HCCA HEALTH CARE COMPLIANCE ASSOCIATION

# Compliance TODAY

September 2016

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

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## Culturally appropriate compliance in rural Alaska

**an interview with Michael Cruz**
**Director of Quality, Compliance and Privacy**
**Kenaitze Indian Tribe**
**Dena'ina Wellness Center**
**Kenai, Alaska**

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*Questions? jennifer.parrucci@corporatecompliance.org*

by Roy Snell, CHC, CCEP-F

# Tone in the trenches

*Please don't hesitate to call me about anything any time.*
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Is leadership solely responsible for tone? Shouldn't everyone have the proper tone when it comes to compliance and ethics? The latest catch phrase is, "Tone in the middle." It got me to thinking about tone. I am going to coin a new phrase, "Tone in the trenches." It may not catch on, but I need it for this article.

Snell

I have seen leadership blamed for pretty much everything bad that ever happens in a company. I see people putting all the responsibility on leadership. It's like open season on business leadership. The thought police will not allow us to discuss any alternative explanation for wrongdoing other than, "It's leaderships fault." I agree that leadership needs to own everything that goes on in a company. And leadership has to set the tone. But I just can't agree that it's always "only their fault," and they are the only ones who should have "tone."

Let me give you an example. Businesses have goals, quotas, and bonuses that reward the hardest workers. Not everyone who ever said, "I don't care what it takes, we are going to hit our goals," meant the people in the trenches should break the law. In fact, I believe most everyone who ever said that didn't intend to have people interpret it as, "Go break the law." But every time I see someone get caught doing something wrong, they blame someone else for their behavior or blame it on quotas, goals, bonuses, and leadership.

> I get frustrated every time someone "in the trenches" behaves unethically and gets to play the "blame leadership" card.

I get frustrated every time someone "in the trenches" behaves unethically and gets to play the "blame leadership" card. I think that we ought to have tone in the trenches. We should expect everyone to have the proper tone. We expect the mature people in the trenches to be examples for the younger people. We expect the company veterans in the trenches to be examples for the new employees. We should expect tone in the trenches. The more the thought police convince society that leadership is always the problem, the more problems we will have, because they are giving everyone an excuse. We need tone at the top, we need tone in the middle, and we need tone in the trenches or none of our efforts to fix ethical and regulatory problems is ever going to work.

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> "…if we had someone from the outside who gave us a templated compliance program and did not explain the reason why, we would still be at the starting line…"

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## ARTICLES




# Compliance TODAY





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VOLUME 18, ISSUE 9

# LexisNexis study shows cross-industry fraud is widespread and has substantial financial impact

Recently, LexisNexis® Risk Solutions announced the release of "its annual LexisNexis® Fraud Mitigation Study, indicating 84 percent of fraud mitigation professionals see cross-industry fraud in some of their cases and 76 percent of these cross-industry fraud cases have a moderate to high financial impact. The study of more than 800 fraud mitigation professionals reinforces that cross- or multi-industry fraud exists and confirms its significant effect across financial services, insurance, health care, retail, communications and government.

"Cross-industry fraud is defined by a fraud case where the perpetrator's activity touches multiple industries and organizations, habitually exploiting system gaps. For example, a fraudster might commit claims fraud against an auto insurer and also commit government benefits fraud or banking fraud."

According to the LexisNexis press release, "Almost half of companies responding spend more than $500,000 annually on fraud mitigation vendors, and over half of the professionals indicate that cross-industry fraud has extreme/high impact on their organizations. Over a quarter (29 percent) of fraud mitigation professionals see cross-industry fraud as having a larger impact than within-industry fraud, while nearly two-thirds (63 percent) see cross-industry fraud as creating at least an equal impact."

For more: *http://bit.ly/29MxyQ9*

# AT&T releases Cybersecurity Insights, Volume 3

AT&T has issued three Cybersecurity Insights, and the latest volume, "The CEO's Guide to Cyberbreach Response," provides information on what to do before, during, and after a cyberbreach. According to the report, "in 2015, 62% of organizations acknowledged they were breached, yet only 34% of organizations believe they have an effective incident response plan."

Complete report: *http://soc.att.com/2904KDb*

# DLA Piper's "Compliance & Risk Report" survey results

According to the DLA Piper's inaugural "Compliance & Risk Report" survey results, "81 percent of compliance officers have increased apprehension when it comes to their personal liability in situations of corporate misconduct."

The DLA Piper survey press release also noted, "The survey results demonstrate that the majority of CCOs are deeply concerned, especially those at private companies within the most heavily regulated industries, including financial services, healthcare and chemicals. Compounded with the fact that nearly a quarter of respondents don't believe they have adequate resources to address emerging issues, many are likely to experience acute anxiety in this shifting compliance landscape."

For more: *http://bit.ly/29Vwzs3*

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# Regulatory News

## OIG Issues nationwide analysis of common characteristics in OIG home health fraud cases

In June 2016, the Health and Human Services Office of Inspector General released a report on the common characteristics in OIG home health fraud cases. The analysis noted, "OIG home health investigations have resulted in more than 350 criminal and civil actions and $975 million in receivables for fiscal years (FYs) 2011–2015. Additionally, previous reports from OIG and the Government Accountability Office (GAO) have raised concerns about questionable billing patterns, compliance problems, and improper payments in home health."

According to the OIG analysis, "identified a substantial number of providers—over 500 HHAs and over 4,500 physicians—that were outliers in comparison to their peers nationally with respect to multiple characteristics commonly found in OIG-investigated cases of home health fraud. It is important to note that our analysis does not demonstrate that these providers were engaged in fraudulent activity. Our analysis also identified 27 geographic hotspots in 12 States—i.e., areas where characteristics commonly found in OIG home health fraud cases are prevalent. Many of these hotspots are areas already recognized as having high rates of Medicare fraud."

This OIG data brief is being released in tandem with an OIG Alert, which focuses on improper arrangements and conduct by HHAs and physicians.

Complete report:
*http://bit.ly/29Ws94M*

OIG Alert: Improper Arrangements and Conduct Involving Home Health Agencies and Physicians

For more:
*http://bit.ly/2add6p4*

## CMS issues final rule, makes enhancements to the Medicare Shared Savings Program to strengthen incentives for quality care

The Centers for Medicare & Medicaid Services (CMS) has released a final rule improving how Medicare pays Accountable Care Organizations in the Medicare Shared Savings Program for delivering better patient care. According to the CMS press release, "Medicare is moving away from paying for each service a physician provides towards a system that rewards physicians for coordinating with each other. Accountable Care Organizations are a major part of that transition, rewarding providers that deliver high-quality, efficient, and coordinated care for patients.

"Medicare bases Accountable Care Organizations' payments on a variety of factors, including whether the Accountable Care Organization can deliver high-quality care at a reasonable cost. The final rule should help more Accountable Care Organizations successfully participate in the Medicare Shared Savings Program by improving the shared savings payment methodology and providing a new participation option for certain Accountable Care Organizations to move to the more advanced tracks of the program."

For more:
*http://go.cms.gov/29Uso1C*

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# HCCA *conference news*

## Healthcare Enforcement Compliance Institute

**October 23–26, 2016 | Washington DC**

*www.hcca-info.org/heci*

HCCA is pleased to announce its second annual Healthcare Enforcement Compliance Institute coming to Washington DC on October 23–26, 2016.

Learn best and leading-edge practices for those involved in enforcement actions and regulatory compliance at the Healthcare Enforcement Compliance Institute. The education offered at the conference will go beyond legal analysis and address implementing compliance practices to manage enforcement and regulatory risk. You will be provided practical advice from enforcement and regulatory officials, attorneys, and compliance professionals in an interactive forum that facilitates greater collaboration between the Legal and Compliance teams. Confirmed speakers include those from U.S. Department of Justice, Office of Inspector General - HHS, FDA's Center for Drug Evaluation and Research, Center for Medicare and Medicaid Services, Office for Civil Rights, and the United States Congress.

The conference features a full day of pre-conference workshops on Sunday, two days of the main conference on Monday and Tuesday, and a half day of post conference sessions on Wednesday. The Certified in Healthcare Compliance (CHC)® exam will be offered on Wednesday.

Don't miss out on the following general sessions.

- ***Influencing Decision-Making 2.0: Moving the Meteor:*** Jenny O'Brien, Chief Compliance Officer, United Healthcare; Roy Snell, CEO, SCCE/HCCA.
- ***CMS Update:*** Jerry Mulcahy, Director Program Compliance and Oversight, Centers for Medicare & Medicaid Services.
- ***General Session:*** Andrew Weissmann, Chief, Fraud Section, Criminal Division, Department of Justice Enforcement.
- ***Compliance: Strategies for Organizational Counsel and Compliance Professionals:*** Gabe Imperato (Moderator), Managing Partner, Broad and Cassel; Lesley Skillen, Getnick & Getnick LLP; Nicholas E. Surmacz, U.S. Department of Justice, Criminal Division, Fraud Section; Richard Westling, Partner, Waller Lansden Dortch & Davis, LLP; Nancy Guller-Hayt, Corporate Responsibility Officer, Adventist Health Systems.

Be sure to make your plans early to take advantage of the early bird discount rate. And don't forget to book your room at the Capital Hilton while space remains.

See full agenda and learn more at *http://bit.ly/1VCWief*.

***Questions?***

***Email: jennifer.parrucci@corporatecompliance.org***

***Visit: www.hcca-info.org/heci***

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

# HCCA *website news*

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

## Top pages last month

Home Page | Job Board | My Account | Academies | National Conferences

Number of website visits last month

**64,246**

### Weekly e-newsletter

**Corporate Membership**

Are you enjoying your membership? Think others at your company would like to join, too? Consider getting a corporate membership. Corporate membership comes with four full memberships, plus some free advertising in a few of our publications, on our website, and at some of our events.

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### Video of the month

**Are companies providing compliance officers with unfiltered reporting to the board?**


See this video and more on board engagement at: *http://bit.ly/votm-ct-2016-09*



**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.*

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

Stop by The Compliance & Ethics Blog to check out discussions about hot topics and breaking news in Compliance & Ethics. Be sure to subscribe to have a daily digest emailed to your inbox. One recent post:

### How to Hire Honest People

By Bruce Weinstein, Ph.D.
The Ethics Guy®
Tweet @TheEthicsGuy

*The following is an excerpt from my book, The Good Ones: Ten Crucial Qualities of High-Character Employees.*

## Facebook — *www.facebook.com/hcca*

We're on Facebook, too! "Like" our page for healthcare compliance news and networking. One recent post:


## SlideShare — *www.slideshare.net/theHCCA*

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

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## Twitter — *www.twitter.com/theHCCA*

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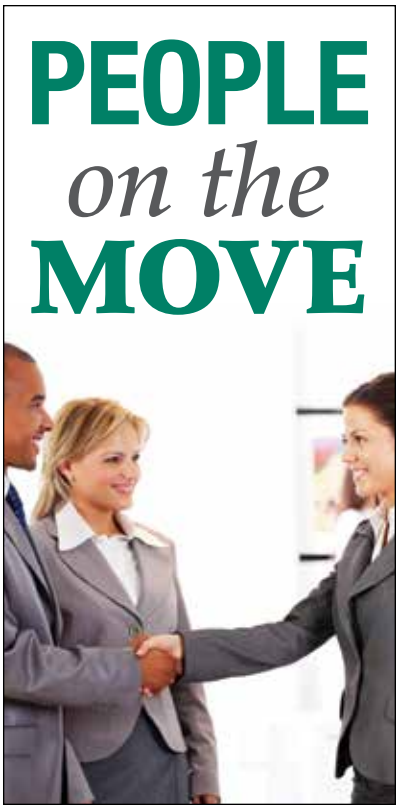


▶ **Eileen M. Coggins** was recently promoted to General Counsel and Senior Vice President, Long-Term Services and Supports/Medicare Solutions by AmeriHealth Caritas, Philadelphia. AmeriHealth Caritas also promoted **Mark T. Bullock** to Senior Vice President and Chief Administrative and Compliance Officer.

▶ **David B. Pearce** has joined Amedisys, Inc. in Baton Rouge as Senior Vice President and Chief Compliance Officer.

▶ **Deb Santos**, CPC, COC, CPMA, Certified Green Belt in Lean Six Sigma, has been named Manager Compliance and Coding for Baylor Scott & White Health in Temple, TX.

▶ **Katharine Roberson**, JD, has been named Manager Compliance for HealthTexas Provider Network, a premier practice management organization affiliated with Baylor Scott & White Health in Dallas.

▶ **Jessica Squeglia**, CHC, has been named the Corporate Compliance Manager for Meridian Health in Neptune, NJ.

▶ Diamond Healthcare Corporation in Richmond, VA, recently announced the appointment of **Rebekah M. Stewart** as Chief Ethics and Compliance Officer.

## Received a promotion? New staff member in your department?

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

## Authors Earn CEUs: CCB awards 2 CEUs to authors of articles published in *Compliance Today*

# *Compliance Today* needs you!

Every month *Compliance Today* offers healthcare compliance professionals information on a wide variety of enforcement, regulatory, legal, and compliance program development and management issues.

We are particularly interested in articles covering compliance concerns involving hospitals, outpatient services, behavioral health, rehab, physician practices, long-term care/homecare/hospice, ambulatory surgery centers, and more.

Articles are generally between 1,000–2,500 words (not a limit). Submit your article as a Word document with limited formatting. The article title and author's contact information must be included in the article.


**Email your topic ideas, format questions, and more to *CT* Story Editor Margaret Dragon: margaret.dragon@corporatecompliance.org**

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**Michael Cruz,**
**Director of Quality, Compliance and Privacy**
**Kenaitze Indian Tribe**
**Dena'ina Wellness Center**
**Kenai, Alaska**

an interview by Debbie Troklus, CHRC, CHC-F, CCEP-F, CHPC, CCEP-I

# Meet Michael Cruz

*This interview with **Michael Cruz** (MCruz@kenaitze.org) was conducted in June by **Debbie Troklus** (dtroklus@aegis-compliance.com) Managing Director at Aegis Compliance and Ethics Center in Louisville, KY.*

**DT:** Tell me about the Dena'ina Wellness Center.

**MC:** The Dena'ina Wellness Center is a fully integrated medical facility offering a holistic approach to care. Our customers, who we call un'ina ("those who come to us"), receive access to all our services beneath one roof. This includes medical, dental, behavioral health, chemical dependency, wellness, physical therapy, pharmacy support, and traditional healing. The building also features a gym, classroom space, and wellness kitchen. Alaska Native and American Indian people have access to all programs, while programs that receive state funding – primarily behavioral health – are open to the entire community.

**DT:** Mike, tell me a little about your background.

**MC:** I have worked within the Alaska tribal health system for the last 14 years in many different capacities. I started out as a project manager, Business Office manager overseeing the Billing/Accounts Receivable, and then as a Behavioral Health administrator. My current position with Kenaitze Indian Tribe is the Director of Quality, Compliance and Privacy for Dena'ina Wellness Center. Prior to working in the healthcare industry, I managed a lodge in Katmai National Park called Brooks Lodge. Duties not only included managing the day-to-day operation of the

lodge, but also working with the National Park Service to make sure we were meeting our contractual obligation as a contractor.

**DT:** What made you interested in the field of Compliance?

**MC:** Working in the healthcare field, I was always exposed to it as an employee on an annual basis. My interaction with a compliance officer really stepped up when I was working as the business manager for another tribal health organization. I was always being pulled into meetings and asked to explain the workings of our electronic health record billing module. Then came our annual internal audits and pulling billing data for review. That was really my first bit of working closely with a compliance officer and understanding more in depth of the role of the compliance program. Although I had a small portion to contribute to the compliance officer or specialist role from my previous work, it was not until after an accreditation survey that I was asked to pull a group together to identify components of a compliance program and evaluate our current status to meeting the standards of a compliance program for Dena'ina Wellness Center. I started to learn more in depth of the different components of a compliance plan and, at the same time, building relationships with our internal stakeholders. I started to get a feeling from staff that we were moving forward towards a full development of a compliance program with a person overseeing the day-to-day activity.

**DT:** What steps did you take to prepare for the role of compliance officer?

**MC:** The first step was to reach out to local compliance officers, specifically ones working within a tribal organization. I wanted to understand from a tribal facility the setup structurally of a compliance officer and role. Second, was my membership with HCCA and accessing resources and the listserv to help understand the role of a compliance officer. Third, was to poll internal key stakeholders who were already doing some part of a compliance program, talking to them on what they believe a compliance program would look like in two to three years.

**DT:** Since you work in a small organization, do you hold other roles? If so, which ones?

**MC:** Yes. Originally, I was hired on as the Quality Systems Manager for the Dena'ina Wellness Center. As I worked with the health system programs for improvement projects, my role started to expand into the Compliance and Privacy Officer.

**DT:** When did you begin implementing a compliance program?

**MC:** The need was identified early on, during our initial readiness for CARF accreditation in 2014. It was not until after our survey that we put together a fully functional compliance workgroup to work towards a functional compliance program.

**DT:** Who in the organization do you report to?

**MC:** I currently report to our director of operations, but have a dotted line to our executive director and governing Tribal Council members. Our executive director has been designated to oversee matters related to our compliance program by our governing Tribal Council, and I have day-to-day operations of the compliance program.

**DT:** How has the Tribal Council been instrumental in supporting compliance?

**MC:** Our Tribal Council members have always been committed in doing the right thing, at the same time assuring we are

following culturally appropriate principles. Tribal Council commitment to the in-house training on governance responsibility and the general compliance program training were key factors of them being supportive of a compliance program. Shortly after the training, all members of our Tribal Council and our executive director attended the annual HCCA Alaska Regional Conference in Anchorage. They wanted to stay informed of local issues from other organizations and stay current with the ever-changing landscape in the healthcare compliance program.

**DT:** For those that are not from Indian Health, could you explain the role of Tribal Council in the organization?

**MC:** In accordance with our constitution, by-laws, ordinances, and resolutions, the Kenaitze Indian Tribe is governed by a seven-member Executive Council. Council members are elected by voting tribal members at an annual meeting every October, and they serve staggered terms. The Council appoints an executive director to manage the tribe's day-to-day operations and a chief judge to oversee Tribal Court and uphold tribal laws. It consists of a chairperson, vice chairperson, secretary, treasurer, and three general members.

**DT:** I noticed you talk about "Just Culture." Please explain what that means.

**MC:** "Just Culture" is the necessity of an effective compliance program. "Just Culture" for Dena'ina Wellness Center starts with our Tribal Council and executive leadership team committed to supporting a compliance program, and actively seeking out risks to manage before they cause harm. Staff feel comfortable reporting mistakes and finding solutions to continuously improve. We focus on improving our systems, rather than blaming individuals.

**DT:** In rural Alaska, what do you see as your biggest compliance risk areas?

**MC:** I would say our biggest compliance risk is the Privacy and Security Rule. We have worked hard to build the trust of our tribal members and not only educate/train our staff, but also explain to our patients the reason why we are limited on releasing information.

**DT:** What has been your biggest challenge in implementing your compliance program?

**MC:** Our biggest challenge is not trying to do too much, too soon. During the compliance training, everyone's awareness is up, so issues will come up around compliance. We have to stop and take our time working through the issue in a fair and consistent manner. So, our compliance program has had to do a stop and go, but we remain steady to the work plan of a mature compliance program.

**DT:** What advice do you have for new compliance professionals in small organizations?

**MC:** Build relationships, own the program, work with your workgroup on input and design of the compliance program, and take the time to help folks understand why a compliance program is essential. Develop a realistic timeline for creating a compliance program. Don't try to hit the grand slam right out the box; work your way around the bases and enjoy different stops. I believe if we had someone from the outside who gave us a templated compliance program and did not explain the reason why, we would still be at the starting line, getting folks on the same playing field.

**DT:** Now for the fun stuff, I hear fishing is great in Alaska. Are you a fisherman?

**MC:** Absolutely, I have to be careful to balance my love for fishing vs. family time. My children, who are 11 and 9, are at that age where I can take them out and they can fish

and have the same joy I get when fishing. Fishing for our family is a way we can gather as a family, share with others, and really appreciate the outdoor beauty Alaska has to offer. I'm truly blessed to have the ability to work and play on the Kenai Peninsula of Alaska and enjoy the tremendous opportunity for fishing, either in the river or out on the ocean.

**DT:** Thank you, Michael for sharing your experiences with us.

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Wolters Kluwer

by Catherine Boerner, JD, CHC

# Are you doing too much?

***Catherine Boerner*** *(cboerner@boernerconsultingllc.com) is President at Boerner Consulting, LLC located in New Berlin, WI.* /in/catherineboerner

Let's start with not just tone at the top, but also tone of the compliance officer. The hardest discipline of the job may just be in slowing down! Until you have a mature compliance culture, compliance officers need to be very careful not to do too much, too fast. Setting the wrong tone could undermine the effectiveness of the compliance program.

Boerner

Remember, you know a lot about the compliance world that others do not. You are in this world 24/7 and constantly learning and becoming aware of compliance risks. You are keeping up with enforcement efforts and engaging in continuing compliance education. Others do not constantly operate and see the organization through the same lens as you do. To be effective, this requires you to understand the perspectives of executives, directors, managers, and employees and take the time to figure out what is the best way for you to present information to them. What truly is the most effective way to train them regarding the compliance program and/or compliance risks? What do they need to hear that will help them understand the value of the compliance program and how it works? I know some of you have a mature compliance culture and this is no longer a challenge, but for others, this may just be the key to getting buy in.

There are certain phrases that may assist you as you navigate through your organization and interact with various departments. Some of these phrases and questions are:

- "Help me understand."
- "What are your thoughts?"
- "This is what I know about this risk that we are trying to prevent. Can you explain this to me? How well do you think this risk is controlled in this organization?"
- "Can we get a few people in a room and discuss the concern(s) I have and my thoughts about potentially fixing it?"
- "I am interested in learning your thoughts on how to handle this concern."

This is a never-ending effort to get concerns identified, resolved, and mitigated while preserving and building the compliance culture.

Although difficult at times, taking a step back and getting a good perspective on what individuals need to understand about the compliance program and/or to reduce risk is time well spent in maintaining an effective compliance program. Communication and listening skill are so key to this job.

by Douglas E. Roberts, Marc S. Raspanti, and Pamela C. Brecht

# A new era of laboratory fraud, Part 1: Operation LabScam redux

» The Biodiagnostics cases have brought lab fraud back into the news.
» Twenty years ago, Operation LabScam returned more than $800 million to taxpayers.
» HHS-OIG targeted questionable billing practices, upcoding, and kickbacks to physicians.
» Large settlements and corporate integrity agreements were supposed to deter fraud.
» Fines paid by labs are some of the largest settlements ever recovered under the False Claims Act.

***Douglas E. Roberts*** *(DER@Pietragallo.com) is a Senior Litigation Associate, and* ***Marc S. Raspanti*** *(MSR@Pietragallo.com) and* ***Pamela C. Brecht*** *(PCB@Pietragallo.com) are Partners, in the Philadelphia office of Pietragallo Gordon Alfano Bosick & Raspanti, LLP.*

In the 1990s, a series of *qui tam* law suits, along with an enduring, multi-agency government investigation, returned more than $800 million to the government coffers from clinical laboratories that had (1) billed Medicare and other government healthcare programs for medically unnecessary tests, upcoded tests, and tests that were never conducted; and (2) provided kickbacks to physicians who referred patients for the illegal testing. "Operation LabScam," as the government called its investigation and the related suits, was supposed to reform the entire laboratory industry. But two decades later, a new rash of lab-based fraud and abuse has emerged. This article traces industry fraud from Operation LabScam to its current incarnation and discusses the enforcement responses that may be on the horizon.

## The Biodignostics cases

Laboratory fraud has returned to the public eye through one brazen scam, with it salacious details and consequent criminal prosecutions. The government's filing documents are a study in cinematic largess. A parking lot full of exotic vintage cars, some worth up to $600,000; hundreds of thousands of dollars spent on chartered jets; a $700,000 Manhattan apartment for a "female companion"; and personal seat licenses for the Philadelphia Eagles, Pittsburgh Steelers, and the New York Jets—three teams that typically play on the same day many miles apart from one another. These were the fruits of a massive scam orchestrated over a seven-year period, from 2006 to 2013, by David Nicoll and his Parsippany, New Jersey-based lab, Biodiagnostics Laboratory Services, Inc.


Roberts


Raspanti


Brecht

Biodiagnostics bribed doctors in three states to refer patients to the lab for medically unnecessary testing. The illegal kickbacks took many forms, including sham consulting fees, above-market payments for blood-processing services, and phony leases, pursuant to which Biodiagnostics

placed its phlebotomists in physicians' offices and paid for far more space than the blood draw operations occupied. Government healthcare programs and private insures funded the scam, paying Biodiagnostics in excess of $100 million, according to the U.S. Attorney's Office for the District of New Jersey.

The Biodiagnostics scam resulted in a mass prosecution of laboratory executives and associates and, notably, physicians. Indeed, U.S. Attorney Paul Fishman called it "the largest number of medical professionals ever prosecuted in the same case."[1] Thirty-nine individuals involved in the Biodiagnostics scam have pleaded guilty to criminal charges, and at least one more is being prosecuted. Among those convicted are 26 doctors and one physician's assistant who profited from kickbacks. Many of those healthcare professionals were sentenced to prison time that can be measured in years, and not just months. The New Jersey physician who led the scheme in kickbacks received an admitted $1.8 million and was slapped with a sentence of 63 months' (more than five years') imprisonment.[2]

Of course, Biodiagnostics and its principals profited most from the fraud. The $1.8 million in kickbacks referenced above were a fraction of the $6 million that Medicare, Medicaid, and private insurers paid for the medically unnecessary tests that the now-former physician referred to Biodiagnostics. Under the federal sentencing scheme, fraud sentences are driven by "loss amount," and specifically the amount of pecuniary harm that is reasonably foreseeable to the defendant. And in the Biodiagnostics case, the person in the position to foresee the greatest loss amount was the company's president, Nicoll. In June 2013, he pleaded guilty to one count of conspiracy to commit bribery, in violation of 18 U.S.C. § 371; and one count of money laundering, in violation of 18 U.S.C. § 1956(a)(1)(B)(1).[3] Nicoll also agreed to forfeit $50 million in cash and possessions, including the aforementioned luxury cars. Nicoll has yet to be sentenced, in part because his wife and "female companion" have fought to keep real property that the government claims is subject to forfeiture. But according to media reports, Nicoll's sentencing range under the advisory U.S. Sentencing Guidelines may be as high as 210 – 262 months' (17.5 – 21.8+ years') imprisonment.

Consistent with its usual practice in high-profile cases, the Department of Justice (DOJ) has deemed the criminal prosecution as evidence of its commitment to fighting the crime at issue. The Biodiagnostics case, per U.S. Attorney Fishman, "shows how pervasive [laboratory fraud] can be."[4] The scope of the prosecution, and the fact that doctors — and not just the lab or its executives — were prosecuted criminally "have made people in the profession sit up and take notice and made the deterrent message that much louder."

## Operation LabScam and its aftermath

Fifteen years ago, the government thought the "deterrent message" regarding laboratory fraud had been received. And it had good reason to believe that was the case. From 1992 through the end of the decade, so-called "Operation LabScam" resulted in a federal recovery of more than $800 million from laboratories that charged government healthcare programs — Medicare, Medicaid, the Federal Employee Health Benefits Program, Tricare, and others — for millions of blood tests that were not medically necessary, not ordered by physicians, or not performed.

At its core, Operation LabScam was a series of four lawsuits and settlements under the federal False Claims Act (FCA),[5] that spanned from 1992 to 1997. Its impetus was a $111 million settlement with National Health Laboratories (NHL) — then one of the nation's largest providers of clinical diagnostic testing. At the time, it was the largest settlement

ever reached between the government and a healthcare provider. In addition, NHL and its president, Robert Draper, pleaded guilty to two counts of submitting false claims to Medi-Cal and the U.S. Civilian Health and Medical Program. Draper was sentenced to five months' imprisonment, though he was eligible for home confinement at the end of three months.

According to court filings, NHL manipulated doctors into ordering medically unnecessary tests for iron and cholesterol, as part of a basic panel of bloodwork. Through a process called "unbundling," NHL then billed government healthcare programs and insurers for the tests separately from the bills for the basic panels. Prosecuting U.S. Attorney, William Braniff from the Southern District of California dubbed this practice a "primary reason" for escalating costs for insurance providers.[6] At the time of settlement, NHL claimed, through its counsel, that it had done nothing different from its competitors.

That contention proved to be accurate. Over the next few years, the three largest independent clinical laboratories in the nation paid large monetary civil settlements to resolve *qui tam* lawsuits. In 1996, Laboratory Corporation of America (LabCorp) and Damon Clinical Laboratories, Inc. (Damon) settled FCA claims arising from schemes—similar in substance to NHL's—to bill government healthcare programs for medically unnecessary tests and tests that were not performed. LabCorp paid $187 million for the conduct at two laboratories it purchased, Roche Biomedical Laboratories and Allied Clinical Laboratories.[7,8] It also agreed to enter into pre-trial diversion to avoid criminal charges. Damon paid $119 million, $84 million to settle the FCA case and $35 million in fines to resolve a criminal prosecution for the same conduct. Though no individuals were convicted, Damon pleaded guilty to one count of conspiracy to defraud the federal government and was prohibited from participating in most government healthcare programs thereafter.[9]

The turn of the calendar to 1997 brought one of the largest civil FCA settlements ever, and the largest healthcare FCA settlement by an order of magnitude. In February, SmithKline Beecham Clinical Laboratories paid $334 million, which included interest, to settle two whistleblower lawsuits that were consolidated in the U.S. District Court for the Eastern District of Pennsylvania.[10,11,12] The SmithKline Beecham fraud was larger in scope than, though similar in character to, the conduct undertaken by NHL, Damon, and LabCorp. SmithKline Beecham billed insurers and government healthcare programs for tests that were not performed, added tests to "automated chemistry" profiles and then billed separately for those tests, double-billed for tests, and paid illegal kickbacks to healthcare professionals who referred patients for testing.

The fraud came to light primarily due to the efforts of relator Robert J. Merena of Reading, Pennsylvania. Merena, a long-time senior billing systems analyst at SmithKline Beecham, filed the first FCA lawsuit against SmithKline Beecham. He provided detailed evidence, including reams of corporate billing records, to the government. In addition, he spent hundreds of hours over the course of a year helping FBI agents sort documents, interpreting evidence, and suggesting witnesses to be interviewed. Although the government fought to limit the relator share, the court awarded Merena and the relator from the second-filed *qui tam* case, Dr. Charles Robinson, $52 million in total. At the time, it was the largest sum awarded to relators under the FCA.

In the afterglow of the SmithKline Beecham settlement, then-Secretary of the Department of Health and Human Services (HHS) Donna Shalala called Operation LabScam "a clear success story."[13] Beyond the

financial recoveries, the government claimed that substantial industry-wide reform would flow from the FCA settlements. The laboratories involved enter into what then-U.S. Attorney General Janet Reno dubbed, "extensive corporate integrity agreements that are designed to prevent the abuse from occurring again." More broadly, the HHS Office of the Inspector General (HHS-OIG) rolled out compliance plans designed to educate labs and other healthcare providers about their obligations when billing programs like Medicare and Medicaid in order to protect those programs from fraud, abuse, and waste. In concert with promoting voluntary compliance efforts, Shalala asserted that the federal government would have a "zero tolerance policy" concerning laboratory fraud.

And whether due to education, reform, the deterrent effect of prosecution and litigation, or a combination of all those things, laboratory fraud appeared to recede significantly in the early 2000s. Annual reports from the Centers for Medicare and Medicaid Services (CMS), issued pursuant to the Clinical Laboratory Improvement Act,[14] showed relatively few laboratories that were convicted of fraud-related offenses under federal or state law or that had been excluded from Medicare or Medicaid for committing fraud and abuse.

HHS-OIG, the OJ, and FCA litigants shifted their enforcement efforts to other sectors, like Big Pharma. Pharmaceutical industry leaders like Pfizer, Abbott Laboratories, Johnson & Johnson, and the aforementioned SmithKline each paid settlements in the billions of dollars to resolve criminal charges and civil claims alleging kickbacks and off-label marketing.

**Part 2 of this article will appear in the October issue of *Compliance Today*.**

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3. *United States v. Nicoll*, Case No. 2:13 CR 385-SRC (D.N.J.), Dkt. # 37 (Transcript of Plea Hearing).
4. Ibid, Ref #1
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7. *United States ex rel. LaCorte v. Roche Biomedical Labs., Inc.*, Case No. 2:96-cv-417-NCT. Available at http://bit.ly/2af4boB
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11. *United States ex rel. Grossenbacher v. SmithKline Beecham Corp.*, Case No. 2:95-cv-6953-VA (E.D. Pa.) See http://bit.ly/2at0hKE
12. False Claims Resource Center: "SmithKline Beecham Clinical Laboratories, Inc. Pays $334 Million in a Historic Settlement" Available at http://bit.ly/2af4DTu
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by Lynda S. Hilliard, MBA, RN, CCEP, CHC

# Reporting to leadership

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What, when, and how to report newly identified substantive compliance issues to the chief executive officer (CEO) is always a question posed by newly appointed compliance officers. Do you report immediately? Do you wait until the problem is resolved? When is the right time, and how much should you disclose? This isn't a question just for compliance managers; it is one that new managers in other industries have as well.

Hilliard

Management courses typically include instruction on this subject; however, many new compliance officers are appointed from within, may not have had previous senior management experience, and do not have experience in reporting to senior officers. In addition, they may have a reporting structure to a leader other than the CEO, except in cases related to compliance risk. So what guidelines should a new compliance officer use?

One of the first things a newly appointed CO should do in their initial days on the job is to schedule a meeting with the CEO to clarify how the CEO wants emergent issues presented to him/her. Regularly scheduled meetings should have an informal agenda that includes a summary of compliance operations and outstanding issues to make sure the CEO is aware of what is happening in the compliance arena. However, emergent issues should not be presented in a "chaotic," non-organized manner.

In the absence of specific requirements, the following guidelines could be used:

- Assess the seriousness of the issue and determine the need to schedule an immediate meeting with the CEO or whether a phone call notification would suffice until more information is available to present a fuller report;
- Similarly, depending upon the seriousness of the issue and the potential impact to the organization, the CO should alert his/her board contact that there is a potential issue that needs to be discussed;
- Gather the facts and develop a "talking points" document that includes all the pertinent issues related to the compliance risk, including length of time it has been occurring, potential financial and/or organizational consequences, and any other important facts;
- Identify the regulation(s) involved and any potential legal considerations; and most importantly,
- Prepare one or more recommendations for the CEO to consider as a potential response to the issue, with a corresponding plan of action to resolve this situation and improve the processes involved.

Effective and comprehensive reporting to leadership is an integral element of a compliance program.

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by Lynn Asher, RN, CHC

# Reporting quality data: Getting it right

» Content experts should be readily available to answer questions.
» Flow diagrams are useful tools for understanding the reporting process.
» Organizations are responsible for confirming timely reporting by vendors.
» Interviews are a key component of the audit process.
» Unintentional errors may be introduced into data by electronic systems.

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Over the past few years, there has been considerable expansion in the quality initiatives implemented by the Centers for Medicare & Medicaid Services (CMS). One of the goals for CMS is to transform its payment methodology to one that is linked to high quality and efficient care. Value-based purchasing programs provide incentive payments based upon how well a provider performed on specific quality measures. Over time, it is expected Medicare payments will be less about what services a beneficiary received and more about the experience related to that service.

Asher

A review of the Work Plans for the Office of Inspector General (OIG) reveals a focus on quality reporting. The Work Plan for FY 2012 included reviews of the reliability of quality data reported by hospitals and CMS oversight of Outcome and Assessment Information Set (OASIS) data submitted by home health agencies.[1] In 2013, a review was added to evaluate the oversight by the states and CMS related to the accuracy and completeness of Minimum Data Set (MDS) data reported by nursing facilities.[2]

The introduction section for Medicare Part A and Part B of the Work Plan for FY 2015 discusses the OIG's plan to "expand" their work related to the re-design of programs to improve quality of care.[3] Part of this work will include examination of "data and metrics to document and measure quality and performance." As CMS adds more providers to quality reporting and value-based programs, organizations will want to include this area in their compliance program.

A basic outline of a risk assessment to evaluate the accuracy and completeness of reported data is provided in Table 1 (on page 30). The process can be tailored to any organization or type of provider. It includes the key areas that need to be addressed and activities that should be undertaken to evaluate risk areas.

## Getting started

The first step to conducting a risk assessment is obtaining a basic understanding of how quality data is collected and submitted by the organization. For entities that are comprised of more than one provider type, data may be captured and reported in multiple areas. It is important to determine who has responsibility for oversight of the

Table 1: Outline of Risk Assessment

| Source | Key Activities |
|---|---|
| Staff responsible for quality reporting | ▸ Determine oversight process.<br>▸ Confirm how quality data has been captured for the organization over time.<br>▸ Establish a flow of the quality data reporting process that includes required timeframes for data collection and submission.<br>▸ Request policies and information on training programs. |
| Conduct interviews | ▸ Discuss the training that staff received.<br>▸ Determine the procedures that are followed when an error is identified.<br>▸ Confirm the process to monitor third-party vendors.<br>▸ Determine if the functionality of appropriate systems has been reviewed. |
| Validation audit | ▸ Select a sample of records and re-abstract the data used for quality reporting.<br>▸ Consider the accuracy, completeness, and timeliness of the submitted data. |
| Training | ▸ Evaluate content of training programs.<br>▸ Confirm completion of required training. |
| Policies | ▸ Determine if the documents accurately reflect quality reporting procedures.<br>▸ Consider expectations across departments related to the accuracy and timeliness of data. |

process. If no single individual or group has responsibility for oversight, the assessment should consider the impact this decentralization of duties has upon the submission of quality data.

Understanding how quality data has been collected and submitted over time can be useful at later steps of the risk assessment. Data is generally collected in a paper or electronic format. The transition from paper to a point-of-care system or the transition between different vendors from one point-of-care system to another can be times of increased risk for loss of data. Knowledge of these transition points can be incorporated into interview questions and assist with the identification of a universe of records for focused reviews during the data validation phase.

Flow diagrams are useful tools for organizations with multiple provider types or locations reporting quality data. The diagram can include areas related to the collection of quality data, quality checks for accuracy, submission of data, and resolution of errors. Information regarding required timeframes for data collection and submission are needed to confirm the effectiveness of the organization's procedures. Process flows may already be available from the quality reporting staff, because it is a common format for presentations to committees and other departments that support the quality reporting function.

Information related to training programs and policies can be gathered at this time. It is recommended that an in-depth review not be performed until after the completion of the interviews to prevent confirmation bias being introduced into the findings. Interviews discussed in the next step are best performed by someone who is

not knowledgeable of expected processes and procedures.

### Conduct interviews

Three main groups of individuals have roles in the quality reporting process. Data collection starts in the clinical setting when care is being rendered by physicians and staff. During data submission, data entry staff respond to feedback edits and error messages regarding the accuracy and completeness of the data. Quality and auditing staff may review documentation at various points along the process from the initiation of service to closed records.

Confirm with individuals the training they have received regarding their role in the quality reporting process. Include in the discussion both formal classroom instruction and on-the-job training they may have received. Identify if there are experts who are readily available to answer any questions.

One of the goals for the organization is to ensure the accuracy of the submitted data. Potential errors may be identified at any time in the process. During the interviews, discuss with individuals any errors they have identified and the steps taken for resolution. Confirm if the individuals who review closed records have a process to respond to potential errors. If specific patient information is provided regarding a corrected error, it is recommended the record be included in the validation audit discussed below. During discussion of potential errors, ask individuals if they felt pressured at any time to collect or report data that was not accurate. Appropriate follow-up action should be taken on any identified concerns.

During discussion of potential errors, ask individuals if they felt pressured at any time to collect or report data that was not accurate.

The organization should also take steps to limit the occurrence of future errors. Determine if there is a process to provide feedback to an appropriate person or group if trends are noted. For example, a data entry person identifies that nursing staff are entering birth dates incorrectly, because the field is set up as "DDMMYYYY" with the day first instead of the month first. The process for communicating identified issues should go beyond reporting the concern and include coordination across departments with a method to track resolution.

Measurements related to patients' perception of care are reported to a third-party vendor that submits data on behalf of the organization. If the vendor fails to report the data in a timely manner, the organization is at risk for a payment reduction. During interviews, identify the individual or group responsible for monitoring and reporting on the vendor's performance.

Electronic systems may automatically collect quality data. Determine if the organization has taken steps to review and address functionality that may impact the accuracy of the reported data. For example, systems that pre-populate clinical notes may result in data being copied from one note to the next. Pain is a common component of many quality measures. The copying of pain scores from one note to the next may indicate there is no improvement, when actually the patient is experiencing less pain.

## Validation audits

The basic process for validation audits includes selecting a sample of records and re-abstracting the data to confirm the accuracy of submitted data. These audits can also include confirmation that any required timeframes and organization-specific policies were met. It is recommended that some records be selected randomly and others be selected from any high-risk time points or records identified during the interviews.

The results of the re-abstraction are compared to the data submitted by the organization after all corrections have been completed. The percentage of agreement between the two data sets can serve as an error rate to help monitor the process over time. Organizations may want to consider performing a small monthly validation audit that can be aggregated and reported quarterly. This will provide on-going feedback regarding the accuracy, completeness, and timeliness of submitted data.

## Training programs

The content of training programs is reviewed for completeness based upon the role the individuals will perform in the reporting of quality data. Essential topics for training programs include:

- Commitment to accurate data collection and submission,
- Any required timeframes for completion of an activity,
- Procedures related to accurate data collection or submission, and
- Processes for the correction of data.

The training material can be reviewed to determine if it is current and reflects actual best practice. Confirm that evidence of required training is maintained by the organization. If training occurs in an informal setting, determine how this is documented and included in training records.

## Policies

One of the goals of the review of policies is to determine if the documents accurately reflect the procedures discussed in the interviews. Another goal is to evaluate the expectations across departments regarding the accuracy and timeliness of data. For example, disciplinary measures for non-compliance with procedures should be consistent from one department to the next. If reporting of quality data is decentralized in the organization, the review can include the impact this has on the reported data.

## Going forward

Once an initial assessment has been performed, on-going focus in this area can be incorporated into other compliance activities. A commitment to accurate and complete reporting of quality data may be added to the organization's Standards of Conduct. Procedures for staff leaving the organization can include a request for information regarding pressure to record inaccurate data. Audit activities may be revised to include a sample of validation audits. The annual review of policies can be a time to follow up with quality staff to discuss revisions to the reporting of quality data.

## Conclusion

Over time, it is expected that CMS will transition more providers to a value-based purchasing program that links reimbursement to actual performance. The role of compliance professionals will also expand as payment adjustments are tied to quality data. Now is the time for organizations to implement processes to confirm that reported data is accurate, complete, and timely.

1. Department of Health and Human Services: Fiscal Year 2012 OIG Work Plan, pp. 1-2, 1-4. Available at http://bit.ly/2acBEOJ
2. Department of Health and Human Services: Fiscal Year 2013 OIG Work Plan, p. 10. Available at http://bit.ly/2aeJWK1
3.. Department of Health and Human Services: Fiscal Year 2015 OIG Work Plan, p. 1. Available at http://bit.ly/2aeKI9V

by Donna Abbondandolo, MBA, CHC, CPHQ, RHIA, CCS, CPC

# MACRA and MIPS: Documentation confusion

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In May 2016, the proposed rule that outlines the provisions for physician payment for professional services as required by the Medicare Access and CHIP Authorization Act of 2015[1] (MACRA) was published by the Department of Health and Human Services. The rule provides details for payment based upon one program called the Quality Payment Program (QPP). The QPP structure allows clinicians to follow one of two paths: the Merit-based Incentive System (MIPS) or Advanced Alternative Payment Models (AAPMs). MIPS incorporates the current Physician Quality Reporting System (PQRS), the Value Modifier Program (VM), and the Medicare Electronic Health Record Incentive Program, also known as Meaningful Use (MU), into one streamlined system. AAPMs provide those clinicians who participate in these advanced models an incentive payment and exempt them from MIPS payment adjustments.

Abbondandolo

Physician reimbursement under MIPS is determined by four performance categories: (1) Quality (replaces PQRS and the quality component of VM); (2) Advancing Care Information (replaces MU); (3) Clinical Practice Improvement Activities (includes care coordination, patient engagement, and safety); and (4) Cost (replaces cost component of VM). Performance in these four categories will determine the composite performance score, which will determine if the clinician will receive positive, negative, or neutral Part B payment adjustments.

The streamlining of the various quality reporting programs that physicians participate in to report on the care they provided is a good thing. Having had many conversations with physicians regarding documentation when it comes to specific requirements that may vary from program to program, it is easy to see how they are overwhelmed and confused. One of the goals under MIPS is to ease the reporting burden for physicians. Many of the documentation requirements of quality reporting programs for both hospitals and private practices have inconsistencies with the reported measures. Throw in some of the complicated and extensive documentation guidelines for billing purposes, and now you have multiple competing requirements.

Clinician education on documentation requirements for both quality and billing comes from many sources within healthcare. Hospitals may educate physicians on documenting in the inpatient medical record through their clinical documentation improvement efforts, which are specific to hospital documentation and billing requirements; vendors assisting clinicians with MU may educate them on only those areas that they may be reporting on; and compliance staff may educate clinicians on multiple areas, including appropriate documentation for Part B billing, MU, and documenting specificity of diagnoses. It's important to keep these competing interests in mind when discussing documentation specifics with clinicians.

1. http://bit.ly/2a7ccbQ

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by Elizabeth A. Kastner, Esq. and Jessica Hudson Bechtel, Esq.

# Medical records access: Are you following the rules?

» A HIPAA authorization is not required when an individual requests access to his/her own records.
» An individual may direct records to a third party pursuant to a request for access.
» Fees must be based on an actual, average, or flat cost approach.
» Fees may only include labor, supplies, and postage costs.
» HIPAA overrides a state law that authorizes higher fees.

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Many healthcare providers' compliance efforts have recently been focused on responding to Office for Civil Rights (OCR) audits and preventing cyber breaches, but an area that likely has received far less attention is the U.S. Department of Health and Human Services (HHS) OCR guidance on patient access to medical records.

In early 2016, OCR issued guidance for healthcare providers regarding an individual's right to access his/her health information[1] under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (HIPAA).[2] The guidance consisted of a fact sheet and FAQs addressing patients' right to access their medical records (collectively, the Access Guidance). The Access Guidance sets forth requirements healthcare providers must follow when responding to a patient's (or a patient's personal representative's) request for access to his/her medical records. According to OCR, its hope is that the Access Guidance will "engage and empower patients to take control of their healthcare decisions"[3] and put patients in the "driver's seat" regarding their health.[4]

## Medical records right of access requirement

Kastner

Bechtel

HIPAA provides patients with the right to access their protected health information (PHI) maintained by a healthcare provider in a designated record set, such as medical records, billing and payment records, and insurance information.[5] Health plans may also maintain PHI in a designated record set and therefore are required to comply with an individual's access right.[6] Patients have the right to request, inspect, and/or obtain a copy of their PHI, as well as to direct the healthcare provider to transmit a copy of their PHI to a designed third party or entity of the patients' choice. A patient's right of access is subject to certain exceptions, such as for psychotherapy notes and information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

When providing a patient with a copy of his/her PHI pursuant to an access request, a healthcare provider may charge an individual:

> a reasonable, cost-based fee, provided that the fee includes only the cost of: (i) Labor

> for copying the protected health information requested by the individual, whether in paper or electronic form; (ii) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; [and] (iii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; (iv) Preparing an explanation or summary of the protected health information, if agreed to by the individual.[7]

## Access Guidance

The Access Guidance was issued because, according to OCR, although HIPAA has always provided individuals with a right to access their health information, healthcare providers have not always understood this right and, in OCR's experience, created obstacles for individuals attempting to exercise their rights.[8] The Access Guidance addresses various aspects of the right to access, including, the mechanics of providing access (e.g., form, format, manner, cost, etc.), an individual's right to direct PHI to another person, and the interplay with state laws.

The Access Guidance clarifies that pursuant to a right to access, an individual can direct the healthcare provider to transmit his/her PHI directly to another person or entity designated by the patient and, importantly, such direction does not require a formal HIPAA authorization. Rather, an individual's right to direct his/her information to a third party is complete so long as it is in writing, signed by the patient, clearly identifies the designated person, and where to send the PHI.

Three aspects within the Access Guidance may be of particular interest to healthcare providers and suggest best practices for compliance.

## Right of access versus third-party initiated request

OCR reiterates in the Access Guidance that a request made pursuant to an individual's right to access is different than a request made by a third party on its own behalf. OCR describes the distinction as follows:

> …third parties often will directly request PHI from a covered entity and submit a written HIPAA authorization from the individual (or rely on another permission in the Privacy Rule) for that disclosure. Where the third party is initiating a request for PHI on its own behalf, with the individual's HIPAA authorization (or pursuant to another permissible disclosure provision in the Privacy Rule), the access fee limitations do not apply. However, as described above, where the third party is forwarding - on behalf and at the direction of the individual - the individual's access request for a covered entity to direct a copy of the individual's PHI to the third party, the fee limitations apply."[9]

The differences between a patient access request directing records be sent to a third party and a request initiated by a third party on its own behalf might seem immaterial on first blush, but the characterization impacts the manner in which a healthcare provider must process the requests. The characterization is significant because the HIPAA fee limitations and timeliness requirements apply only to requests pursuant to the access right. If the request is not a request for access, then a healthcare provider does not have to follow the Access Guidance (i.e., fee limitations, timeliness requirements, etc.), but is still bound by state laws that may dictate allowable fees for medical record copies.

Determining whether a request is an access request may not always be easy, because an access request may be submitted by a

patient, a patient's personal representative, or by a third party on behalf and at the direction of the individual. Where a healthcare provider has any questions regarding the nature of the request—whether it is an access request or a request from a third party on its own behalf—the Access Guidance suggests that the healthcare provider should check with the patient regarding whether the request was a direction from the individual (i.e., pursuant to the access right).

Being able to properly identify an access request is important, because the Access Guidance discusses that healthcare providers may not circumvent the rules by requiring an authorization where an individual requests access to his/her PHI. The Access Guidance emphasizes that healthcare providers cannot create impermissible obstacles to a patient's ability to exercise his/her access right.

For example, assume a healthcare provider's policy requires a patient to sign an authorization if the patient wants the healthcare provider to send the patient's medical records to a third party for non-treatment purposes, such as a request to disclose medical records to the patient's attorney in connection with an auto accident lawsuit. This policy could be inconsistent with the right of access to the extent the patient can properly be viewed as initiating the request and directing the medical records to be sent to a third party. In this situation, requiring an authorization (which OCR points out requires more

**Table 1: Access Guidance on Patient Rights**

| HIPAA Authorization | Right of Access |
|---|---|
| Requires a number of elements and statements, which include a description of who is authorized to make the disclosure and receive the PHI; a specific and meaningful description of the PHI; a description of the purpose of the disclosure; an expiration date or event; signature of the individual authorizing the use or disclosure of her own PHI and the date; information concerning the individual's right to revoke the authorization; and information about the ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization | Must be in writing, signed by the individual, and clearly identify the designated person and where to the send the PHI |
| No timeliness requirement for disclosing the PHI | Covered entity must act on request no later than 30 days after the request is received |
| Reasonable safeguards apply (PHI must be sent securely) | Reasonable safeguards apply, including a requirement to send securely; however, individual can request transmission by unsecure medium |
| No limitations on fees that may be charged to the person requesting the PHI; however, if the disclosure constitutes a sale of PHI, the authorization must disclose the fact of remuneration | Fees limited as provided in 45 CFR 164.524(c)(4) |

information than is necessary or that may not be relevant for individuals to exercise their right to access) could be viewed as creating obstacles to the patient's ability to exercise the access right. Table 1, excerpted from the Access Guidance, differentiates between a right of access and a HIPAA authorization. [10]

Healthcare providers should review their policies and procedures to ensure that they are not imposing additional requirements upon individuals requesting access to their medical records and have polices in place to distinguish between a request from a third party on its own behalf and an access request directing records to a third party.

## Approved ways to charge

Once a request is determined to be an access request, then the healthcare provider must comply and provide the records free of charge or at a "reasonable, cost based fee." The Access Guidance suggests that while limited fees may be charged, healthcare providers should forgo fees for all individuals, especially where the individual cannot afford the fee.

If a healthcare provider decides to charge a "reasonable, cost-based fee," then the Access Guidance identifies three methods that may be used to determine the amount of the fee (1) actual costs; (2) average costs; or (3) flat fee for electronic copies of PHI maintained electronically. Additionally, the Access Guidance makes clear that a healthcare provider may not charge a fee when it fulfills an access request using the view, download, and transmit functionality of the provider's Certified EHR Technology.

A healthcare provider may use actual costs to determine the fee for medical records. Actual costs may include labor, supply, and postage costs. Labor costs are limited to the time spent creating and delivering the electronic or paper copy in the form and format requested, including time spent photocopying records, scanning records into an electronic format, converting electronic format into another format, or transferring (e.g., uploading, downloading, attaching, burning) electronic records. Labor costs do *not* include costs associated with reviewing the request or searching for, retrieving, segregating, or preparing the records responsive to a request. Though this is consistent with the language of HIPAA, OCR noted that it was clarifying this, because it has observed confusion regarding labor costs among healthcare providers. In calculating the cost of labor, a healthcare provider must, according to the OCR, determine the actual amount of time spent by an employee on the includable tasks and multiply the time by a reasonable hourly rate. Labor costs can be added to postage costs and supply costs, which include the cost of paper, toner, or electronic media necessary to provide the records to the individual in the requested format.

Instead of actual costs, a healthcare provider may calculate the fee based on the average cost for labor to fulfill standard access requests. In setting the average cost, the healthcare provider may only include labor costs (as described above, which only includes costs for copying, scanning, and/or converting electronic formats and not costs for searching or retrieving), supply costs, and postage. This standard rate can be calculated and charged as a per-page fee only in cases where the records are maintained in paper form.

Lastly, healthcare providers may charge a flat fee, not to exceed $6.50, for all standard requests for electronic copies of PHI maintained electronically. This approach is available for healthcare providers who do not want to go through the process of calculating actual or allowable costs for requests for electronic copies of PHI maintained electronically.

Regardless of the method used to calculate the fee, healthcare providers are required

to provide advance notice to individuals of the approximate fee that it will charge for record requests.

Healthcare providers should review their policies and procedures surrounding charging for medical records to ensure that when they receive an access request they are: (1) using one of the three methods to determine costs associated with access requests; and (2) only charging for the allowable costs. The Access Guidance is flexible to allow healthcare providers to use more than one method to calculate fees. For example, a healthcare provider may use the average cost method to charge for records maintained in paper form and the flat fee approach for records maintained electronically. In addition, if a healthcare provider uses the flat fee approach or the average cost method, but receives an unusual or uncommon type of request that it did not consider in determining its fee structure, it may decide to calculate the fee through the actual cost method.

The Access Guidance provides answers to many questions that healthcare providers may struggle with, but some questions remain. For example, the calculation for both average costs and flat fee costs involves "standard" requests, however "standard" is not defined. Or in setting a flat fee, must the fee be related to actual or average costs, or is any fee under $6.50 reasonable *per se*?

OCR's Access Guidance may also signal that additional changes may be in the not-too-distant future. The Access Guidance states that:

> [f]urther, while the Privacy Rule permits the limited fee described above, covered entities should provide individuals who request access to their information with copies of their PHI *free of charge*. While covered entities should forgo fees for all individuals, not charging fees for access is particularly vital in cases where the financial situation of an individual requesting access would make it difficult or impossible for the individual to afford the fee. (emphasis added)[11]

Based on OCR's statements that healthcare providers should allow individuals access to their medical records free of charge and, that as technology evolves, labor costs associated with copying and transferring medical records will diminish or disappear completely, it seems reasonable that OCR may eventually no longer allow healthcare providers to charge patients for access requests.

## State law

OCR also uses the Access Guidance to clarify how state law and HIPAA interact with respect to fees charged for access requests. Where state law provides individuals a greater right of access to their medical records when compared to HIPAA, then the healthcare provider must also follow state law. This includes state laws that prohibit fees to be charged to individuals for copies of medical records, requires that a free copy of medical records be provided to an individual, or requires fees less than what HIPAA allows to be charged for copies.

On the flip side, HIPAA overrides state laws that authorize higher or different fees from those allowable under HIPAA when a patient requests access to his/her records. Examples of practices that may be permitted under a state law but are prohibited under HIPAA's right of access include: (1) fees for search and/or retrieval and (2) per-page fees for electronic records. For example, HIPAA's prohibition on charging a per-page fee for electronic records would override Ohio law authorizing healthcare providers to charge a per-page fee, dependent on the total number of pages requested, for electronic records.[12]

The challenge faced by healthcare providers when setting fees for records requests is that the fees permitted under a state law for medical records copies may not be aligned with fees permitted under HIPAA. For ease of administration, a healthcare provider may consider implementing a uniform fee structure that is consistent with both the fee limitations under the right of access and any applicable state law requirements.

## Conclusion

In light of the Access Guidance, healthcare providers should review their policies, procedures, and fee schedules relevant to granting access to and charging fees for copies of medical records to ensure compliance with the Access Guidance.

*This article is of a general nature and is not intended to be, nor should it be construed or relied upon, as legal advice.*

1. Department of Health and Human Services: Individual's Right under HIPAA to Access their Health Information. Available at: http://1.usa.gov/1SzKnMD.
2. See 42 U.S.C.A. § 1320d et seq.; 45 C.F.R § 164 et seq.
3. See Jocelyn Samuels, Director, Office for Civil Rights: "New HIPAA guidance reiterates patients' right to access health information and clarifies appropriate fees for copies" HHS Blog, February 25, 2016. Available at http://bit.ly/2aeUwv3
4. Ibid, Ref #1.
5. The right of access is specified in 45 C.F.R. § 164.524.
6. Ibid, Ref #5
7. 45 C.F.R. § 164.524(c)(4)
8. Ibid, Ref #3.
9. Ibid, Ref #1.
10. Ibid, Ref #1.
11. Ibid, Ref #1.
12. Ohio Revised Code § 3701.741(B)

by Frank Ruelas

# A handful of EXCEL-lent tips

***Frank Ruelas*** *(francisco.ruelas@dignityhealth.org) is a Facility Compliance Professional with Dignity Health in Phoenix.* *bit.ly/in-FrankRuelas* *@Frank__Ruelas*

One popular program that people use is Microsoft Excel. Some people use it extensively, while others tend to use it sparingly and only when absolutely necessary. Some of this apprehension may be caused by having to deal with large blocks of data that can cause navigating or using Excel to appear less than user friendly. However, here are some tips that I think many people will find very useful, because they involve situations commonly encountered by Excel users.

Ruelas

## Take control

When working with large blocks of data and the need comes up to move the cursor to the top, bottom, right, or left edge of the block of data, the Control key can come in handy. While holding the Control key, press any of the arrow keys to move to the edge of the data that corresponds with that key. So let's say you want to get to the bottom value of a continuous list of data. Hitting Control + Down Arrow moves your cursor immediately to the bottom edge of the list.

## Adding and deleting rows or columns

When working with Excel, inserting or deleting rows or columns almost seems like a given. A quick way of doing this is to click on the row heading (the numbers on the left edge of a worksheet) or column heading (the letters on the top edge of a worksheet) and hit the Control key and the "+" (plus) key on the numeric keypad. That's it! This can come in handy, because it allows for rows or columns to be added with minimum disruption to what you are working on as you juggle equations or functions in your head while working in Excel.

To delete a row or column, again highlight the column or row heading of the column or row you wish to delete and hit the Control key and the "–" (minus) key on the numeric keypad. Just that quickly, the row or column is gone.

Remember, if you accidentally delete the wrong column or row, using the Control + Z key will undo the last operation and restore whatever you deleted.

These are just a few of the many helpful hotkeys that are available in Excel. Before long, you will be EXCEL-lent at working with worksheets.

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by Maggie Perritt, RPh, MBA, CHC

# Creating an ambassador program for continuing compliance training

» Offering compliance training for associates will provide opportunities for acheiving CHC designation, which otherwise may be unattainable.
» Developing a flexible platform to help your associates obtain certification takes thought and creativity.
» Building compliance ambassadors in your organization spreads the word that compliance is a resource to help your business succeed.
» Fostering positive compliance training for personal development reinforces a strong culture of compliance.
» Ingraining compliance as part of your core business model and strategic vision will advance associate adoption.

***Maggie Perritt*** *(Maggie.perritt@WellCare.com) is Senior Director Corporate Compliance, Policies and Training with WellCare Health Plans, Inc. in Tampa, FL.*

When you hear that someone is Certified in Healthcare Compliance (CHC), you should know that the designation requires commitment, integrity, dedication, and more.


Perritt

Every organization in a healthcare-related environment has compliance training required by regulatory components that drive the business. Depending on individual areas of expertise and commitments, an average compliance professional may invest up to 18 hours a year in required compliance training, while others take training to the next level by becoming CHCs.

But how do organizations foster this higher level of compliance or help employees become compliance professionals? By creating an environment that celebrates compliance and encourages continuous and ongoing learning. Organizations can make this happen by thinking outside the box to develop supplemental training and fostering a culture of compliance that, in turn, creates compliance ambassadors for your organization.

## Develop supplemental training

To create a supplemental training program, you must first and foremost engage your audience about compliance. In our experience, associates who are more engaged tend to be more productive and go that extra mile.

Although it sounds easy, anyone who has created training knows it's not that simple. It's easier to start a training program when you have a specific target—a new law, a new regulation, or a new requirement—but even that can be a challenge. Starting a supplemental training program designed to develop professionals on compliance, as opposed to training employees on compliance requirements, takes work. Compliance is not an easy concept, so to create engaging supplemental training can be an even greater challenge.

The best place to start is the Compliance Certification Board (CCB) *Candidate Handbook*.[1] Whether you are

looking to facilitate your associates' obtaining national certification or just developing as compliance professionals, the handbook provides an outline of topics and a road map to developing compliance professionals.

This can be a start, but developing a comprehensive program requires you to go beyond the basics. If you are fostering supplemental learning designed to support national certification and professional development, you must develop content about compliance, not just about your organization.

To accomplish this goal, bring in real-world examples or current news that individuals know and can relate to. Just because we are in a healthcare environment doesn't mean we have to exclusively look to our industry for examples of compliance or non-compliance, and with a supplemental program, you can be creative. For example, in 2015, two well-known global organizations faced compliance-related issues—Volkswagen with its emissions scandals and FIFA with accusations of bribery and corruption. Of course, there is also my personal favorite—fraud perpetuated by reality TV stars, such as the star of Dance Moms indicted on bankruptcy fraud charges. Encourage participants to talk through the ethical issues around these scandals. Then encourage them to relate that to everyday compliance.

## Fostering a culture of compliance

As compliance professionals, we know the best way to achieve compliance is to make it part of your culture, your core business model, and your strategic vision.

Create a culture by regularly engaging associates in both real and hypothetical discussions of compliance-related issues. Get them talking and thinking about compliance. The more they engage in compliance, the more they will incorporate it into everyday activities. Allow associates to go beyond the basics for what is required, give them the opportunity to excel by providing them the tools they need to be successful compliance professionals and, if they desire to, obtain national certification.

> …as an added benefit, your ambassadors…may be more proactive, rather than reactive, in identifying compliance-related issues.

Engaging associates in other activities, such as Corporate Compliance & Ethics Week and ancillary compliance communications, such as newsletters, creates an environment that supports "doing the right thing because it's the right thing to do." That is the basic definition of a culture of compliance.

## Creating compliance ambassadors

Developing a program that stimulates compliance learning not only fosters a culture of compliance, but it also develops compliance ambassadors.

As associates engage with the program, they also become ambassadors, acting as compliance champions throughout your organization. They spread the word that compliance is a resource to help your business succeed, and as an added benefit, your ambassadors (now armed with a higher level of understanding about compliance) may be more proactive, rather than reactive, in identifying compliance-related issues.

Some individuals may use the training opportunity only to advance their own careers

to new compliance-related positions, but many will do it for the understanding, especially in organizations with a strong culture of compliance. Most associates take pride in doing a good job and want to do the right thing.

Ultimately, giving associates this opportunity and engaging them in compliance continues to foster their desire for more learning, which continues to foster a culture of compliance and continues to develop your compliance ambassadors.

## A lasting impression

Although it's not quick or easy, as your company continues on its compliance journey, you will likely be pleased with the adoption of compliance by your associates. It may take a few cycles or even a few years to reap the benefits, but before you realize it, you have reached a new level for your compliance program.

WellCare Health Plans, Inc., embarked on this path several years ago. We began by branding the program and then introduced a continuing education program to assist our compliance professionals. At first, we opened it to *all* associates, not just those in Compliance. We were amazed by the number of non-compliance associates who were dedicated to compliance and wanted to participate. In fact, today more than 75% of our program participants are not compliance associates. Now, in its third year, our program enrollment has grown exponentially and, more importantly, interest has grown exponentially as well. People are more engaged in compliance as a whole, fostering a culture of compliance throughout the company.

I am proud that hundreds of our current compliance graduates are integrating this information in to their everyday work or preparing to take the national certification exam. I am also proud of the nearly 500 participants enrolled in our 2016 program. Every day, our team of ambassadors continues to strengthen our culture of compliance.

1. The *CCB Candidate Handbook - Certified in Healthcare Compliance (CHC)* is available at http://bit.ly/29OTgD5

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

# Compliance in animal research

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

The ethical principles that underlie all animal research regulations are to reduce the number of animals used in research; refine experiments to minimize pain and suffering; and replace animal experiments with alternatives, when feasible. According to Emory University Chief Compliance Officer Kris West, research compliance officers need to understand these principles, as they are especially important when working with principal investigators who develop research protocols and use Institutional Animal Care and Use Committees (IACUCs) in their review of those protocols.

Willenberg

The two main federal agencies that regulate animal research are the Office of Laboratory Animal Welfare (OLAW) and the U.S. Department of Agriculture (USDA). OLAW regulates animal research funded by the Public Health Service (PHS) and enforces the PHS's *Policy on the Humane Care and Use of Laboratory Animals*. The USDA enforces the Animal Welfare Act and implementing regulations, but its jurisdiction only covers certain species of animals. Most notably, the USDA does not have jurisdiction over rats and mice used in research. Both agencies require compliance with the *Guide for the Care and Use of Laboratory Animals* and require that research institutions have an IACUC that holds regularly convened meetings and, according to the NIH's Institutional Animal Care and Use Committee website, must have five members, including:

- One veterinarian with training or experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the institution;
- One practicing scientist experienced in research with animals;
- One member whose primary concerns are in a non-scientific area (e.g., ethicist, lawyer, member of the clergy); and
- One member who is not affiliated with the institution other than as a member of the IACUC.

The main responsibility of the IACUC is to perform initial and continuing review of animal research protocols. Other responsibilities include investigating concerns of non-compliance, conducting inspections of animal facilities, reporting any serious or continuing non-compliance, and filing of an annual report. Since the lack of proper oversight in laboratories can lead to non-compliance, monitoring protocol implementation after IACUC approval is imperative.

Taking care of animals involved in research can be challenging. Ensuring the drug development process is carried out in a humane and compliant fashion is imperative, because there are frequently negative portrayals by the media and special interest groups, such as People for the Ethical Treatment of Animals (PETA). Pre-clinical research using animals, however, is an FDA-required component of the drug approval process, so a research compliance professional must have a strong program in place.

# LEARN THE ART AND SCIENCE OF INVESTIGATIVE INTERVIEWING

By Meric Craig Bloch, Esq, CCEP, PCI, CFE


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by Mary Jean Geroulo, MBA, JD

# Not all management service organizations are created equal

» Management service organizations (MSOs) are useful tools for management of healthcare entities.
» Physician-owned MSOs can be structured to comply with the law.
» MSO arrangements have also been used to disguise payments for referrals.
» Limited service MSOs and percentage fee arrangements are red flags.
» Excluding federal healthcare payers does not eliminate the risk.

***Mary Jean Geroulo*** *(maryjean.geroulo@wilsonelser.com) is a Partner in the Dallas office of Wilson Elser.*

The management service organization (MSO) has been a useful and versatile tool for healthcare providers, including physicians, for many years. Providers use the MSO to provide the management and administrative services necessary to run medical practices and other healthcare businesses. Contracting with an MSO gives healthcare providers the ability to have essential services (e.g., revenue cycle management, credentialing, staffing, human resources management, leasing, managed care contracting, etc.) furnished by an entity with the expertise and experience that the healthcare provider usually does not have. MSOs frequently contract with multiple providers, and as such, are often able to reduce the costs associated with these services through simple economies of scale. Lastly, contracting with an MSO gives healthcare providers the ability to focus the majority of their efforts and time on caring for patients.


Geroulo

MSOs can be owned and operated by lay persons, but it is not unusual for them to be owned, at least in part, by physicians or other healthcare providers. As a general rule, MSOs that provide the types of services described above can operate in compliance with the federal and state Stark and anti-kickback laws, even those owned in part or in whole by physicians, because in most MSO arrangements the owner physicians do not "refer" services to their own medical practices or to the entities contracting with the MSOs. However, the last several years have seen a tremendous growth in physician-owned organizations that contract with healthcare entities other than medical practices (the contracted entity). Sometimes instead of using the term MSO to describe the contracting entity, the participants refer to it as a physician-owned entity (POE).

## Non-compliant MSOs

Many of these "sham MSOs" are arguably nothing more than a mechanism by which the MSO owner-physicians can capture a share of revenues derived from their orders or referrals to the contracted entity. These sham MSOs put all the participants at risk for prosecution and/or enforcement activity under the federal and/or state anti-kickback

laws. The federal Anti-Kickback Statute (AKS) states:

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.[1]

In some cases, the federal Stark Law may be implicated. Stark prohibits a physician from referring a Medicare or Medicaid beneficiary for designated health services (DHS) payable under Medicare or Medicaid to an entity in which the referring physician (or a member of the referring physician's immediate family) has a financial relationship unless an exception applies.[2]

The following is an example of an arrangement that illustrates how these noncompliant MSOs might be at risk under one or more of the above laws. I refer to this as the "Pain Cream Arrangement," but similar arrangements can include a wide variety of diagnostic and treatment products, including toxicology labs, pharmaco-genetic testing entities, physical therapy services, and other healthcare entities that receive their business from physician referrals or orders. Pain cream providers are currently under investigation by the FBI for participating in potentially fraudulent practices.[3]

The participants in the Pain Cream Arrangement example include: (1) a compounding pharmacy that provides a pain cream that can, according to the proponents of these arrangements, substantially reduce the use of opiates and/or injections in patients with chronic pain; (2) physicians with pain management practices; and (3) an MSO owned, at least in part, by pain management physicians. The MSO contracts with the pharmacy to provide management and marketing services.

## Inside the arrangement

The management and marketing services provided by the MSO are typically very limited and, in many cases the MSO is doing nothing more than "marketing" the pharmacy's pain cream to the physician-owners of the MSO or "facilitating" the processing of the prescribing physicians' prescriptions for the pain cream. This so-called processing of the prescriptions or orders is often limited to tracking how many orders each owner physician makes for the pain cream product and passing the orders on to the pharmacy. The pharmacy's fee to the MSO for these "services" is a percent of the revenues generated by orders for the pain cream, which is frequently priced at between $3,000 and $5,000 per order/prescription (there are reports of even higher fees). The "management fees" are often 40%–60% of the revenues generated by sales of the pain cream, so the compensation back to the MSO can be substantial.

The MSO's profits are, of course, shared with the owner physicians, usually based on the ownership interest held by the physicians. However, some of these arrangements allow for the distribution of profits based on the number of orders for pain cream generated by each physician. Lastly, to avoid implicating the federal AKS, the owner-physicians only submit orders for pain cream

that are payable in cash or by commercial health insurance.

## Red flags

As noted above, there are many variations of these arrangements. However, the "red flag" elements of questionable MSOs include one or more of the following: (1) MSO ownership interests are only offered to physicians who have the capability to refer to the healthcare entity contracting with the MSO; (2) only limited (and sometimes unnecessary) services are provided by the MSO; (3) compensation is a percentage-of-revenues payment methodology; and (4) governmental payers are excluded from the arrangement. Some arrangements do provide *bona fide* administrative services, such as billing and collections services, but frequently the fees associated with these services are far higher than fees charged by MSO arrangements that do not involve referrals by owner-physicians to the contracted provider/supplier.

The MSO participants attempt to reduce the risk associated with the federal AKS (and Stark Law, where applicable) by excluding federal healthcare business from the arrangement. This is usually done by securing agreements from the owner-physicians that they will not refer any patients or order any services payable to the contracted entity under a federal healthcare program. Some arrangements permit referrals or orders payable by government healthcare programs, but do not include the revenues generated by those orders/referrals in the calculation of the MSO's fees. This only minimally reduces the risk associated with the AKS, because the Office of the Inspector General has repeatedly stated that even where a payment arrangement does not include federal healthcare dollars, the compensation based on non-governmental payor sources may be sufficient to induce the owner physicians to refer or order services payable by government healthcare programs, thereby putting the participants at risk for federal anti-kickback violations.

Eliminating referrals or orders paid for by government healthcare payers from the arrangement does not eliminate the risk associated with these arrangements. Most states, including Texas, have counterparts to the federal AKS that apply to fees arising from any source, including cash, commercial health plan payments, and government health plan programs. The Texas counterpart to the federal AKS states in part:

> "a person commits an offense if the person knowingly offers to pay or agrees to accept, directly or indirectly, overtly or covertly any remuneration, in cash or in kind, to or from another for securing or soliciting a patient or patronage for or from a person licensed, certified, or registered by a state health care regulatory agency."[4]

Like the federal law, these state laws prohibit the payment, solicitation, or receipt of payments of any kind, whether direct or indirect in return for referrals, orders, or to induce a healthcare practitioner to make a referral or order. Although the Texas law has been infrequently enforced, it is punishable by civil fines up to $10,000 per day for each offense.[5]

The proliferation of these arrangements is driven, at least in part, by the belief the participants' risk is reduced by carving out the federal healthcare payers from the payment arrangements, the relative lack of state enforcement activity, and the ability for these relatively small arrangements to operate inconspicuously or "under the radar" by keeping the arrangement limited to a small number of physicians and contracted entities. Additionally, both the physician-owners of the MSOs and the contracted

entities stand to benefit financially from the arrangement. The owner physicians benefit by receiving compensation they would not otherwise receive for their referrals, and the contracted entities (i.e., the labs, pharmacies, or suppliers) benefit by securing a guaranteed flow of referrals or orders from the owner-physicians. For those willing to accept the consequences if the arrangement is investigated, it can be a "win-win" arrangement.

However, despite the low probability of having any individual arrangement involved in an investigation, the financial consequences to the parties if the arrangement is investigated and prosecuted can be substantial. As an example of the potential financial consequences for a Texas arrangement with a urine toxicology lab, if the fines are set at $1,000/day for each violation and the 10 physicians each make 10 referrals each business day for a year, the civil penalty for the MSO would be $26,000,000.

## Reducing the risks

So, how can healthcare providers identify potentially risky MSO arrangements? The primary indicators of a suspicious arrangement are:

- Investment in the arrangement is limited primarily to physicians who can refer to the contracted entity;
- The MSO's compensation for its services is a percent of revenues generated by the contracted entity; and
- The arrangement excludes federal healthcare business and does not otherwise comply with an applicable federal AKS safe harbor.

Risk associated with an MSO, even one that provides limited management services and relies on referrals from the owner-physicians, can be substantially reduced or even eliminated by structuring the arrangement to comply with the AKS personal services/management safe harbor. This safe harbor requires, in part, that the compensation paid to the MSO does not vary with the value or volume of services provided by the contracted entity. MSO arrangements that do not rely on referrals or orders from the MSO's owner-physicians to the MSO's clients and those that structure the MSO's compensation arrangement to comply with AKS personal services/management safe harbor are, in comparison, much more likely to be appropriate, low-risk arrangements.

1. 42 U.S.C. §1320a-7b
2. 42 U.S.C. §1395nn
3. Michael Addady: "U.S. Is Probing a Possible Half-Billion Dollar Health-Care Fraud" *Fortune Magazine*, February7, 2016. Available at http://for.tn/2aghFwr
4. See, Tex. Occ. Code §102.001.
5. Tex. Occ. Code §102.010.

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by Ann Meehan, RHIA

# Information governance: What is it? Why is it important to me?

» Trustworthy information provides "evidence" of activities that have taken place.
» Information governance provides infrastructure to manage and coordinate information.
» Key principles for information governance were developed by AMRA International.
» Information governance addresses the lifecycle of information: creation, use, and disposition.
» Compliance professionals have a seat at the information governance table.

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Information is growing at an unprecedented rate due to the increasing number of mobile devices, wearables, and other innovative technology. In fact, information has grown by approximately 90% in the past two years. By the year 2020, there is predicted to be 40 zettabytes of data, which is equivalent to 5,200 gigabytes per person.[1] And while technology is growing and information is increasing, only about 25% of information is truly valuable. It's mind-boggling. How does an organization manage it all?

Meehan

Compliance professionals understand that trustworthy information is vital to healthcare organizations that provide documentation of patient care and organizational assets. Trustworthy information provides the "evidence" of activities that have taken place, and healthcare organizations must ensure information is current, complete, accurate, consistent, and available. One cannot simply assume that the information is trustworthy. Strategic steps must be taken to ensure integrity of that information. In other words, information must be governed in order to guarantee that all aspects are formally managed and controlled. That governance needs to occur in a centralized manner across the entire organization.

## What is information governance?

The American Health Information Management Association (AHIMA) defines information governance (IG) as "an organization-wide framework for managing information throughout its lifecycle and supporting the organization's strategy, operations, regulatory, legal, risk, and environmental requirements."[2] Let's break this definition down into parts:

- **An organization-wide framework –** Information governance is a formalized program with a defined infrastructure that reports to senior leadership and upward to the governing body.
- **Lifecycle –** Information governance addresses every aspect of information

from its creation, use, reporting, and disposition.

- **Organization's strategy –** A key concept underlying information governance is to ensure that the goals of an IG program support the organization's strategic goals, mission, and values.
- **Regulatory, legal, risk, and environmental requirements –** Currently, information governance is not mandatory or required by any regulatory or accreditation agency. However, the goal of an information governance program is to fully support regulatory, legal, and other requirements that require trustworthy information. Therefore, an argument can be made that information governance is necessary to support healthcare requirements and obligations.

Most healthcare professionals are familiar with traditional health information management (HIM). The focus of HIM is the oversight and management of clinical information. IG takes this concept and expands it across all information and across the entire organization, whether it pertains to clinical, financial, human resources, vendor contracts, purchasing and supplies, etc. Information governance is not just a buzz word, but is a commitment that should be made by every healthcare organization.

Think of information as you would water flowing through the pipes of a community. Information flows throughout the healthcare ecosystem. And just like water, we all share and use it. We then must all be custodians of it, keeping it clean and consumable.

Governance of clinical and organizational information is required in support of:

- Quality patient care
- Accurate and appropriate reimbursement
- Regulatory requirements
- Ethical hiring practices
- Reduced operational costs through improved efficiencies
- Minimized risks
- Standardized auditing and monitoring processes

## Origins of information governance

To provide a brief summary of the origins of IG, let's go back to ARMA International. In 2009, ARMA International released the Generally Accepted Recordkeeping Principles (GARP®)[3] to put definitions around information concepts. There are eight information governance principles that are applicable to all industries. AHIMA, under the guidance of the Information Governance Task Force and IG Advisory Group, defined the eight principles for healthcare, now known as the Information Governance Principles for Healthcare (IGPHC™).

**1. Principle of accountability**

Each healthcare organization should designate a member of senior leadership as accountable for its information. A supporting committee or council should be formed with key stakeholders to ensure that governance activities are agreed upon and driven down through the organization. Ultimately, the governing body should oversee all activities around information creation, use, and disposition.

**2. Principle of transparency**

The healthcare organization should document all processes and activities around information and those documented processes should be verifiable and available to the workforce and others who need it.

**3. Principle of integrity**

The healthcare organization should ensure that information is reliable and authentic. This applies to both internally created

information as well as information received from outside sources.

**4. Principle of protection**
A solid information governance program must ensure protection from breach, loss, or theft and applies to clinical information, private information, and the intellectual property of the healthcare organization.

**5. Principle of compliance**
Healthcare organizations are obligated to ensure that all legal and regulatory requirements and organizational policies are met.

**6. Principle of availability**
Healthcare organizations must ensure that information can be retrieved and made available for use in a timely, efficient, and accurate way.

**7. Principle of retention**
Healthcare organizations must ensure that information is retained for the required time specified by state and federal laws. Information should be maintained for the time required and also for as long as it's needed for patient care and business purposes.

**8. Principle of disposition**
Once it is determined that information has been maintained for the time required to meet statutory requirements and is no longer needed for business purposes, information should be disposed of in an appropriate manner. Disposition may include destruction; a change in ownership or management, as in the case of an acquisition or merger; or transferred to another, permanent media.

Each of these principles is written to address the ongoing challenges that healthcare organizations are facing with information and to ensure that a formalized information governance program addresses each across the enterprise.

## Why is information governance important?

Do any of these terms cause you discomfort: hackers and ransomware attacks; breaches; sentinel events and hospital acquired conditions; duplicate medical record numbers; unlimited and ongoing storage of information and data? These are just a few examples of the types of real-world challenges that organizations face each day and that IG can work to resolve.

An enterprise-wide IG framework will positively affect the areas most often in question and under investigation. Compliance is one of several key stakeholders with a place at the IG table.

An IG program provides a centralized approach to the oversight and management of organization-wide information, but that does not mean that all areas where information is produced, used, reported, or dispositioned must report to an IG department. It does mean that all activities related to information should have a centralized oversight function.

In healthcare organizations today, there are many activities addressing the creation and use of information and the technologies that run behind the scenes. These activities typically occur in various business units and each business unit is tasked to manage its own processes and information. Unfortunately, there is not always a collaborative effort across the business units to ensure that information is managed under the same policies, definitions, and auditing processes. This results in inconsistencies, risk, questionable patient care, and bad business decisions. IG provides a single line of oversight for the organization.

## Getting started

If your organization does not have a formalized information governance program, there are several steps to get that discussion going:

- Learn as much as you can about information governance in healthcare. Articles are surfacing on the Internet and in-person, and virtual training options are available. Network with your peers!
- Educate senior leadership on IG and what it means to an organization. Start with your direct manager, and together determine the best senior leader to get involved.
- Download available tools and resources and share them with other key stakeholders.
- Discuss information governance as part of ongoing compliance meetings. Begin discussing IG in association with compliance issues being reported and discussed.
- Evaluate trends in compliance issues, identifying those where consistency in information management, policies, and practices would have prevented these issues.

A formal IG program ensures health information is effective and trustworthy. IG must be enterprise-wide and apply to all types of data and information.

1. Lucas Mearian: "By 2020, there will be 5,200 gigabytes of data for every person on Earth" *Computerworld*, December 11, 2012. Available at http://bit.ly/2a2x2Nq
2. American Health Information Management Association: Information Governance Principles for Healthcare (IGPHC™), 2014. Available at http://bit.ly/29RwxBM
3. ARMA International: Generally Accepted Recordkeeping Principles® 20140. Available at www.arma.org

by Anthony W. Minge, MBA and Matthew R. Streger, Esq

# Scrutiny of ambulance operations highlights need for compliance

» Increased attention on ambulance use demonstrates the need for compliance plans to include emergency and non-emergency ambulance operations.

» The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) has published voluntary compliance program guidance for ambulance suppliers.

» Ambulance billing should reflect the care provided by the emergency medical services (EMS) personnel, not the hospital diagnosis of the patient.

» Training for billing personnel and EMS providers on documentation and billing for ambulance services is often inadequate.

» Ambulance suppliers should conduct regular claims reviews to ensure problems are identified and corrected prior to an audit.

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In 2015, nine Florida hospitals and one ambulance service paid $7.5 million to settle a case involving accusations of billing Medicare for unnecessary ambulance transports. According to media reports, the hospitals and ambulance company were accused of using ambulances to take people home from the hospital when a taxi or family member's car would have been appropriate instead.[1] In addition to the fines, the ambulance service entered into a corporate integrity agreement with U.S. Department of Health and Human Services (HHS).

Rather than an aberration, this story is part of a trend.

Not long after the case was settled, the HHS Office of the Inspector General (OIG) released a report entitled, "Inappropriate Payments and Questionable Billing for Medicare Part B Ambulance Transports."[2] In a review of ambulance billing claims over a six-month period in 2012, investigators determined that 20% of ambulance providers had "questionable" billing practices, and that Medicare paid tens of millions of dollars for ambulance transports that were not justified.

Minge

Streger

The OIG report concluded that these billing practices pose "vulnerabilities to Medicare program integrity," and made several recommendations, including enhanced monitoring of ambulance billing. As the Florida case shows, even hospitals that do not own or operate an ambulance service are at risk. In that case, the hospitals were accused of benefiting from improper ambulance utilization, because they were able to discharge and admit patients more quickly.

The potential fraudulent practices described by HHS include:

- Improper transport of individuals where other means of transportation are more appropriate,
- Medically unnecessary trips,
- Trips claimed but not performed,
- Misrepresentation of the transport destination to make it appear as if the transport was covered,
- False documentation,
- Billing for each patient transported in a group as if they were transported separately,
- Upcoding from basic life support (BLS) to advanced life support (ALS) services, and
- Payment of kickbacks.

In addition to increased scrutiny from regulators, unnecessary ambulance transports have also become a popular target in the media. Recent reports have questioned the billing practices of services that provide both 911 response and non-emergency transports.[3] With the public, private insurers, and HHS looking for ways to reduce costs, it appears that the use of ambulances will be a prime target.

## What hospitals need to know

For many hospitals, ambulance transport constitutes such a small part of overall operations that it is often overlooked. But, the increased scrutiny on billing practices should raise concerns for every hospital executive, especially those that own or operate ambulance services. More than ever, hospitals need to consider ambulance and other transport services when creating and maintaining compliance plans. The OIG has voluntary guidelines for ambulance compliance programs, published in the Federal Register in 2003.[4] The guidelines for ambulance providers are similar to those for other healthcare organizations, but reiterate the importance of including ambulance programs within a hospital's compliance efforts. There are, however, some specific aspects of compliance for ambulance providers that might be unknown to other hospital or healthcare compliance officers.

### Compliance programs

It has become common place for hospitals to maintain compliance programs, but many often forget to include the ambulance service in the plan or to educate the ambulance billing representatives or contractor on plan specifics. Compliance plans must be regularly reviewed and updated, and the leaders of the hospital-based ambulance service must be periodically trained on the plan to ensure they are up to date on these changes. Even if an organization contracts with an outside billing service or an outside ambulance provider, it is the hospital's responsibility to verify the compliance and training efforts implemented by their partners.

Critical elements of an EMS compliance program include:

- A risk analysis of program status,
- Written policies and procedures,
- Initial and ongoing training for employees and partner agencies,
- Regular internal review of documentation practices and billing procedures, and
- External validation of documentation practices and billing procedures.

### Ambulance billing

Billing for ambulance services differs from billing for in-hospital care and other outpatient services. Like other areas of healthcare, such as dialysis or durable medical equipment, transport services have specialized

**Table 1: Levels of Service**

| Basic life support (BLS) |
|---|
| **Emergent** |
| **Non-Emergent** |
| **Advanced life support (ALS)** |
| **Emergent** |
| ▶ALS1: The administration of at least one medication |
| ▶ALS2: The administration of at least three medications and at least one of the following: |
| • Manual defibrillation/cardioversion |
| • Endotracheal intubation |
| • Central venous line |
| • Cardiac pacing |
| • Chest compression |
| • Surgical airway |
| • Intraosseous line |
| **Non-Emergent** |
| **Specialty care transport (inter-facility transfers)** |

billing processes. Knowledge of rules and regulations specific to billing for reimbursement of ambulance service is either not known or is overlooked by centralized billing offices where representatives may have the responsibility of billing for a variety of services.

One of the biggest mistakes ambulance providers make is inappropriate assignment of service levels. For ambulance transports, Medicare currently reimburses by the level of services required: basic life support (BLS), advanced life support (ALS), or specialty care transport (SCT). Within ALS, two categories, ALS1 and ALS2, differentiate between patients, based on multiple factors, including but not limited to patient condition, the number of invasive procedures performed or medications administered. Furthermore, both BLS and ALS have emergent and non-emergent billing designations for billing that may require additional certification to meet the criteria for medically necessary provision of service in those non-emergent instances. With minimal exception for instances that allow for the billing of ALS emergent assessment, these categories are to be determined by the level of care required by the patient's condition at the time of transport. Table 1 is a very simple outline of the categories. For a more complete description, see the Medicare Benefit Policy Manual, Chapter 10.[5]

Another common mistake is the use of the patient's inpatient diagnosis for coding and determination of the billing rate. A patient who was in the hospital for several days with a cardiac problem may seem like an obvious choice for an ALS transport but, at the time of discharge, they often require only BLS care. These determinations must be made by reviewing the documentation from the ambulance transport, not the hospital inpatient records.

SCTs are reserved for inter-facility transfers in which the patient requires the services of a specialist, such as a registered nurse, respiratory therapist, physician, or paramedic with additional training. Not all inter-facility transfers meet this criteria. Additionally, not all transfers to a higher level of care are emergent in nature, which is another common misconception resulting in billing errors.

**EMS provider documentation**

Most education for emergency medical service (EMS) providers, including both emergency medical technicians (EMTs) and paramedics, focuses on the provision of emergency care in response to 911 calls. Documentation is a very small portion of the training, typically centered on liability and transfer of care, but not billing practices. Many EMS practitioners have no concept of how their services are billed, or how what they document can impact reimbursement or open up an agency to allegations of fraud. Training providers to ensure they accurately and appropriately document care in all transport settings is critical to any hospital-operated ambulance service's compliance program.

> … it is almost a question of when, not if, a service will be audited.

For example, in addition to a physician's certification of medical necessity for a patient to qualify for scheduled transportation, the EMS providers may also need to document bed-confined status of the patient confirming that they are:

- Unable to get up from bed without assistance,
- Unable to ambulate, *and*
- Unable to sit in a chair and wheelchair.

Although the physician's certification is required, it does not provide the final determination of medical necessity and the EMS providers who conduct the transport must also document these requirements. And although drop-down fields or check-boxes help ensure completeness, written documentation of these elements in the report's narrative is also beneficial.

With electronic records, organizations can also create automated systems that flag reports with missing critical information, such as zip codes, Social Security numbers, or signature forms. Often the fields that are essential for billing practices can be set as required fields, even prior to submission of the record, so the EMS provider must complete them in order to close and submit their chart. This can assist with compliance and improve time from transport to submission of the claims for reimbursement.

**Prepare for an audit**

With the heightened scrutiny on ambulance services, it is almost a question of when, not if, a service will be audited. A compliance program should put a high priority on maintaining a complete and secure records system, with appropriate access to dispatch records, patient care reports, billing records, patient signature forms, and physician certification statements. Billing representatives need access to each of these elements to submit accurate claims. When an audit happens, you must be able to provide those records in a timely and orderly fashion.

Maintaining a consistent claims review process at all times will assist in preventing an audit by uncovering unknown issues. It is much easier to identify and correct a problem (e.g., not collecting patient signatures) when it occurs, rather than trying to explain it months or years later to an investigator.

**OIG exclusion list**

Checking the HHS Inspector General's exclusion list on a regular basis is also critical—and that means more frequently than once a year. Often EMS practitioners work multiple jobs, and many are part-time employees with healthcare organizations, such as nursing homes or other EMS services, making it even more likely that an event might occur that places them on the

exclusion list. In these instances, an ambulance provider that employs them may not know they are excluded, unless they are regularly checking their employees against the published list. In some cases, services have owed thousands of dollars after it was discovered that an individual who was involved in the care and transport of dozens of patients had been on the exclusion list. It is important to check employees involved in the dispatch and billing processes as well.

## Conclusion

A robust compliance plan that is regularly reviewed, updated, and communicated with hospital-based ambulance providers and outside partners is the heart of a healthy revenue cycle management process for any ambulance program. Although ambulance operations may only make up a small proportion of operating costs and revenue for a hospital system, recent attention from the media and regulators makes compliance critically important in all emergency and non-emergency ambulance operations.


1. John Carreyrou: "Florida Hospitals Agree to Settle Medicare Fraud Allegations" *Wall Street Journal*, April 30, 2015. Available at http://on.wsj.com/2acetYQ.
2. HHS Office of the Inspector General: "Inappropriate Payments and Questionable Billing for Medicare Part B Ambulance Transports" September 2015. Available at http://bit.ly/2ayf83s.
3. Elizabeth Rosenthal: "Think the E.R. is Expensive? Look at How Much it Costs to Get There" *The New York Times*, December 4, 2013. Available at http://nyti.ms/2angzDA.
4. Federal Register Vol. 68, No. 56; March 24, 2003: OIG Compliance Program Guidance for Ambulance Suppliers. Available at http://bit.ly/2aKUf46.
5. Medicare Benefit Policy Manual, Chapter 10 is available at http://go.cms.gov/14j4wQB

by Daniel Fabbri, PhD

# Trade-offs of EMR access monitoring

» Open-access environments are common across electronic medical record (EMR) systems despite their associated privacy risks.
» Privacy officers must monitor EMR accesses for inappropriate use.
» Manual EMR auditing techniques cannot scale to meet the needs of modern healthcare, necessitating automated monitoring systems.
» When selecting an EMR monitoring system, privacy officers should consider system responsiveness, false positive rates, and monitoring coverage.
» Machine-learning systems can leverage clinical context to reduce false positives, decreasing the time to complete access audits.

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Substantial discussion has occurred regarding the need to monitor accesses to electronic medical record (EMR) systems to detect inappropriate use, such as snooping and identity theft. The need for efficient and effective EMR monitoring systems is apparent, given the increasing number and magnitude of breaches.[1] However, understanding when and how often monitoring solutions should be executed presents many trade-offs.


Fabbri

Generally, the timing and frequency of EMR access monitoring solutions can be broken down into three classes: "real-time," "near real-time," and "reactive." Real-time monitoring, as its name suggests, analyzes accesses and flags suspicious activities as they occur. Near real-time monitoring analyzes accesses intermittently after some delay (e.g., every 24 hours). Reactive monitoring analyzes accesses either when a complaint is filed or after long delays (e.g., monthly or quarterly audits).

## Monitoring isn't easy

Hospitals must monitor accesses to protected health information (PHI) in their EMR systems and ensure data are used only for treatment, payment, and operations. Laws and organizational policies do not permit curious or snooping accesses.

The challenge of ensuring appropriate use is complicated by the fact that most hospitals deploy "open-access environments," in which authenticated employees (i.e., employees who have presented valid credentials) can access any patient's record in the system, even if they are not treating the patient. Open-access environments exist across the major EMR vendors.

The choice to deploy an open-access environment instead of fine-grained access controls is often based on the need for caregivers to access information in emergencies. For example, if an EMR blocks access to a caregiver, the caregiver will not be able to identify the patient's medication allergies and, if given in an acute setting, certain medications may cause harm or even death. Hospitals therefore

have traded assured patient privacy for caregiver utility and efficiency.

Additionally, fine-grained access controls are difficult to setup and update over time for medium and large organizations with rounding physicians, medical students, and residents who treat thousands of patients per day. To provide a middle ground, some EMR vendors provide access escalation systems that require the user to escalate their permission and document their reason for access. Unfortunately, these systems often are narrowly deployed to a small subset of patients and have been known to require unnecessary escalations for caregivers involved with patient care. This is further complicated by the trend toward integrated healthcare, which produces evolving patient care teams that can span multiple sites and departments.

## Privacy officer workflows

Privacy officers are responsible for identifying and reporting breaches. Hospitals, by law, must record every access to their EMR for years, in case of an access log request. The challenge is monitoring these large logs. EMRs typically record millions of accesses per week, if not per day, preventing manual auditing approaches from scaling. In contrast, privacy officers often deploy simple flags to detect high-risk behavior. When high-risk behavior occurs, such as employees accessing records of VIPs, co-workers, patients with the same last name, or neighbors, the privacy officer is alerted and manually reviews the access.

The process for reviewing a flagged access involves going through the accessed patient's medical chart to determine if the accessing employee had a clinical or operational reason for access. This manual process takes time, ranging from minutes to days. Even worse, most manual reviews result in false positives. For example, false positives can occur when accesses are flagged because the patient and employee have the same last name, but the accesses are actually appropriate due to a scheduled appointment. These false positives waste privacy officer time and reduce the resources available to investigate actual breaches.

## Tips for selecting monitoring systems

Several aspects of monitoring systems must be understood before implementation. When selecting a monitoring system, consider system responsiveness, false positive rates, and monitoring coverage. Privacy officers can work with their hospital administration to select the system most appropriate for their hospital, taking into account their EMR database size and auditing needs.

### System responsiveness

Real-time monitoring systems are able to react quickly to suspicious activity and can notify privacy officers seconds after an access has occurred. Responsiveness is valuable when VIPs are in the hospital and the time-to-react is imperative. However, it is important to understand the types of inappropriate access real-time monitoring systems miss and the mistakes they can produce.

### False positive alerts

Given the need to respond quickly, real-time systems often look at the access in isolation, without considering clinical context. Even if the real-time monitoring system could incorporate all clinical context in its decision-making process, the clinical context may not exist in the EMR at the time of access. Physicians regularly see numerous patients, give verbal orders, and later document their care plan (sometimes days later). As a result, real-time monitoring systems can produce tremendous numbers of false positive alerts that could have been filtered away had the system waited (e.g., the doctor and the patient have the

same last name, but the doctor did not write a note about the patient until after her shift). These false positives directly result in wasted privacy officer effort, and can be overwhelming to a privacy program.

**Coverage**

Additionally, it is important to consider the types of breaches that real-time systems are capable of detecting. If the real-time monitoring system only uses previously specified flags, then the real-time system will never be able to identify other types of inappropriate use. For example, if you don't have an "ex-girlfriend flag," you will never be able to catch it.

Unfortunately, most systems only allow users to audit high-risk accesses, a subset of the entire access log. For example, some monitoring systems are set up to flag accesses to co-workers' records, or patients and employees with the same last name or who live in the same zip code. If none of these characteristics are applicable to a given access, the access will not be reviewed. The proportion of EMR accesses to be monitored will vary between monitoring systems. It is up to the privacy team to identify the balance between monitoring coverage and privacy officer burden.

Near real-time monitoring systems are delayed in their ability to alert on suspicious activities but are able to incorporate more clinical context than real-time systems. The addition of clinical context drastically reduces false positive alerts, because the clinical context can be used to filter away accesses that occur for appropriate reasons. Moreover, by auditing for both appropriate and inappropriate accesses, the monitoring coverage drastically increases as the system can analyze more types of access. If privacy officers are overburdened by the number of manual accesses they must review, the ability to automatically audit and filter appropriate accesses using clinical context can mean the difference between practical management of potential breaches and drowning in alerts.

Reactive monitoring systems have many of the same benefits of near real-time systems, but suffer from long detection delays. Specifically, the system can utilize the complete clinical context to understand and identify suspicious activity, again resulting in broader monitoring coverage than real-time systems. However, breaches may have occurred for months without detection.

Finding the optimal access monitoring delay (i.e., real-time, near real-time, or reactive) for an organization can be informed by considering responsiveness, false positive rates, and monitoring coverage. Consider these factors when developing your EMR access monitoring plan.

## Filtering appropriate behavior

One of the main benefits of near real-time and reactive monitoring systems is their ability to incorporate clinical context into their decision-making processes and filter away appropriate accesses. For example, accesses that occur because of an appointment should be filtered away and not flagged—even if the patient and employee have the same last name. Defining how to accurately filter away appropriate behavior has been a challenge for many years.

Recent published and peer-reviewed research has developed machine-learning methods to address this problem.[2] These methods can intuitively filter away appropriate accesses by identifying connections between a patient and the employee accessing the patient's record. For example, an appointment can connect a patient and employee and serve as the explanation for an access. Instead of manually specifying every explanation in an EMR, such explanation-based auditing systems can infer relationships from a hospital's data, display them to a privacy officer for approval, and once approved, apply them to

future accesses. Using this approach, machine-based learning systems have been shown to filter more than 95% of accesses, so privacy officers can focus on suspicious behavior.

## Conclusion

As EMRs continue to scale to keep up with modern healthcare, there is an ever-growing need for efficient and workable auditing approaches. These approaches must take into account emerging privacy laws, the inherent burden on privacy teams, and the unique needs of each hospital.


1. Carolyn Y. Johnson and Matt Zapotosky: "Under pressure to digitize everything, hospitals are hackers' biggest new target" *The Washington Post*, April 1, 2016. Available at http://wapo.st/2ayUL9w
2. Daniel Fabbri and Kristen LeFevre: "Explanation-Based Auditing," *Proceedings of the VLDB Endowment* 2011; Vol. 5, No. 1: 1-12. Available at http://bit.ly/2agi1n3

by Kathryn Evans

# Talking trash: Ensuring proper waste disposal

» Proper waste disposal ensures staff, environmental, and business safety.
» Identify the types of waste you produce.
» Develop a waste disposal plan for each type.
» Make disposal easy, convenient, and safe.
» Provide adequate staff training annually and at orientation.

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By their very nature, healthcare organizations generate a lot of waste. Beyond regular trash, there are regulated medical waste (e.g., needles, bloody bandages), hazardous pharmaceutical waste (e.g., unused medications, empty asthma inhalers), and secure documents (e.g., those that include sensitive patient health information that must remain private). Healthcare organizations of all sizes and types have to appropriately handle the diverse waste streams present in their facilities and follow the relevant disposal requirements. Unfortunately, staff often get confused, throwing out empty medicine bottles in regulated waste bags or placing a needle in a pharmaceutical waste container. This introduces a host of risks.


Evans

## The dangers of improper disposal

When organizations do not consistently follow waste disposal standards, there can be personal safety, environmental safety, and business security ramifications.

### Personal safety

Poor disposal can expose staff to dangerous chemicals, pathogens, and other items that could cause harm. For example, if staff don't use the correct personal protective equipment when throwing away needles and items saturated with blood or body fluids, they are at risk for exposure to dangerous pathogens. Similarly, if needles are not thrown away in sharps containers, they can poke through trash receptacles and cause needle sticks. Due to these risks, the Occupational Safety and Health Administration (OSHA)[1] requires facilities to segregate their regulated medical waste from regular trash.

### Environmental safety

A large body of evidence points to increasing levels of dangerous minerals and chemicals—such as mercury—in our clean water supply.[2] Some of this contamination is caused by inappropriate hazardous pharmaceutical disposal. For instance, when organizations put pharmaceuticals into sharps containers for regulated medical waste, they make it impossible to treat the drug waste in a manner that eliminates its potential to harm the environment. Even more serious is when

staff toss hazardous chemicals into the regular trash. In this case, the negative environmental effects are nearly immediate, because the chemicals aren't treated before disposal.

**Business security**

Organizations must have a reliable process for dealing with sensitive information. Without a secure document destruction plan, as well as a method for disposing of hard drives, a healthcare organization can increase the likelihood of HIPAA compliance lapses or data security breaches.

## Getting a handle on what you have

A key first step in improving waste compliance is to fully appreciate the types of waste your organization produces. As mentioned earlier, most facilities will have regulated medical waste. This includes any items that are saturated with blood or body fluids (as defined by OSHA and state regulations), needles or other sharps that have been used on a patient or contaminated with blood or body fluids, and pathological and microbiological wastes. Regulated medical waste is treated most commonly through autoclaving and/or incineration. Normally it is easy for a facility to identify this type of waste, and organizations should use red bags and sharps containers for placement of the material prior to disposal.

Organizations also tend to have some degree of hazardous waste. There are many types as defined in the Resource Conservation and Recovery Act of 1976,[3] which outlines and describes in detail what constitutes a hazardous waste.

Pharmaceuticals can be considered hazardous if a chemical contained in the drug is dangerous or if the chemical combination exhibits hazardous characteristics. Due to the volume and variety of pharmaceuticals, it can be difficult for organizations to comprehensively quantify their hazardous waste.

## Making it easy to do the right thing

After identifying what waste streams are present, an organization must create a disposal plan for each type of waste. The best plans incorporate clear-cut disposal pathways, meaning they make the process straightforward and convenient. For example, there are hundreds of thousands of different pharmaceuticals, and it isn't practical to think that a busy healthcare employee would know all the various types and only throw out the hazardous ones in the hazardous waste bin. Instead, an organization can have an overall plan for pharmaceutical waste that over-classifies and treats all drugs in a manner that is completely compliant. This helps employees perform their jobs quickly and safely.

As for regulated medical waste, having sharps containers in the right place, at the right height, and in the right style is essential to reduce the risk of exposure.

As for regulated medical waste, having sharps containers in the right place, at the right height, and in the right style is essential to reduce the risk of exposure. If a sharps container is too far away or too high, causing the healthcare professional to dispose of a needle by reaching, there is a danger. In addition, if the sharps container is too hard to see through (sometimes the lid configuration makes it difficult to tell if the container is full) healthcare professionals could incur a needle stick.

For document destruction, it is essential to have secure bins available at key areas within the office. Make sure they are not difficult to get to and are clearly marked so staff can dispose of sensitive information quickly and efficiently.

## Avoiding staff confusion

Training is central to this mission. You can have the best disposal plans in the world, but if you don't take the time to train staff on how to follow them, you still open yourself up to risk. Most organizations provide waste management training at least annually and when new employees join the organization. Online trainings can be beneficial, because they are convenient and staff members can fit them in easily in between other activities. A key part of this training should be requesting input from the staff. They might have great suggestions on container placement or other ways to effect proper disposal. Organizations should also provide reminders to staff throughout the year, such as posters placed in key areas.

## As easy as one, two, three

Although the types of waste streams and the concerns around them can be complex, ultimately, consistent compliance comes down to three essential things: (1) identifying your waste streams, (2) having a plan and system for disposal, and (3) training your staff. Organizations that embrace these strategies will not only improve compliance, but preserve the safety of their staff and environment as well.

1. U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) website: https://www.osha.gov/
2. U.S. Environmental Protection Agency (EPA): Drinking Water Contaminants – Standards and Regulations. Available at http://bit.ly/2axkY6S
3. EPA: Resource Conservation and Recovery Act (RCRA) Laws and Regulations. Available at https://www.epa.gov/rcra

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HEALTH CARE COMPLIANCE ASSOCIATION

by Michael Maciol, MD; Wendy Brizer-Maciol MPH, CHC; and Sabreen I. Abdullah

# Launching and maintaining an effective compliance program in long-term care

» A long-term care (LTC) compliance program should be developed in accordance with the eight elements of compliance.

» The LTC compliance officer typically has multiple responsibilities and may need to juggle several hats in order to ensure compliance program effectiveness.

» There are many high-risk areas in the LTC setting, which will need to be prioritized when establishing the annual risk assessment.

» Compliance education on hire/engagement and a minimum of annually for employees, board members, volunteers, and vendors is essential to promoting a culture of reporting potential compliance concerns/violations.

» Disciplinary policies will need to be in place to assist in addressing compliance violations.

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Since March 2013, it has been mandatory for long-term care (LTC) facilities to have a compliance program in place. When it comes to developing and maintaining an effective compliance program, in fact there is no cookie-cutter, one-size-fits-all program. Understanding this will help you establish the foundation of your compliance program. The eight elements required by New York's Office of the Medicaid Inspector General (OMIG)[1] should be implemented as a standard. Even though these are only guidelines, it's the facility's responsibility to adhere to them.

Without the support of senior management, implementing and maintaining the program could pose a challenge. Equally important is to engage employees at all levels in the compliance process and make them feel that their feedback and participation is essential. The success or failure will be dependent on the compliance officer who will have the leading role. The following highlights methodologies for compliance with each of the eight elements.

Maciol

Brizer-Maciol

Abdullah

## 1. Develop policies and procedures

Policies and procedures that reflect compliance guidelines will need to be developed. These should be reader friendly and understandable by all levels of staff. They should be available on the facility's webpage to be accessible for all. Departmental policies and procedures specific to each department will need to be available as well. These should be updated on an annual basis, if needed, or additionally if changes in regulatory requirements occur.

## 2. Designate a compliance officer and committee

An individual should be designated to assume the role of compliance

officer. The individual will preferably not have multiple responsibilities and will serve only as a compliance officer, which can make a difference in terms of a potential conflict of interest and truly dedicating the time to ensure compliance with the eight program elements. LTC compliance officers should share some universal characteristics (e.g., being credible, attentive, a motivator, a collaborator, a strategic thinker, a good investigator).

Additionally, skills specific to LTC are preferable, including familiarity with the specified regulations, guidelines, and day-to-day operations of this unique setting. This knowledge will assist with ongoing auditing and monitoring of some key areas of focus—Medicare and Medicaid reimbursement, documentation, Minimum Data Set (MDS) accuracy, credentialing, Quality Measure data, bed hold, advance directives, use of anti-psychotic medications, and multi-disciplinary care planning documentation. Staying current with the ever-changing regulations (e.g., e-prescribing, transition of Medicaid nursing home residents into Managed Care, payroll-based journals, LTC regulations) can be a challenge for the compliance officer.

LTC compliance officers need to be visible. This may include displaying their picture and phone number throughout the facility, conducting onsite audits or training, attending management meetings, and coordinating Compliance Committee and workgroup meetings. It is essential to reinforce that the compliance officer is there to help proactively and shouldn't be called upon solely when a potential violation exists. Staff are often intimidated by reporting their concerns to the compliance officer and need to be encouraged to come forward willingly, without fear of retaliation.

A Compliance Committee should be interdisciplinary and composed of representatives from senior management. Meetings should be held a minimum of quarterly or as deemed necessary. It is not the compliance officer's responsibility to speak for the entire meeting. Participation should be encouraged. An outline should be provided to enhance the specific reporting requirements for the management team to present at each meeting. Highlights of committee discussions should be reported to the board of directors at designated frequencies. Compliance workgroups including all levels of staff can be productive methods for gaining feedback and identifying potential compliance issues.

### 3. Training and education

Compliance education is not only for employees, but for board members, volunteers, per-diem contract staff, student interns, and vendors. It is an opportunity to use your creativity and foster the compliance learning process. It is difficult attempting to keep a crowd awake after lunch, trying to teach them about compliance and HIPAA. It is essential to develop fun, practical educational methodologies for learning. This can include reviewing *Compliance Weekly News*[2] scenarios and the OIG most-wanted fugitive lists. That always keeps the momentum going. Ongoing training is mandatory to ensure that the staff is kept up to date with compliance guidelines and regulations.

### 4. Lines of communication

Fostering a culture of open communication with staff is the key to ensuring that potential violations or other issues are reported and investigated promptly. Having an open door policy is great for those who feel comfortable and, additionally, a confidential and anonymous hotline should be established either through a third-party vendor or internally. Retrieval and follow-up of all reports and calls in a timely manner will encourage good faith reporting. It is essential that ongoing reinforcement for reporting be provided

through staff education and increased awareness. Aggregation of hotline calls and investigations will need to be done to identify trends and track concerns by category.

### 5. Disciplinary policies to encourage good faith reporting

Organizations/facilities should have clear and specific, well-publicized disciplinary policies for employees to adhere to regarding non-compliance with policies and the Code of Conduct. Disciplinary action should be based on the specific infraction and be administered on a fair and equitable basis, according to the seriousness of the violation. Enforcement of disciplinary action depends on the type and severity of the violation. Employees should be made aware that disciplinary action could be taken for failure to report a potential compliance violation.

### 6. Identification of compliance risk areas

An annual risk assessment will need to be completed to determine high-risk areas and facilitate the development of an annual work plan. It can be conducted by querying the administrative staff regarding high-risk areas that they have identified during the year, reviewing survey deficiencies and trends in complaints or investigative findings, and OMIG and OIG hot spots pertinent to the LTC setting. The work plan should be prioritized for the four quarters and be realistic to the number of accomplishable audits. Additional topics may have to be prioritized during the year. The compliance officer should determine which areas require auditing versus monitoring. The compliance officer, facility staff, or a third-party vendor should be engaged to assist with the auditing process. All audit findings and plans of correction will need to be submitted to the compliance officer.

The rewards of managing an effective compliance program will be reaped when you conduct an annual assessment and identify that you are relatively satisfied with your compliance achievements for the year, or when OMIG arrives for a compliance program audit and the results are successful.

The following topics for review may be considered high-risk for the LTC setting.

**Physician documentation**

When an auditor reviews medical records and comes across monthly electronic notes that are identical to the last, this will red flag the physician for the possibility of billing improprieties. Facilities should discourage draft notes and electronic copying and pasting. A medical note is a snapshot of how that patient is doing at that particular time. Coming back at a later date to complete a note will cause the auditor to suspect that there may be an impropriety when that medical note does not correspond with the nursing note that was written on that same date. Therefore, the physician must document all changes that have occurred since the last visit by quoting what the patient's complaint was on the specified day and making appropriate changes in the treatment plan. This will substantiate a face-to-face encounter by the orders that have been written, dated, timed, and picked up by the nurse.

As per Medicare and Managed Care requirements, a physician can only bill for a patient visit monthly or if there is a change in the patient's medical condition. For example, it would be acceptable for the physician/facility to bill if an MD is called to see a patient who has developed an acute medical condition. The MD prescribes a medication and documents in the progress note, "Will follow up in 48 hours to see if the treatment is effective." The MD has documented a reason for follow-up. This would be acceptable billing. An MD reviews a lab report and documents in the chart that the lab is unchanged and that no change is indicated. This is good medical

practice, but the MD is not allowed to bill for their time. The time and documentation must accurately reflect the exam. It is essential that all lab and x-ray reports provided are checked and reviewed before being signed off or co-signed. The physician will need to document their acknowledgement of the note.

**Physician credentialing**
The physicians' credentials are required to meet the standards of the state licensing agency, as well as the specified facility. A standard process must be in effect to ensure that all credentials meet the requirements on hire and upon re-credentialing every 2 years. Tracking of document expiration can be done internally or through use of an outside vendor. A Credentialing Committee must review the physician's credentials to ensure that they meet the mandated requirements. Audits should be done periodically to determine compliance with credentialing requirements.

**Documentation to support rehabilitation services**
A nursing home patient/resident cannot receive rehabilitation services without a physician's order and licensed therapist's evaluation. Documentation must meet the requirements for regulatory agencies and the frequency of progress notes varies by payer source. Billing must be reviewed prior to submission and include a verification of compliance with documentation requirements.

**Care planning process**
An interdisciplinary team needs to participate in the process and determine the optimum plan of individualized, measurable, and realistic resident-specific goals. Care plans must be updated on a quarterly or annual basis or if a significant change results. Residents and/or family members will need to be invited to participate in the care planning process according to facility policy. Documentation of the individualized plans of care by the team will need to be completed accurately in order for the MDS assessment to be completed.

**Advance directives**
Assessment and documentation of advance directives is essential to ensure that the residents and/or family members/designated representatives' preferences are met. Failure to follow New York State Regulations and a facility's policy can result in negative resident/patient consequences, and serious and increased liability to a facility.

**Anti-psychotic drug monitoring**
Anti-psychotic drug monitoring is essential by the medical staff. There are designated schedules for monitoring of these medications, and efforts to discontinue and/or wean and use less pharmacologic alternatives must be attempted. Additionally, there are testing and assessment protocols for residents receiving these medications, which vary from facility to facility.

**MDS documentation**
The LTC Minimum Data Set (MDS) is a standardized, primary screening and assessment tool of health that creates the foundation of the comprehensive assessment for all residents in a Medicare and/or Medicaid-certified LTC facility. The accuracy of the MDS assessment plays a critical role in that it is related directly to resident care, reimbursement, Quality Indicator data, and subsequent care of the resident. If the MDS is completed inaccurately, there is the potential for billing issues, which may result in potential compliance violations.[3]

### 7. A system for responding to compliance issues

Response to all potential complaints and violations should be provided promptly. Once an investigation has been completed, the results

should be discussed with the complainant (as applicable). Specific findings should be addressed and plans for correction developed. Confidential details of the investigation do not require disclosure.

Corrective action will need to be taken, based on the specific issue. A root cause analysis should be conducted to determine why the incident or concern arose, and then a plan for remediation will be developed. In-service education is usually the initial remedy depending on the violation; however, disciplinary action may be taken, up to and including termination.[4]

### 8. A policy of non-intimidation and non-retaliation

A policy and procedure must be developed regarding non-intimidation and non-retaliation. This should include a process for encouraging good faith reporting for individuals who make all efforts to bring forth potential compliance concerns and participate in investigations. This policy should be included in the organization's code of conduct and reinforced during new hire and annual orientation or additionally, if warranted.[5]

### Summary

This article is a supplement for a LTC compliance program, which emphasizes the importance of the elements of a compliance program, as well as areas of focus. It is important to remember that the challenges faced in each facility differ and must be assessed on an individual basis, from the tone at the top to the cooperation provided by all levels of staff. Over the last 15 years, Compliance has expanded beyond a program into a profession. Nothing replaces the experience of working in the LTC setting and being witness to the evolution of a compliance program.

1. New York State Office of the Medicaid Inspector General website. Available at http://on.ny.gov/2a7dSDU
2. Subscribe to HCCA's *Compliance Weekly News* at http://bit.ly/29XhGua
3. Centers for Medicare and Medicaid Services: MDS 3.0 for Nursing Homes and Swing Bed Providers. Available at http://go.cms.gov/2auuHvG
4. Steve Vernon blog: "Long-Term Care: What are the real risks?" *CBS MoneyWatch*, July 19, 2010. Available at http://cbsn.ws/2a4JOIc
5. Terese Farhat: "Mandatory compliance programs for nursing facilities" *McKnight's*, December 4, 2012. Available at http://bit.ly/2aCz0Bi

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## A new era of laboratory fraud, Part 1: Operation LabScam redux

*Douglas E. Roberts, Marc S. Raspanti, and Pamela Coyle Brecht (page 22)*

- The Biodiagnostics cases have brought lab fraud back into the news.
- Twenty years ago, Operation LabScam returned more than $800 million to taxpayers.
- HHS-OIG targeted questionable billing practices, upcoding, and kickbacks to physicians.
- Large settlements and corporate integrity agreements were supposed to deter fraud.
- Fines paid by labs are some of the largest settlements ever recovered under the False Claims Act.

## Reporting quality data: Getting it right

*Lynn Asher (page 29)*

- Content experts should be readily available to answer questions.
- Flow diagrams are useful tools for understanding the reporting process.
- Organizations are responsible for confirming timely reporting by vendors.
- Interviews are a key component of the audit process.
- Unintentional errors may be introduced into data by electronic systems.

## Medical records access: Are you following the rules?

*Elizabeth A. Kastner and Jessica Hudson Bechtel (page 35)*

- A HIPAA authorization is not required when an individual requests access to his/her own records.
- An individual may direct records to a third party pursuant to a request for access.
- Fees must be based on an actual, average, or flat cost approach.
- Fees may only include labor, supplies, and postage costs.
- HIPAA overrides a state law that authorizes higher fees.

## Creating an ambassador program for continuing compliance training

*Maggie Perritt (page 43)*

- Offering compliance training for associates will provide opportunities for achieving CHC designation, which otherwise may be unattainable.
- Developing a flexible platform to help your associates obtain certification takes thought and creativity.
- Building compliance ambassadors in your organization spreads the word that compliance is a resource to help your business succeed.
- Fostering positive compliance training for personal development reinforces a strong culture of compliance.
- Ingraining compliance as part of your core business model and strategic vision will advance associate adoption.

## Not all management service organizations are created equal

*Mary Jean Geroulo (page 49)*

- Management service organizations (MSOs) are useful tools for management of healthcare entities.
- Physician-owned MSOs can be structured to comply with the law.
- MSO arrangements have also been used to disguise payments for referrals.
- Limited service MSOs and percentage fee arrangements are red flags.
- Excluding federal healthcare payers does not eliminate the risk.

## Information governance: What is it? Why is it important to me?

*Ann Meehan (page 54)*

- Trustworthy information provides "evidence" of activities that have taken place.
- Information governance provides infrastructure to manage and coordinate information.
- Key principles for information governance were developed by AMRA International.
- Information governance addresses the lifecycle of information: creation, use, and disposition.
- Compliance professionals have a seat at the information governance table.

## Scrutiny of ambulance operations highlights need for compliance

*Anthony W. Minge and Matthew R. Streger (page 58)*

- Increased attention on ambulance use demonstrates the need for compliance plans to include emergency and non-emergency ambulance operations.
- The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) has published voluntary compliance program guidance for ambulance suppliers.
- Ambulance billing should reflect the care provided by the emergency medical services (EMS) personnel, not the hospital diagnosis of the patient.
- Training for billing personnel and EMS providers on documentation and billing for ambulance services is often inadequate.
- Ambulance suppliers should conduct regular claims reviews to ensure problems are identified and corrected prior to an audit.

## Trade-offs of EMR access monitoring

*Daniel Fabbri (page 63)*

- Open-access environments are common across electronic medical record (EMR) systems despite their associated privacy risks.
- Privacy officers must monitor EMR accesses for inappropriate use.
- Manual EMR auditing techniques cannot scale to meet the needs of modern healthcare, necessitating automated monitoring systems.
- When selecting an EMR monitoring system, privacy officers should consider system responsiveness, false positive rates, and monitoring coverage.
- Machine-learning systems can leverage clinical context to reduce false positives, decreasing the time to complete access audits.

## Talking trash: Ensuring proper waste disposal

*Kathryn Evans (page 67)*

- Proper waste disposal ensures staff, environmental, and business safety.
- Identify the types of waste you produce.
- Develop a waste disposal plan for each type.
- Make disposal easy, convenient, and safe.
- Provide adequate staff training annually and at orientation.

## Launching and maintaining an effective compliance program in long-term care

*Michael Maciol, Wendy Brizer-Maciol, and Sabreen I. Abdullah (page 71)*

- A long-term care (LTC) compliance program should be developed in accordance with the eight elements of compliance.
- The LTC compliance officer typically has multiple responsibilities and may need to juggle several hats in order to ensure compliance program effectiveness.
- There are many high-risk areas in the LTC setting, which will need to be prioritized when establishing the annual risk assessment.
- Compliance education on hire/engagement and a minimum of annually for employees, board members, volunteers, and vendors is essential to promoting a culture of reporting potential compliance concerns/violations.
- Disciplinary policies will need to be in place to assist in addressing compliance violations.

# HCCA's Upcoming Events

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

## September 2016

| Sunday | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday |
|---|---|---|---|---|---|---|
| 28 | 29 | 30 | 31 | 1 | 2 | 3 |
| 4 | 5<br>HCCA OFFICE CLOSED<br>*Labor Day* | 6 | 7<br>WEB CONFERENCE<br>*Controlled Substances Oversight- It takes more than a Village* | 8<br>WEB CONFERENCE<br>*Translating Vital Medical Documents for Your Limited English Proficient Patients* | 9<br>**Regional Conference**<br>**Boston, MA** | 10 |
| 11 | 12<br>**Basic Compliance Academy**<br>**Chicago, IL** | 13<br>WEB CONFERENCE<br>*Nondiscrimination under Section 1557 of the ACA: Compliance, Risk, and Litigation*<br>*Eid al-Adha* | 14 | 15<br>**CHC Exam** | 16<br>**Regional Conference**<br>**Minneapolis, MN** | 17 |
| 18 | 19<br>WEB CONFERENCE<br>*Physician Supervision…Having It Mean Something to Front Line Clinical Professionals* | 20 | 21 | 22<br>*Equinox* | 23<br>**Regional Conference**<br>**Kansas City, MO** | 24 |
| 25 | 26 | 27 | 28 | 29 | 30<br>**Regional Conference**<br>**Indianapolis, IN** | 1 |

## October 2016

| Sunday | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday |
|---|---|---|---|---|---|---|
| 25 | 26 | 27 | 28 | 29 | 30 | 1 |
| 2<br>*Rash Hashanah begins* | 3<br>**Basic Compliance Academy**<br>**Las Vegas, NV**<br>*Muharram* | 4 | 5 | 6<br>**CHC Exam** | 7<br>**Regional Conference**<br>**Pittsburgh, PA** | 8 |
| 9 | 10 | 11<br>*Yom Kippur* | 12 | 13<br>**Regional Conference**<br>**Honolulu, HI** | 14 | 15 |
| 16 | 17<br>*First Day of Sukkat* | 18 | 19 | 20 | 21<br>**Regional Conference**<br>**Denver, CO** | 22 |
| 23<br>**Healthcare Enforcement Compliance Institute**<br>**Washington, DC**<br>**Clinical Practice Compliance Conference**<br>**Phoenix, AZ** | 24<br>**Basic Compliance Academy**<br>**Nashville, TN**<br>**Healthcare Privacy Basic Compliance Academy**<br>**Nashville, TN** | 25 | 26<br>**CHC Exam** | 27<br>**CHC Exam**<br>**CHPC Exam** | 28 | 29 |
| 30<br>*Diwali* | 31<br>*Halloween* | 1 | 2 | 3 | 4 | 5 |

### Clinical Practice Compliance Conference
October 23–25 • Phoenix, AZ

### Healthcare Enforcement Compliance Institute
October 23–26 • Washington, DC

### Regional Conferences
September 9 • Boston, MA
September 16 • Minneapolis, MN
September 23 • Kansas City, MO
September 30 • Indianapolis, IN
October 7 • Pittsburgh, PA
October 13–14 • Honolulu, HI
October 21 • Denver, CO
November 4 • Louisville, KY
November 11 • Phoenix, AZ
November 18 • Nashville, TN
December 2 • San Francisco, CA
December 9 • Houston, TX

### Basic Compliance Academies
September 12–15 • Chicago, IL — **SOLD OUT**
October 3–6 • Las Vegas, NV — **SOLD OUT**
October 24–27 • Nashville, TN — **SOLD OUT**
November 14–17 • Orlando, FL — **SOLD OUT**
December 5–8 • San Diego, CA — **LIMITED SEATS**
December 12–15 • Orlando, FL — **LIMITED SEATS**

### Research Basic Compliance Academies
November 7–10 • San Diego, CA

### Healthcare Privacy Basic Compliance Academies
October 24–27 • Nashville, TN — **SOLD OUT**
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*Dates and locations are subject to change.*

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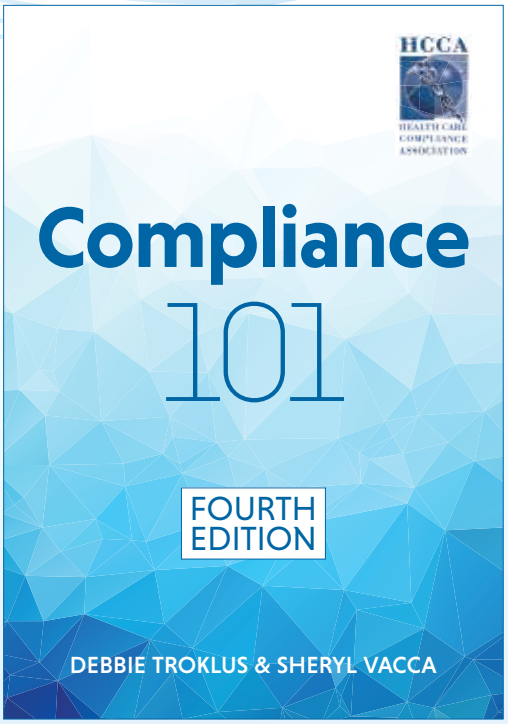


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