable to the practice.

Auditing

In addition to a baseline audit and ongoing monitoring efforts, small group physician practices would be wise to consider a yearly claims review audit. Although internal monitoring of high-risk areas serves as an important step towards maintaining a compliant practice, it is vital that the practice's claims development and submission processes are independently audited for accuracy and effectiveness.

Further, practices can also consider periodic (at least yearly) compliance program audits. Periodic external audits serve an as independent evaluation of the practice's compliance program structure, effectiveness, and risk areas and can provide a fresh perspective. The practice may also conduct a yearly internal audit to assess compliance program efforts by reviewing all elements of the compliance program (see Table 2). From conducting internal or external audits, small physician practices can hope to gain insight into program shortcomings, vulnerabilities, and practice-specific risk areas. Small group physician practices can use this insight to develop a tailored corrective action plan aimed at remedying cited violations and program vulnerabilities.

Furthermore, audit insight will allow further fine–tuning of the compliance program by refocusing its ongoing internal monitoring tasks and goals going forward. These steps will not only strengthen the compliance program substantially but will also demonstrate a good faith effort towards implementing an *effective* compliance program. Documentary evidence of such efforts is critical if an external investigation by the OIG or CMS ever occurs.

Conclusion

Auditing and monitoring is an essential part of a compliance program for all physician practices. A baseline audit, ongoing monitoring efforts, a yearly external claims review audit, and a yearly internal or external compliance program audit will improve the efficiency and quality of services and decrease vulnerability to fraud and abuse. By starting with the systematic and preventative action steps outlined above, small group physician practices can develop a healthy and strong compliance culture that will defend against potential legal pitfalls.

1. The Patient Protection and Affordable Care Act, Public Law 111-148, 124 Stat. 127 (2010). Available at http://bit.ly/1MFijiw
2. Department of Health and Human Services Office of Inspector General: Compliance Program for Individual and Small Group Physician Practices: Notice. 65 Fed. Reg. 194, 59434-59452 (Oct. 5, 2000). Available at http://1.usa.gov/1np3hDY

by Cindy Hart, LPN, CPA, CGMA, CPC, CHC; Walter E. Johnson, MSA, CHC, CRCMP; Adam K. Weinstein, FACHE; and Frank Ruelas

Compliance 101

The seven essential elements, Part 4: Auditing & Monitoring

» Aligning your risk areas with the OIG's focus areas helps your organization to prove adherence to regulations.
» OIG has developed a series of voluntary compliance program guidance documents.
» The single biggest risk area for hospitals is the preparation and submission of claims.
» Functions common to all healthcare organizations should be monitored for compliance.
» Auditing and monitoring may identify risk areas that prompt discussions between the Compliance department and legal counsel.

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Now that you are getting settled and more comfortable in your role as the compliance officer (CO), it is time to develop an audit plan and begin monitoring the processes you have put in place to mitigate risk. The Work Plan published by the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) is a good place to start when developing your audit plan. Aligning your risk areas with the OIG's focus areas helps your organization to prove adherence to regulations. In addition, you should review program guidance documents for your specific segment of healthcare.


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The OIG has developed a series of voluntary compliance program guidance (CPG) documents directed at various segments of the healthcare industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.[1] The CPG supplement offers a set of guidelines that providers are encouraged to consider when developing and implementing a new compliance program or evaluating an existing one.

Perhaps the single biggest risk area for hospitals is the preparation and submission of claims or other requests for payment from the federal healthcare programs.[2] Effective auditing and monitoring plans will help hospitals avoid the submission of incorrect claims to federal healthcare program payers. Hospitals should develop detailed annual audit plans designed to minimize the risks associated with improper claims and billing practices. As described in the Federal Register (Vol. 70, No. 19, January 31, 2005), some factors hospitals may wish to consider in developing their audit plans include the following:

- Annual re-evaluation of the audit plan to address areas of concern identified through the findings from previous years' audits, risk areas identified as part of the annual risk assessment, and high-volume services;
- Assessment of billing systems and claims accuracy to identify root causes of billing errors;
- Clearly established roles for auditors, and assurance that coding and audit personnel are independent and qualified with requisite certifications;
- Ability of Audit department to conduct unscheduled reviews;
- Mechanism that allows the Compliance department to request additional audits or monitoring if the need arises;
- Evaluation of error rates identified in annual audits;
- Additional investigation into other aspects of the hospital compliance program to determine hidden weaknesses and deficiencies when error rates do not decrease; and
- Review of all billing documentation, including clinical documentation in support of the claim.

The OIG states: "The best evidence that a provider's compliance program is operating effectively occurs when the provider, through its compliance program, identifies problematic conduct, takes appropriate steps to remedy the conduct and prevent it from recurring, and makes a full and timely disclosure of the misconduct to appropriate authorities." To identify the problem areas, use of internal and external audits is the key. A good compliance plan that uses both internal and external auditors shows your facility's desire to operate within the guidelines.[3] The OIG strongly recommends that a hospital conducts an external compliance effectiveness review of its compliance program at least every three years.[4]

Common audits and methods

Certain functions common to all healthcare organizations should be monitored for compliance, such as Stark violations; Anti-Kickback Statute; record retention; bad debts, credit balances, and cost reports; marketing; background checks and excluded individuals; security breaches; Health Insurance Portability and Accountability Act (HIPAA) violations; and claim submissions.

Stark and Anti-Kickback audits

Your organization should have a policy that explicitly prohibits remuneration for referrals and requires disclosure of financial conflicts. Your compliance team should periodically conduct audits to ensure this policy is followed. During your annual compliance training, ask about referrals and conflicts. Each year, all employees should read the policy and sign a statement signifying their understanding and compliance. The CO should use the questioning method to elicit responses and make a determination of risk. Develop a question set and meet with individual physicians and other employees to review the questions. A good tool to use during an

audit is a conflict-of-interest questionnaire. The CO may elect to use a confidential survey to promote honesty. It is also important to include patients in your audit. Ask patients about their experience, their referral source, and if they felt compelled to see a particular physician or patronize a certain facility.

Record retention, background checks, excluded individuals audits

Record retention and destruction laws vary by state. The CO should be aware of the laws for each state in which your organization operates. Read all sections pertaining to retention and destruction, paying close attention to differences for minors and types of records. Some states suggest destruction every 10 years, except for pathology reports which must be kept in perpetuity. The compliance team should periodically audit for compliance by randomly selecting cases that are approaching and beyond the destruction date. Very old records may not have been converted to electronic media and may actually be in storage at a separate location. Visit the location to determine safety from fire, water, and vandalism.

Record retention and destruction laws vary by state. The CO should be aware of the laws for each state in which your organization operates.

Background checks and checks for excluded individuals should be conducted at least yearly. Many large organizations contract with a vendor who conducts monthly background checks. Continuous monitoring enables your organization to become aware of changes in a timely manner and address the issue immediately. Background checks should be conducted on all new hires, all employees who come in contact with patients, Accounting and Finance personnel, Human Resources personnel, vendors, contractors, and volunteers. In addition, employees who are promoted should have a background check completed. A check for excluded individuals is conducted for physicians, non-physician providers, referring physicians, and vendors. Although background and excluded-individuals checks are time-consuming and tedious, some smaller organizations prefer to perform the checks internally to eliminate the expense of a vendor. The audit method typically used is investigation via database searches.

Bad debts, credit balances, cost report audits

Financial audits are conducted by external accounting firms that attest to management's assertions regarding bad debts, credit balances, and cost report data. Your role as CO may require you to review the financial audit report, participate in the exit meeting with Finance and the accounting firm, and report to the executive compliance committee or the board of directors. The chief financial officer (CFO) is typically responsible for reporting the board. However, the CO should be aware of any qualified reports, notes to the financial statements, and/or excessive journal entries, and recommended corrective actions.

Marketing, security breaches, HIPAA audits

Marketing is another business function that requires auditing. Although an organization's primary focus is to ensure marketing materials capture the attention of the target audience, there are potential risks when marketing materials do not meet regulatory standards. It is essential for organizations to obtain

compliance guidance for marketing functions. As CO, establishing and auditing internal controls for marketing processes helps to reduce risk. Marketing products such as websites, brochures, posters, and other customer-facing materials are subject to audit. Each product may include verbiage that requires editing as regulations change. Regulatory requirements can vary from broad to specific verbiage and include specific font type/sizes. Participating in the development process will help the CO to determine the type and frequency of marketing audits.

Similarly, auditing and monitoring are vital when assessing compliance in areas where non-compliance can have devastating effects. One such example is protecting the privacy and security of patient information. Organizations have invested significant resources to set up effective compliance programs. Some organizations fail to meet HIPAA guidelines. This can be avoided by implementing auditing and monitoring to assess workforce performance in activities that directly contribute to HIPAA compliance. Consequently, if processes are not monitored and work performance is not audited, the organization cannot assess its workforce, thereby exposing the organization to risks.

There are areas within an organization where auditing and monitoring should be considered integral to policy and procedure implementation. The associated training and education should be codified in the policy and procedure.

Claim submission or bill audits

Once you determine what areas to audit, decide whether you will conduct a retrospective or a concurrent audit. You, as the CO, should determine which method is best for your organization and be prepared to explain your rationale to your executive team and board of directors. A retrospective audit is conducted on claims that have already been submitted to payers for reimbursement and often have already been paid. If you use the retrospective audit method, be aware that your organization is required to report errors and refund overpayments to the government. Therefore, the retrospective audit is not the preferred method.

A concurrent audit is conducted prior to claim submission. Therefore, corrections can be made before the claims are submitted, providing a greater level of confidence in the accuracy of claims. The challenge with the concurrent audit method is the need to "hold the bill" until the service has been audited and approved, thereby delaying revenue.

Regardless of the method you employ, if you discover serious infractions (e.g., fraud, abuse, waste, negligence, disregard, misconduct), you should immediately notify your legal counsel, who will make the determination whether to proceed under attorney-client privilege and will properly notify your fiscal intermediary. A CO who holds a law degree should not assume the role of legal counsel for the organization. Rather, remain within the scope of your position and enlist counsel for legal matters.

Other audits

Another area that you may deem necessary for audit is eligibility for healthcare benefits. Select a sample of employees and review their dependents listed on the policy for current eligibility. Employees are not always aware that changes are required in the event of divorce, death of dependent, or when dependents reach 26 years of age. Your insurance carrier may restrict coverage for step-children in the event of a second divorce.

Audits for phantom employees may be needed. Although challenging, it may be prudent for an organization to conduct an audit every couple of years to reduce the risk of phantom employees. One method is to have

every employee pick up their payroll check for a certain pay period at a specific location. Direct deposit makes this method a bit more difficult. However, work with department heads to put a hold on direct deposits for that pay period.

"How to" and auditing fundamentals

Once the decision to conduct an audit is made, the next challenge is to determine the parameters that will be used to design the sample size. A sample is used when the universe (i.e., total size of the audit area) is large. The size of the audit depends on your decision to perform a statistically valid sample or not. Statistically valid samples are based on a percentage and depict a true representation of your organization's activities. Statistically valid samples require results to be extrapolated across your universe, and refunds are made to payers based on the extrapolated amount. Internal audits are usually random, but not statistically valid, with a pre-determined number of cases or records making up the sample size.

After the random sample is reviewed, generalities can be drawn based on the findings. A distinct upside to random sampling is that it generates very useful results without placing too much of an administrative burden on the auditors.

Consider three types of audits commonly referred to in OIG and Centers for Medicare and Medicaid Services (CMS) publications that help make auditing more efficient: probe audits, discovery audits, and full audits.

Probe audits

Probe audits are the smallest in terms of the number of elements that are reviewed. Probe audits generally involve sampling 20–40 elements. Probe audits are often conducted to determine if the findings may indicate the need for a more in-depth review. If the findings indicate a need to gather more information, the CO may decide to expand the audit if a process or procedure is not performing at an acceptable level.

Discovery audits

Discovery audits represent the next level, or more in-depth type of audits. Discovery audits typically use a sample size of 50 elements. It is important to note that when moving from a probe audit to a discovery audit, an entirely different sample must be randomly selected. For example, if a probe audit was done using 40 elements, a discovery audit would require selecting 50 new elements at random, not simply selecting 10 more elements to increase the sample size to 50. The reason for this is that sample sizes must be drawn so all elements have the same probability of being selected. This concept is known as equi-probability and is a very important principle when selecting samples.

Full audits

The most comprehensive type of audit involves the largest sample size. Often referred to as "full" audits, sample sizes are derived from mathematical formulas that take into account the confidence level desired and the associated confidence interval. Fortunately, publicly available software (such as RAT-STATS, a statistical software package available from the OIG) can assist practitioners in conducting these three types of audits.[5]

Evolve the auditing program

It is not uncommon to read articles that share a position stating auditing and monitoring may be the weakest element within a compliance program.[6] Too often, the new compliance professional discovers that auditing and monitoring has not occurred recently. To overcome this weakness, the new CO embarks on an aggressive approach, attempting to tackle all types of audits at once. Although ambitious, this approach can cause significant frustration. The CO should take a step back and review

the existing compliance program. Apply the KISS (Keep It Simple Sam) principle by using the existing program as a base and building out the audit process from there.

Start with an audit that is simple and meaningful. Identify one risk area that lends itself to a straightforward analysis. Use the results to recommend mitigating actions for risk reduction. As the CO gains audit experience, self-confidence increases, and he/she begins to feel more comfortable in the position. The CO can now move forward with more complex audit areas.

Auditing and monitoring program overview

Once established, it is essential to document the entire auditing and monitoring program for the organization. The written overview of the entire program must be easily accessible by the CO. This program overview differs from the dashboard regularly shared with senior leadership and presented to the board of directors. The dashboard serves as a snapshot of compliance activities. At a minimum, the auditing and monitoring program overview serves as a master document that should include the title of all auditing and monitoring activities, designated operational area, frequency, and sample size. The auditing and monitoring program overview document may include an appendix consisting of all the results for the previous 12 months. Sharing findings with operational leaders, prior to reporting to the compliance committee, is appropriate.

1. Office of Inspector General: Compliance Guidance. Available at http://1.usa.gov/18VuF7d
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3. Marcia Vaqar: "The Importance of Internal Audits." RMC Compliance Connections, vol. 2, issue 1, 1st Quarter 2011. Available at http://bit.ly/1wR8Jbe
4. Carla Wallace, Karen Voiles, Julie Dean: "Health Care Compliance Program Tips." *Quorum Health Resources*, Article No. 68, Mar. 3, 2011. Available at http://bit.ly/1umYeXB
5. Office of Inspector General: RAT-STATS-Statistical Software. Available at http://oig.hhs.gov/compliance/rat-stats
6. Dorfschmid, Cornelia M: "Billing monitoring: Weakest link or greatest strength?" *Compliance Today*, June 2014, vol. 6, issue 6, pp 33-39

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Hear from your peers

Shakeba DuBose, Esq., CHC, CHPC
Founding Member,
TDLF Healthcare Compliance Consulting Group,
Columbus, OH

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Takeaways

May 2015

Compliance TODAY

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The Two-Midnight Rule: Past, present, and future

Janice Anderson and Sara Iams (page 25)

- The Two-Midnight Rule, effective October 1, 2013, provides guidelines for making Medicare inpatient admission decisions.
- An inpatient admission is "generally appropriate" if the admitting practitioner expects the patient to require a stay that crosses at least two midnights and admits the patient based upon that expectation.
- The two-midnight benchmark and the two-midnight presumption are the medical review policies used by MACs and RACs to evaluate compliance.
- Compliance officers need to use lessons learned from the Probe & Educate audit period to prepare for RAC audits as of May 1, 2015.
- Compliance officers must stay abreast of changes to Two-Midnight Rule policies, including pending case law and proposed legislation, which may further delay enforcement of this controversial rule.

Keys to EMTALA compliance

Kim C. Stanger (page 29)

- Violations of EMTALA may result in significant fines and penalties for hospitals and physicians. Serious violations may result in termination of the hospital's Medicare provider agreement.
- EMTALA applies to all hospitals that participate in Medicare and their affiliated physicians; however, EMTALA requirements differ depending on the type of hospital.
- Understanding when EMTALA applies is crucial to avoiding fines and penalties.
- Hospitals that violate EMTALA are not generally required to report themselves, but they should take steps to mitigate their liability if a violation is discovered.
- A provider is unlikely to face a significant EMTALA penalty if it does what is best for the patient and documents its actions.

Drug diversion in healthcare facilities, Part 1: Identify and prevent

Erica Lindsay (page 35)

- Drug diversion is the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber.
- One out of 10 nurses may be dependent on controlled substances.
- Compliance has an important role on the multidisciplinary team when conducting a drug diversion investigation.
- Policies should be established within the Compliance department on how to handle drug diversion investigations and should be applied consistently.
- Being proactive through education, competencies, and anonymous reporting can lead to a dramatic decrease in drug diversion within your facility.

Recent corporate integrity agreements: Best practices for compliance

Wade Miller, Kimyatta McClary, and Amy Bailey (page 40)

- The compliance obligations outlined in corporate integrity agreements (CIAs) can give providers some insight as to what regulators view as best practices in the healthcare industry.
- The standard CIA negotiated by the OIG generally includes provisions pertaining to the seven elements of an effective compliance program.
- CIAs are also a resource as to what might be required of specific providers in particular industries or regarding certain compliance risks.
- A review of recent CIAs for industry best practices should be included in a provider's regular evaluation of its compliance program.
- Implementation and oversight of CIAs require significant personnel and financial resources.

Healthcare providers' False Claims Act self-disclosure "discount"

Winston Y. Chan and Emily C. Aldridge (page 53)

- The government has introduced incentives to healthcare providers that voluntarily disclose potential False Claims Act violations.
- It remains unclear whether there is any discernible financial "discount" to self-disclosing entities.
- Although the OIG states that self-disclosers may not face treble damages, it has not offered any indication of what multiplier it uses.
- The government generally does not impose certification of compliance agreements (CCAs) and corporate integrity agreements (CIAs) in self-disclosure cases.
- This alone may be a sufficient predictable benefit to warrant self-disclosure for healthcare providers.

Embedding financial compliance for clinical trials

Faye Hager (page 65)

- Financial compliance for clinical trials begins long before site initiation.
- Financial compliance affects multiple study documents.
- CMS provides several online resources related to research billing compliance.
- Subject Financial Tracking ensures the appropriate billing route is maintained.
- Systems may be hard-wired to support research billing compliance.

Compliance issues in telemedicine

Bill Wong and Tomi Hagan (page 70)

- Telemedicine is expected to experience continued growth in the healthcare industry.
- Compliance professionals should understand the complex regulatory requirements for the provision of telemedicine.
- The responsibilities of the distant and originating site should be clearly defined.
- Risks and pitfalls include reimbursement issues, fraud and abuse, credentialing and privileging, informed consent, continuity of care, and privacy/security.
- Compliance professionals should take a proactive approach in mitigating compliance risk by adhering to accepted standards.

Live compliance education and training: Five essential components

Linda L. Vila (page 75)

- Live compliance training can be more effective than computerized training, if key imperatives are met.
- A highly seasoned and exceptionally skilled instructor is the key to sustainable, live compliance training.
- The relevance, importance, and necessity of training must be clearly articulated at the onset of the training.
- Global and topic-specific learning goals and objectives should be expressly stated, prior to and during the training, respectively.
- As time is often limited for training sessions, experiential learning modalities, although extremely effective, may be impractical to implement.

Effective auditing and monitoring for small group physician practices

Safa Ansari and Lisa Shuman (page 79)

- Implement proactive auditing and monitoring measures to decrease vulnerability to fraud and abuse.
- Assign responsibility for auditing and monitoring functions to one or more employees.
- Integrate monitoring activities into daily operations of management and staff.
- Develop a consistent and ongoing method for auditing and monitoring.
- Conduct periodic internal or external compliance program audits.

Compliance 101: The seven essential elements, Part 4: Auditing & Monitoring

Cindy Hart, Walter E. Johnson, Adam K. Weinstein, and Frank Ruelas (page 84)

- Aligning your risk areas with the OIG's focus areas helps your organization to prove adherence to regulations.
- OIG has developed a series of voluntary compliance program guidance documents.
- The single biggest risk area for hospitals is the preparation and submission of claims.
- Functions common to all healthcare organizations should be monitored for compliance.
- Auditing and monitoring may identify risk areas that prompt discussions between the Compliance department and legal counsel.

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May 2015

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
26	27 WEB CONFERENCE *OCR HIPAA Audit Program 2015 and Beyond: What We Know So Far* **Basic Compliance Academy** Orlando, FL	28	29	30 **Regional Conference** San Juan, PR **CHC Exam**	1	2
3	4	5 WEB CONFERENCE *Transforming Your RAC Program: It Happens Through Centralization* Cinco De Mayo	6 WEB CONFERENCE *Security Incident Response: Spend a Little Now and Save a Lot Later*	7	8 **Regional Conference** Columbus, OH	9
10 Mother's Day	11	12	13 WEB CONFERENCE *The Role of HIPAA in Your Social Media Guidelines*	14 WEB CONFERENCE *Log Management as an Early Warning System: The Edge for Compliance*	15 **Regional Conference** New York, NY Isra and Mi'raj	16
17	18	19	20	21	22	23
24 Pentecost	25 Memorial Day	26	27	28	29	30
31 **Research Compliance Conference** Austin, TX	1	2	3 **CHC Exam**			

June 2015

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
31 **Research Compliance Conference** Austin, TX	1	2	3 **CHC Exam**	4	5 **Regional Conference** Philadelphia, PA	6
7	8 **Basic Compliance Academy** Scottsdale, AZ	9	10	11 **CHC Exam**	12 **Regional Conference** Seattle, WA	13
14	15 **Healthcare Privacy Basic Compliance Academy** Las Vegas, NV	16	17	18 **CHPC Exam** Ramadan Begins	19 **Regional Conference** Santa Ana, CA	20
21 First Day of Summer Father's Day	22	23	24	25	26	27
28	29	30	1	2	3	4

Dates and locations are subject to change.

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May 31–June 3 • Austin, TX

Clinical Practice Compliance Conference

October 11–13 • Philadelphia, PA

Healthcare Enforcement Compliance Institute

October 25–28 • Washington DC

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Sep 28–Oct 1 • Scottsdale, AZ

October 19–22 • Las Vegas, NV

October 26–29 • Nashville, TN

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Healthcare Privacy Basic Compliance Academies

June 15–18 • Las Vegas, NV

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