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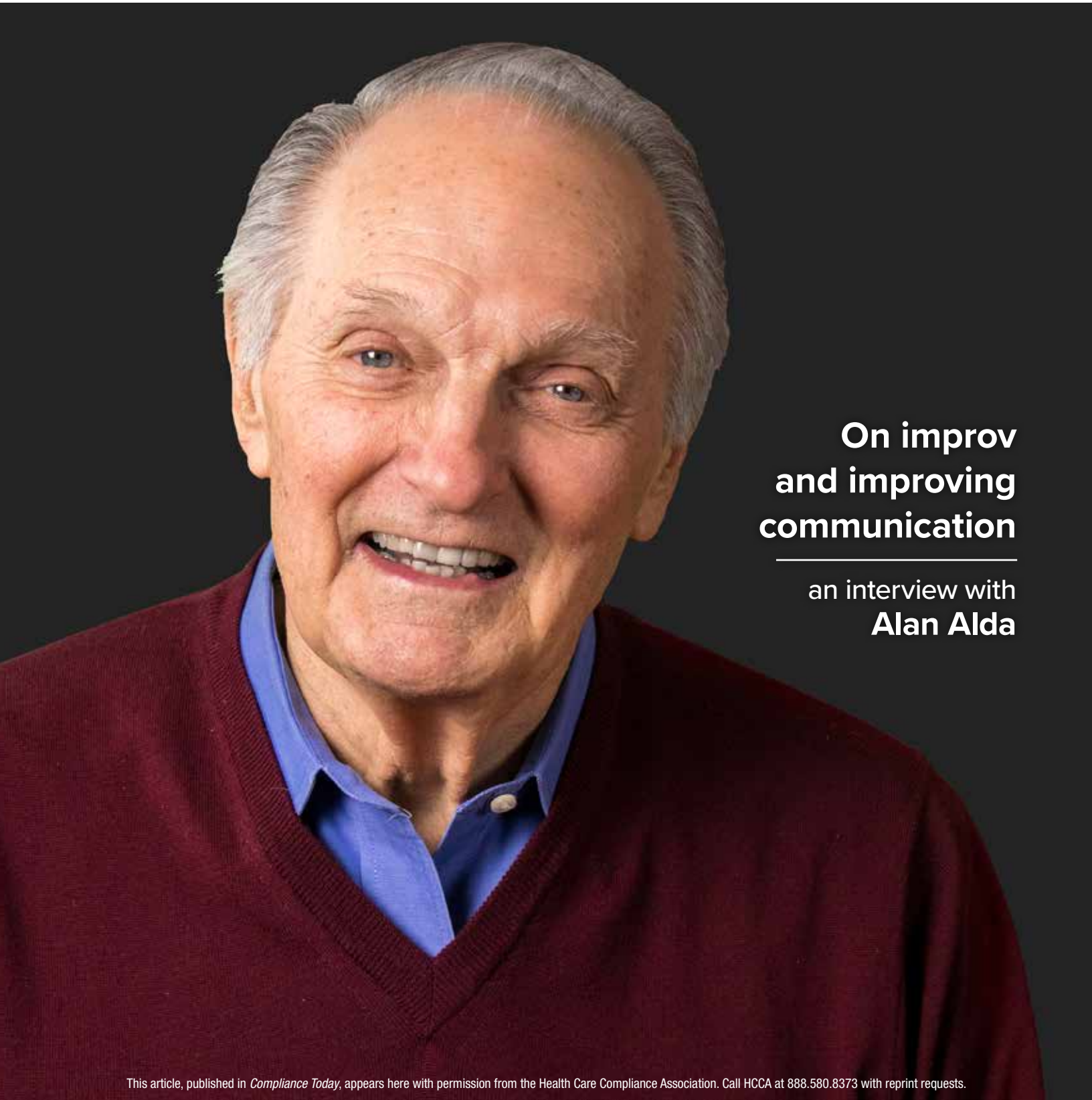
# Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

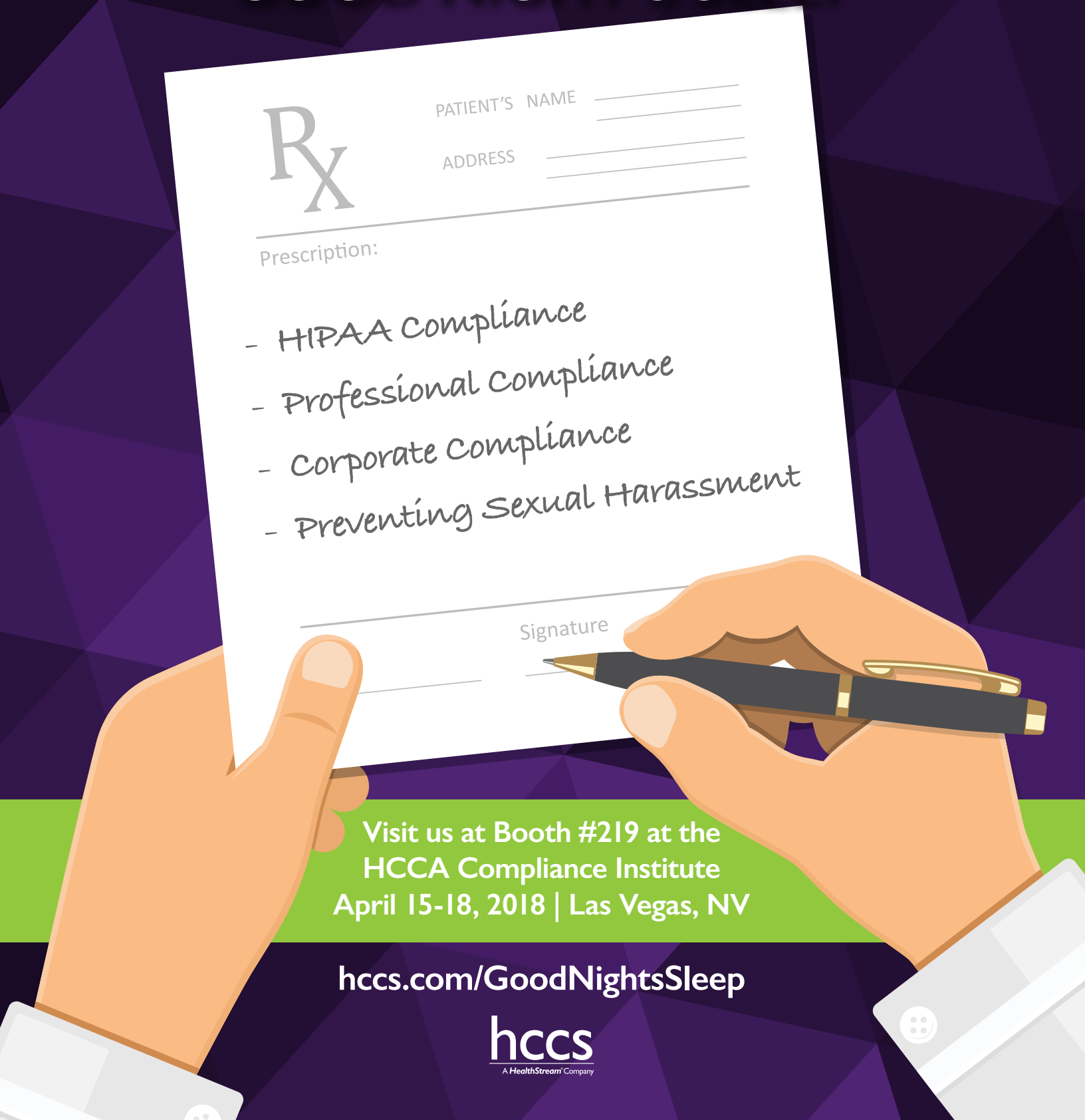
MARCH 2018



## On improv and improving communication

an interview with
**Alan Alda**

# HCCS Online Compliance Training: YOUR PRESCRIPTION FOR A GOOD NIGHT'S SLEEP

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by Gerry Zack, CCEP

# Briber or bribee – Compliance needs to consider both risks

*Please don't hesitate to call me about anything any time.*
*952.567.6215 Direct*
*gerry.zack@corporatecompliance.org*
*@Gerry_Zack* *in/gerryzack*

Much like football teams sometimes have a strong defense but a weak offense, or vice versa, I've seen many organizations with strong defenses against one type of bribery or corruption, while simultaneously being very weak in others.

Zack

Organizational risk involving bribery can stem from employees either receiving bribes or paying them.

From the standpoint of employees receiving bribes, much of this risk focuses on individuals involved in the procurement process or those who have oversight or invoice approval authority associated with suppliers and vendors. Because these bribes or kickbacks aren't on our books, detection of these activities often is dependent on whistleblowers or well-designed data analytics that focus on evidence of what the corrupt vendor is paying for (e.g., a bribe in exchange for rigging a bidding process so the preferred vendor gets a contract leaves a very different type of red flag in the data than when a bribe or kickback is paid to overlook product substitution or pricing discrepancies when approving a vendor invoice).

From the perspective of paying bribes, this most often occurs in connection with a company trying to obtain or retain business, such as the actions covered under the Foreign Corrupt Practices Act (FCPA). But not all risks associated with the payment of bribes involve obtaining new business contracts. I was reminded of this as I read recent news reports about the Florida state official who accepted bribes from assisted living and skilled nursing facilities in exchange for tipping them off about upcoming "surprise" inspections and for detailed information about resident complaints filed with the state. The question I had was the same question I always have when an organization pays bribes: What, if any, indicators were present in the records of these assisted living facilities? These indicators might have nothing to do with sending the payment to the recipient of the bribe, but perhaps involve data surrounding evidence of the information received from the corrupt state employee.

Businesses are well aware of the FCPA risk, and many develop strong monitoring systems to detect signs of the payment of bribes. Often, however, the risks of paying bribes for other types of benefits, like those received by the facilities in the Florida case, aren't even on the company's compliance radar.

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Washington, DC

*Join the Health Care Compliance Association for the 4th Annual Healthcare Enforcement Compliance Conference. Gain practical advice in this one-of-a-kind forum for attorneys and compliance officers. Go beyond legal analysis and learn how to implement systems to stay within the law.*

*Want to become Certified in Healthcare Compliance (CHC)®? Apply to take the optional CHC exam on the last day of the conference.*

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*Questions? jennifer.parrucci@corporatecompliance.org*

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by Roy Snell, CHC, CCEP-F

# Passion for Compliance

*Please don't hesitate to call me about anything any time.*
*612.709.6012 Cell • 952.933.8009 Direct*
*roy.snell@corporatecompliance.org*
*@RoySnellSCCE* *in/roysnell*

As a compliance officer, you have to be passionate about preventing, finding, and fixing problems. If you are, you will prevent, find, and fix problems. People tend to be successful at what they are passionate about. All too often we have compliance officers who are passionate, but they are passionate about one thing. Some are passionate about building an ethical culture. They may have the best ethical culture, but they will not find and fix problems created by unethical people. You can't have a successful compliance program if you don't look for problems. Some are passionate about the rule of law. They may have all the answers about what is within the rule of law, but passion about the rule of law will not educate people as to what the rule of law is. A compliance program will not be successful without education. Some are passionate about risk assessments, but predicting where the big problems might be doesn't find the problems that might be there. Compliance programs will not be successful if you don't audit to see if the problem is where you suspect it is.


Snell

Being passionate about one element of a compliance program will help ensure that one element is successful. However, the whole reason our profession was created was because people were passionate about the rule of law, or risk, or auditing, or building an ethical culture. They failed because they all operated independently, and no single person was passionate about preventing, finding, and fixing ethical and regulatory problems.

Thought leaders will tell you, "The key to compliance is…" The answer is almost always different and, coincidently, happens to be what that thought leader is passionate about. It's a trick question, because there is no key to compliance programs—there are many keys. You have to audit, educate, analyze the rule of law, do risk assessments, develop policies, have an effective reporting system, build an ethical culture, convince people to address known issues, etc. You have to care about the big picture. You have to be passionate about the outcome of the compliance program rather than one element of the process.

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March 2018

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## COLUMNS



## DEPARTMENTS




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

> It brings in the contribution of the other person. It's helpful to think of that person as our communication partner, not the target of our pronouncements.

*See page* 18

## ARTICLES




# Compliance TODAY





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VOLUME 20, ISSUE 3

## Foley survey shows surging telemedicine services across the health care spectrum, into foreign markets

According to a Foley & Lardner LLP survey, "Health care executives and providers have shed fears—and have even become enthusiastic—about the deployment of telemedicine services compared to three years ago… More than 100 respondents from hospitals, specialty clinics, ancillary services and related organizations completed the survey, and nearly half of respondents hold C-suite or senior-level titles."

Foley's "2017 Telemedicine and Digital Health Survey" published in November 2017 "reflects a surging demand for telemedicine-based offerings among providers and patients, and a broader acceptance of the technology by other major players in the health care industry."

http://bit.ly/2mtbf8G

## 21st Century Oncology agrees to pay HHS $2.3 million for its failure to protect the health records of millions of persons

The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) announced December 28, 2017, that 21st Century Oncology, Inc. (21CO) agreed to pay $2.3 million in lieu of potential civil money penalties to the HHS OCR. 21CO also agreed to "adopt a comprehensive corrective action plan to settle potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules. 21CO is a provider of cancer care services and radiation oncology. With their headquarters located in Fort Myers, Florida, 21CO operates and manages 179 treatment centers, including 143 centers located in 17 states and 36 centers located in seven countries in Latin America."

Per the OCR's press release, "On two separate occasions in 2015, the Federal Bureau of Investigation (FBI) notified 21CO that patient information was illegally obtained by an unauthorized third party and produced 21CO patient files purchased by an FBI informant. As part of its internal investigation, 21CO determined that the attacker may have accessed 21CO's network SQL database as early as October 3, 2015, through the remote desktop protocol from an exchange server within 21CO's network. 21CO determined that 2,213,597 individuals were affected by the impermissible access to their names, social security numbers, physicians' names, diagnoses, treatment, and insurance information. OCR's subsequent investigation revealed that 21CO failed to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of the electronic protected health information (ePHI); failed to implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level; failed to implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports; and disclosed protected health information (PHI) to third party vendors without a written business associate agreement."

http://bit.ly/2C4GNJh

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

# Regulatory News

### CMS announces new policy guidance for states to test community engagement for able-bodied adults

On January 11, 2018, the Centers for Medicare & Medicaid Services (CMS) announced the agency's "new guidance that will support state efforts to improve Medicaid enrollee health outcomes by incentivizing community engagement among able-bodied, working-age Medicaid beneficiaries. The policy responds to numerous state requests to test programs through Medicaid demonstration projects under which work or participation in other community engagement activities—including skills training, education, job search, volunteering or caregiving—would be a condition for Medicaid eligibility for able-bodied, working-age adults. This would exclude individuals eligible for Medicaid due to a disability, elderly beneficiaries, children, and pregnant women.

"The new policy guidance sent to states is intended to help them design demonstration projects that promote the objectives of the Medicaid program and are consistent with federal statutory requirements. To achieve the objectives of Medicaid, state programs should be designed to promote better physical and mental health."

*http://go.cms.gov/2mrB6eS*

### New payment model to improve quality, coordination, and cost-effectiveness for both inpatient and outpatient care announced by CMS

On January 9, 2018, the CMS Center for Medicare & Medicaid Innovation (Innovation Center) announced "the launch of a new voluntary bundled payment model called Bundled Payments for Care Improvement Advanced (BPCI Advanced). Under traditional fee-for-service payment, Medicare pays providers for each individual service they perform. Under this bundled payment model, participants can earn additional payment if all expenditures for a beneficiary's episode of care are under a spending target that factors in quality.

"Bundled payments create incentives for providers and practitioners to work together to coordinate care and engage in continuous improvement to keep spending under a target amount. BPCI Advanced Participants may receive payments for performance on 32 different clinical episodes, such as major joint replacement of the lower extremity (inpatient) and percutaneous coronary intervention (inpatient or outpatient). An episode model such as BPCI Advanced supports healthcare providers who invest in practice innovation and care redesign to improve quality and reduce expenditures."

According to the announcement, "The Model Performance Period for BPCI Advanced starts on October 1, 2018 and runs through December 31, 2023. Like all models tested by CMS, there will be a formal, independent evaluation to assess the quality of care and changes in spending under the model.

"For more information about the model and its requirements, or to download a Request for Applications document (RFA), the application template, and the necessary attachments, please visit: http://bit.ly/2DKCEYw. Applications must be submitted via the Application Portal, which will close on 11:59 pm EST on March 12, 2018. Applications submitted via email will not be accepted."

*http://go.cms.gov/2qQ7lc3*

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# HCCA REGIONALS

## 2018 CONFERENCES

Join the Health Care Compliance Association to learn and share compliance successes and challenges in your region. Take advantage of the opportunity to learn from your peers, network, and earn CEUs — all in your area.

**Washington, DC** | March 9, 2018

**New Orleans, LA** | April 27, 2018

**Columbus, OH** | May 4, 2018

**New York, NY** | May 11, 2018

**San Juan, PR** | May 17–18, 2018

**Philadelphia, PA** | June 1, 2018

**Seattle, WA** | June 8, 2018

**Orange County, CA** | June 15, 2018

**Boston, MA** | September 7, 2018

**Minneapolis, MN** | September 14, 2018

**Kansas City, MO** | September 21, 2018

**Indianapolis, IN** | September 28, 2018

**Pittsburgh, PA** | October 5, 2018

**Honolulu, HI** | October 11–12, 2018

**Denver, CO** | October 19, 2018

**Chicago, IL** | October 26, 2018

**Louisville, KY** | November 2, 2018

**Scottsdale, AZ** | November 9, 2018

**Nashville, TN** | November 16, 2018

**San Francisco, CA** | November 30, 2018

**Houston, TX** | December 7, 2018

Questions? beckie.smith@corporatecompliance.org

hcca-info.org/regionals

# HCCA *conference news*

## Earn CEUs and network locally by attending one of HCCA's Regional Conferences

HCCA brings compliance training and networking to your neighborhood with Regional Compliance Conferences. These one-day events, hosted across the United States, include general and specialty sessions and offer high-quality, convenient, inexpensive education and networking opportunities.

See the listing below for remaining Regional Conferences for 2018.

March 9 • Washington, DC
April 27 • New Orleans, LA
May 4 • Columbus, OH
May 11 • New York, NY
May 17 – 18 • San Juan, PR
June 1 • Philadelphia, PA
June 8• Seattle, WA
June 15 • Orange County, CA
September 7 • Boston, MA
September 14 • Minneapolis, MN
September 21 • Overland Park, KS
September 28 • Indianapolis, IN
October 5 • Pittsburgh, PA
October 11 -12 • Honolulu, HI
October 19 • Denver, CO
October 26 • Chicago, IL
November 2 • Louisville, KY
November 9 • Scottsdale, AZ
November 16 • Nashville, TN
November 30 • San Francisco, CA
December 7 • Houston, TX

***Don't miss the chance to attend an HCCA Regional Conference in your area!***

***For more information visit:***
***hcca-info.org/regionals***
***If you have any questions, contact***
***Beckie Smith at beckie.smith@corporatecompliance.org***



**Find the latest conference information online ▶** 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 | Managed Care | About Membership

Number of website visits last month

**122,993**

### Best of Blog

For those who have yet to visit our blog, it contains articles and podcasts from industry leaders in Compliance. With the Best of Blog newsletter, we give you the best articles and podcasts from the past month, delivered right to your inbox.

This email is currently delivered to all our contacts on the current email list, but if you prefer to get ahead of the game and see the stories as they are posted, check out The Compliance and Ethics Blog at *complianceandethics.org*.

### Video of the month

**Why should you send your new compliance staff for training outside your organization?**


Lori J. Strauss talks about how outside training can help when a Compliance department has limited resources. See this and other videos on onboarding and staff training at: *http://bit.ly/votm-ct-2018-03*



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

# HCCA *social media news*

Contact Doug Stupca at 952.405.7900 or email him at doug.stupca@corporatecompliance.org with any questions about HCCA social media.

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

Join us on LinkedIn—a business-oriented network with over 300 million active users. With more than 15,000 members, our LinkedIn group fosters dozens of new discussion posts every week. One recent highlight:


## Facebook — *facebook.com/hcca*

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


## Pinterest — *pinterest.com/theHCCA*

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

## Twitter — *twitter.com/theHCCA*

Join 12,000+ others and follow HCCA for breaking news and insights! Here is one recent favorite tweet:


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

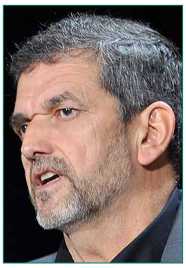
# HCCA *The Compliance & Ethics Blog Highlights*

Contact Doug Stupca at 952.405.7900 or email him at doug.stupca@corporatecompliance.org with any questions about HCCA's Blog.

## Everyday honesty

by Roy Snell

I love "everyday honesty." What I am talking about are people who tell you, respectfully and civilly, what they really think about everyday, run-of-the-mill issues. I love to listen to them. I am not talking about people who lie through their teeth every day or major dishonesty. I am talking about people who take it a step further. The current cultural shift that has put so many things off limits to talk about has caused some people to just stop sharing their opinions.



Snell

The baby has been thrown out with the bath water. It kind of comes off as dishonest to me. Some people have taken the perfectly acceptable effort from our society to become more politically correct and taken it very close to the edge of suppression of thought. When I see people who are returning to the concept of open discussion, it comes off as honesty to me. I miss everyday honesty. I think a lot of people miss it, and they like it more now than they ever have, because it is slipping away from us.

I kind of like civil, everyday honesty rebels. I am not talking about the screaming, hating, finger–pointing, offending types. I am talking about the calm, thoughtful, civil, honest types. They impress me. They say what they think. They talk about the elephant in the room. They address issues that should be addressed. They are civil about it. They do not care if it affects their income or popularity. They don't mind having someone tell them they are wrong. They listen to alternative views. They find out when they are wrong, because they say what they think. They change their minds when they hear a better idea. They think it's OK to risk being wrong. It's an important part of what I would consider the attribute of everyday honesty.

The idea for this post came to me from a couple of people I talk to on a regular basis who I think have this ability. One of them is our incoming CEO, Gerry Zack. When he interviewed for the incoming SCCE & HCCA CEO job, those who talked to him on the phone, and later in person, came out of the room very impressed. For some, it was close to a "coming-out-of-their-shoes impressed." His resume was great, but this was a reaction to a discussion or a person. What I came up with was that he is honest, humble, and confident. Since then, I can't get this out of my head. Our culture is currently coming off a period of possible overreach on "what is OK to talk about." It makes us treasure people like Gerry. People miss honest and civil discourse on everyday issues.

*For more compliance news and insights, visit The Compliance & Ethics Blog at complianceandethics.org, and don't forget to subscribe to the daily digest at bit.ly/SCCEBlogSubscribe*

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*The following is to correct and update information published in the January issue of* Compliance Today *"People on the Move" column.*

▶ **Aurae Beidler**, CHC, MHA, has been appointed Compliance and Privacy Officer at Linn County Department of Health Services in Albany, OR.

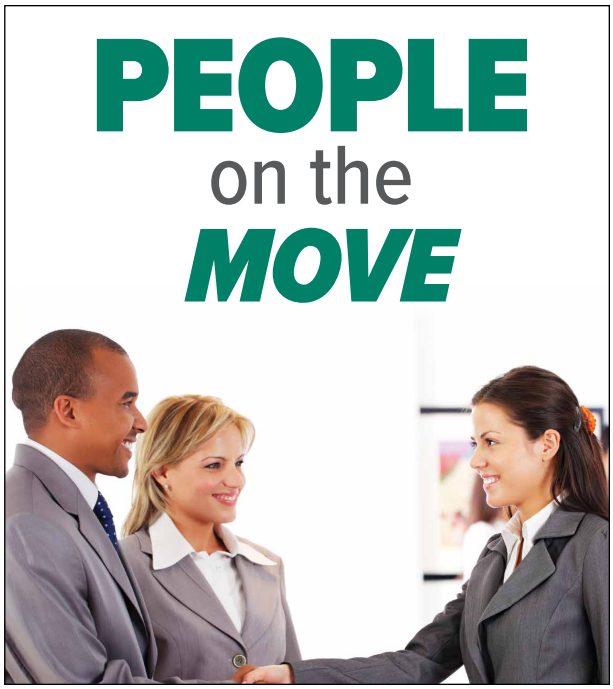
▶ **Andrea Eklund,** Esq. has been named Vice President/Chief Compliance Officer at UnityPoint Clinic in Des Moines, Iowa.

▶ **Margaret (Peg) McKeon,** BSN, Esq., CHC is Chief Compliance Officer at Philadelphia College of Osteopathic Medicine (PCOM).

▶ Sharecare Inc. in Atlanta has named **Ami Patel** as the company's Chief Legal and Compliance Officer.

▶ Southeast Alabama Medical Center (SAMC) named **Deborah A. Reif,** MBA, CHC, CHPC as Corporate Compliance Officer.

▶ **J. Olivia Simmons,** MPC, CHC is now Senior Specialist Organizational Compliance Training at St. Jude Children's Research Hospital - ALSAC in Memphis, TN.




▶ **Lisa A. Taylor,** JD, CCEP has been promoted to Vice President & Chief Compliance Officer at UC Health in Cincinnati, Ohio.

## 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 Can Earn CEUs:

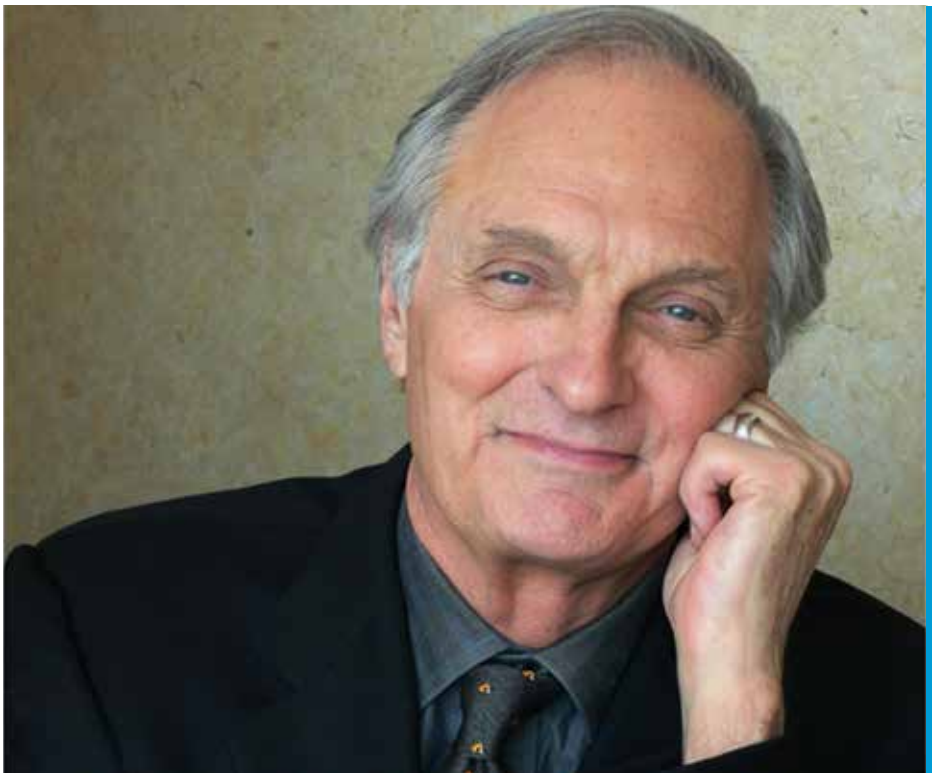
**CCB awards 2 CEUs to authors of articles published in *Compliance Today***

# *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.

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



Alan Alda
Founder
Alda Communication Training
New York, New York

an interview by Adam Turteltaub

# Meet Alan Alda

*This interview with **Alan Alda** (workshops@aldacommunication.com; website: www.aldacommunicationtraining.com) was conducted by **Adam Turteltaub** (adam.turteltaub@corporatecompliance.org), Vice President of Strategic Initiatives & International Programs, Society of Corporate Compliance and Ethics & Health Care Compliance Association.*

*I've had the pleasure of knowing Alan Alda almost as long as I can remember. He and my father worked together in the early 1960s, and our families have been friends ever since.*

*Always thoughtful and inquisitive, his passions and curiosity have led him to star on the stage, on TV, and in film; write and direct; host documentaries; and even author three books. His latest is* The New York Times *bestseller,* If I Understood You, Would I Have This Look on My Face?, *published by Random House.*

**AT**: First, let me tell you how much I enjoyed your book. I think your focus on improving communications is so very important for our members, since their job is about getting others to do the right thing, and that's really a communications challenge.

I'm going to begin and end this interview with questions about stories, since you argue very passionately about the importance of stories for communication. And, in fact, I'm going to start with a story you may not remember.

You were doing a play in Los Angeles, and Rhea (my wife) and I came one night. Afterwards, we went backstage to thank you for the tickets and to tell you how much we enjoyed it. I remember asking you if it was hard to do the same play night after night.

You replied that it was different every night because the audience was always different.

It was something I had never thought of, and I felt both humbled and educated. It was something that I kept thinking about as I was reading your book. To me the central message is that even theater is a discussion, and that we need to think about not just what we're saying, but what the other person's reaction will be.

**AA:** Thanks so much, Adam. I'm really glad you enjoyed the book. Thank you for that story, too. I thought it was going to end with the response I often give to that question: It's different every time, like dancing. If someone says, "Would you like to dance?" you don't say, "No, thanks, I've done that."

**AT:** Where did your drive to improve business communications come from?

**AA:** I realized one day how important communicating with clarity can be when a dentist was holding a scalpel a few inches from my face and was about to cut into my gum. He was getting ready to do a surgical procedure that he had invented and was clearly proud of. He paused long enough to say one inscrutable thing: "Now there will be some tethering." I had no idea what he was saying. I asked him what he meant by "tethering," but his answer was just to bark at me, "Tethering! Tethering!" I was too cowed by his surgical gown to tell him to put the knife down and explain what he was about to do, which he went ahead and did. He severed the little tissue that goes between the upper lip and the gum. This resulted in a smile that looked more like a sneer. I found this out a couple of weeks later when I was playing a scene in a movie. I had to smile in the scene, and the harder I tried to smile, the more I sneered. One good outcome was I could now play a whole new range of villains.

Something else that came out of it was that eventually I would realize that every workplace depends much more on clear communication than we usually think it does. We know what we mean, and we assume the other person does, too. When we're wrong, it can mean hurt feelings, lack of cooperation, and in this case, a smile-ectomy.

**AT:** I really like the point your make in the book that "not being truly engaged with the people we're trying to communicate with… is the grit in the gears of daily life." Why do you think we hold back? Is it because we're distracted, busy, afraid of the intimacy, too focused on what *we* want to say and not what *they* have to say, or some combination of all of that and more?

**AA:** Most of us think of good communication as saying what we have to say using the best possible choice of words. What perfectly expresses my point of view? I think what we forget is that the best message in the world is useless if it doesn't make it into the other person's head and if it doesn't stick there for a while. If we're not engaged with the other person so fully that we're practically reading their mind, then we're not in a position to know if we're reaching them. There are all kinds of things happening on a person's face when we talk to them. If we learn to read those clues, we have a good estimate of what's going on in their mind. That's why my book is called *If I Understood You, Would I Have This Look on My Face?* Understanding what the other person is going through is too often overlooked in communicating.

**AT**: How do we increase our willingness to engage? And how do you let people know you're really there with them and not just going through the motions or talking *at* them?

**AA:** We have to practice. And we have to be genuinely interested in the other person. For instance, we hear a lot of tips about *active listening*—letting the other person know you

heard what they said. But just repeating what another person has said in a mechanical way can be annoying. The underlying connection with the other person has to be authentic. It can start simply with *deciding* to pay attention to what they're thinking and feeling. The more we do it, the better it feels, and the more likely we are to do it the next time.

It sounds simple, but it's not easy. Sometimes we can fall into a mechanical version of paying attention. It's not staring at another person; it's observing and responding to them. It can feel really good.

**AT:** Let me play devil's advocate here for a moment. You write a lot about relating, which is very important; it's part of the glue that binds us as families and a society. But, is it always important? If you have to tell someone something where there's no wiggle room ("You have to do this," or "You can't do that.") is relating really necessary?

**AA:** Giving orders in the military is the only place I can think of where you can tell somebody to do something, and they'd better do it or they'll get shot. But even there, you often have to inspire people to do what you want them to do. ("Once more unto the breach, dear friends…")

In business, let's say in a situation where there's a serious ethical problem, it seems to me you have to be firm about the policy, but that doesn't mean you can forget about what they're going through as they listen to you. What if their eyes are telling you they have no intention of changing their behavior? A little relating would pick that up. Relating isn't always warm and fuzzy. It's mainly being very observant.

And in addition, connecting to the other person can be useful even in a tough situation like this. My guess is that there will be less likelihood of the behavior happening again if you can reach the person at the intersection of your shared values.

**AT:** You're a fan of using improvisation, and by that, I don't mean just winging it, but using specific improvisational techniques. That's a bit of a surprise. Most of us would be tempted to double down on formal, classical preparation when we need to communicate with others. What do you think improv brings to communication?

**AA:** It brings in the contribution of the other person. It's helpful to think of that person as our communication *partner*, not the target of our pronouncements.

**AT:** You talk about relating to people and also of empathy and how improv brings that out. Are relating and empathy one and the same, or do you see them as different?

**AA:** The way I use the term, empathy is being aware of the other person's feelings. Relating, for me, is a way of gathering all the information you can from body language, tone of voice, even syntax to get a good estimate of what's really going on in someone's head.

**AT:** One of the things you write about is making people want to know what you have to say. How do you make that happen when people may really not want to hear what you have to say? Few people go into a compliance training session wanting to know what the law says they can or can't do, especially the can't part. It's a permanent barrier between the workforce and the compliance team. Sometimes it's low, and sometimes it's high, but it gets in the way of people wanting to hear from the compliance and ethics team.

**AA:** I'm not a compliance officer, so I'm leery of stepping in where I don't belong. But I have had times in my life when I've had to make it clear to a business partner, or even

a child, that there's certain behavior we just can't do. Seeing it from their point of view before laying down the law seemed to help the medicine go down. I don't know if it will make people line up at the door of the compliance team in order to hear even more things they can't do, but it might make them dread it less.

**AT:** One of the concepts you talk about that really resonated for me in an uncomfortable way is starting too far in or not too far—basically, giving more information than the person needs or not enough. I think we all go into conversations thinking the person knows a certain amount already, but we've all been in situations where we found we were wrong. How do you calibrate and adjust effectively mid-conversation?

**AA:** Two things. It doesn't hurt to ask questions to make sure they're with you. And it really is not insulting their intelligence to be clear and basic. Sometimes people think they understand something, because they've decided what it *probably* means. As long as we imply that there's no judgement about their not knowing, we can just frankly keep making sure they're up to speed with us. I think it's part of treating the other person as a partner.

**AT:** You talk about the "sound of certainty." Basically, when people are very decisive in a response, it tends to diminish the other person and cut off conversation. How do you avoid that when your job is being the person who *does* have the definitive answer? In Compliance there are often very strict rules. You want the person to understand that there's no wiggle room, but you also need them to feel comfortable coming forward in the future.

**AA:** This is a great challenge. The "sound of certainly" thing is really a tone of voice along with an attitude of "I don't want to hear any more from you on this subject." That tends to cut off listening. But, on the other hand, there *are* some basic truths, like the idea that if you step off of a 50-story building, you're not going to last long. You can declare that gravity exists in a punishing tone, or as a kind of service. Still, gravity is a law you can't wiggle out of. Knowing how the other person feels doesn't mean you can't be firm. On the contrary, it might make the firmness land better.

**AT:** Let me go back to improv for a bit. A lot of readers are going to say, "No way I'm signing up for an improv class." Actually I'm saying the same thing. What should they (and I) do?

**AA:** Here's what I do (because I can't get to an improv class regularly—and they're *not* scary). I practice during the day with strangers and people I know. I get out of the cloud of thoughts I'm in and see if I've actually noticed the color of the other person's eyes. Suddenly, I really see them. Just today, I was delayed for five minutes at a security desk in a fancy building. For some reason, I wasn't on the list of people permitted to enter. It could have been frustrating. But I looked at the guard's face and actually noticed her eyes. I realized she had a happy, pleasant face. After that moment, we were working together on the problem and the time passed without stress.

**AT:** One of the challenges I see for compliance people is that so much of what they communicate is about requirements. No one likes being told the rules, and sometimes they may be counterintuitive. Most laws make sense—you shouldn't pay bribes or rip off the government—but there can be a resistance when you see your competitors doing it with seeming impunity. Also, there are times when the regulations may be counterintuitive or annoying.

When you're the one who has to say "It doesn't matter what they do; we act this way" it can be hard to connect with people. You can

just tell them stories about others who broke the rule and the awful things that happened, but that can get old quickly. How do you build a connection, especially a personal one, when you're trying to get people to understand something that can be a bit technical and mechanical?

**AA:** I sort of know how this feels. I have a friend who was high up in the executive team of a huge company. He once said, "I really wish we could give people bribes in some of these countries, the way everybody else does. We're getting killed." I didn't have to point out how wrong or illegal it was—he knew. But I really wanted him to not *want* so much to pay bribes. It wasn't easy. The more I reminded him that corruption hurts us all, and how much better it is not to poison the reservoir we all drink from, the more forlorn he looked—just hungering to slip somebody a hunk of change. Maybe I just should have let him know I understood his impulse. Maybe sharing with him his feeling that it didn't seem fair would have helped him accept the reality. On the other hand, you have a really tough job.

**AT:** Finally, let's finish where we began with your discussion about stories and how central they are to our sense of the world and our ability to learn. I admit I'm in complete agreement with you. I do a presentation where I underscore that we remember stories more than facts or rules, which is why, I think, most religions don't give you a bunch of rules to follow, but instead have stories that the rules come out of. But, I wonder if part of the resistance we have to what others tell us is that we're caught up in the stories inside our own heads. We build a narrative about how things are supposed to go and who we are. Then, when something differs from that or something goes wrong, we get put into an unfamiliar situation, or a compliance officer says, "No, you can't do that," we have an irrational reaction because our story is being challenged. How does a good communicator overcome the resistance to changing our internal narrative?

**AA:** You suggest an interesting idea that everyone has an internal story that they believe and that they don't like to veer from. Could be. If they do, I doubt if we have much of a chance of reaching them with *our* story until we know what *their* story is. Again—and always—listening. Relating.

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

by Catherine Boerner, JD, CHC

# Not just Medicare, but Medicare Advantage Plans

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

Boerner

Compliance officers tend to focus on Medicare and Medicaid compliance, but should not lose sight of Medicare Advantage Plans and Medicaid Managed Care Plans. There has been an increase in audits from the insurance companies that offer these plans. Compliance officers may want to seek out a process to make them aware on a regular basis what record requests are coming in to the Health Information Management (HIM) department from these Plans. Consider discussing with the Revenue Cycle Integrity team if and how they are tracking the results from these reviews/audits. Compliance officers can contribute to the discussion with revenue cycle in understanding any potential root causes from these recoupments/denials.

We are also seeing an increase in enforcement in this area. The table below shows a few of the enforcement efforts.

| | |
|---|---|
| **November 15, 2017**<br>**U.S. Department of Justice** | Owner and Manager of New York Medical Equipment Provider Charged for Their Roles in Alleged $3.5 Million Scheme to Defraud Government-Funded Health Plans<br><br>The owner and the manager of a purported durable medical equipment (DME) company in the Bronx, New York, were charged in an indictment unsealed today for their roles in an allegedly fraudulent scheme that involved submitting over $3.5 million in claims to private insurers, which included government-sponsored managed care organizations. |
| **November 20, 2017**<br>**U.S. Department of Justice** | Operator of Purported Durable Medical Equipment Providers Pleads Guilty to Health Care Fraud Charges for Role in Durable Medical Equipment Fraud Scheme<br><br>An operator of multiple purported DME companies pleaded guilty today to fraud charges for her role in a scheme to defraud Healthfirst, a non-profit, New York-based health maintenance organization that administers Medicare Advantage Plans and New York Medicaid Managed Care Plans. |
| **August 21, 2017**<br>**U.S. Attorney; Southern District of West Virginia** | A Charleston dentist who falsely billed West Virginia Medicaid and West Virginia Medicaid Managed Care Organizations (MCOs) for more than $700,000 pleaded guilty today, announced United States Attorney Carol Casto. Antoine Skaff, 58, entered his guilty plea to health care fraud. Skaff also entered into a civil settlement today with the U.S. Attorney's Office, the Office of Inspector General for the U.S. Department of Health and Human Services, the West Virginia Department of Health and Human Resources (DHHR), DHHR's Bureau for Medical Services, and the West Virginia Medicaid Fraud Control Unit, in which he agreed to pay treble damages of $2.2 million, or three times the loss suffered by West Virginia Medicaid. |

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by Joan W. Feldman

# False Claims Act 2017 report card: $2.4 billion recovered

» Don't assume that a whistleblower complaint cannot be brought against your organization.
» Address compliance concerns promptly, so they don't fester and result in a *qui tam* action.
» The government will continue to rely on individuals to bring cases to their attention, motivated by sharing in a federal monetary recovery.
» Providing medically unnecessary services to patients is typically not an isolated event.
» The government is likely to increase the use of tools that identify outliers.

***Joan W. Feldman*** *(jfeldman@goodwin.com) is a Partner and Health Law Group Practice Chair at Shipman & Goodwin, LLP in Hartford, CT.*

On December 21, 2017, the Department of Justice (DOJ) issued its yearly report card describing its most noteworthy settlements in fiscal year 2017 with healthcare providers under the False Claims Act (FCA).[1] In addition to praising the efforts of its dedicated enforcement staff, the DOJ sent a message of both acknowledgment and encouragement to the whistleblowers who bring alleged FCA violations to its attention.


Feldman

It makes good sense for the DOJ to use this annual report card as a form of encouragement for those among us who believe in reporting blatant wrongdoing. Unfortunately, this message is sometimes received by bounty hunters, sometimes entirely motivated by retribution or greed, who are tempted to see wrong when there is no wrong. Nevertheless, there is plenty to learn from these significant settlements, and it never gets old reading about those in positions of power who abuse the public's trust and do the indefensible out of greed. Indeed, the cases that were featured were stunningly egregious and involved sophisticated healthcare companies.

## Risks and consequences

One has to wonder why executives would risk so much. Perhaps this risk-taking behavior and the consequences are viewed by some as the cost of doing business, but for the rest of us who believe in complying with the law, the following cases are noteworthy.

**Shire Pharmaceuticals LLC—$350 million**

As a result of a *qui tam* action brought by six whistleblowers,[2] Shire Pharmaceuticals LLC and other Shire subsidiaries (Shire) paid $350 million to resolve FCA allegations that it was providing kickbacks and engaging in other unlawful methods of marketing its product Dermagraft, a bioengineered human skin substitute approved by the FDA for use in the treatment of diabetic foot ulcers. The whistleblowers alleged, among other things, that Dermagraft salespersons unlawfully induced the use of Dermagraft by incentivizing physicians with extravagant dinners, entertainment, and travel; medical equipment and supplies;

unjustified payments for speaking engagements and bogus case studies; and cash gifts, rebates, and credits. Shire was also accused of marketing Dermagraft for uses not approved by the FDA. Shire sold the assets associated with Dermagraft in early 2014. Since late 2014, Shire has been operating under a Corporate Integrity Agreement with the U.S. Department of Health and Human Services that is related to the settlement of separate FCA allegations. The Office of the Inspector General (OIG) will continue to monitor Shire's compliance with federal healthcare laws through its oversight of this agreement.

**Mylan Inc.—$465 million**

Mylan Inc. and Mylan Specialty LP (collectively, Mylan) agreed to pay $465 million to resolve claims that they violated the FCA by knowingly misclassifying EpiPen as a generic drug to avoid paying higher rebates to Medicaid.[3] The rebate program was enacted by Congress to protect Medicaid programs from price gouging relating to drugs available only through a single source. Brand-name drugs are subject to a higher rebate; whereas generic drugs, available from multiple manufacturers, are subject to a lower rebate. By misclassifying the drug as generic, Mylan paid only a 13% rebate to Medicaid while increasing the price of EpiPen by 400%. Sanofi-Aventis was the whistleblower and received approximately $38 million of the federal recovery. Mylan also entered into a five-year Corporate Integrity Agreement.

**eClinicalWorks—$155 million**

eClinicalWorks paid $155 million to resolve FCA allegations that it falsely obtained certification for its electronic health record (EHR) software when it concealed from an independent certifying entity that its software did not fully comply with all of the certification requirements.[4] Specifically, eClinicalWorks complied with coding requirements for only the drugs needed for certification testing, despite the requirement that all drugs be coded for certification. The eClinicalWorks software also failed to satisfy data portability requirements intended to permit healthcare providers to transfer patient data from its software to other vendors. This false certification resulted in false claims being submitted for Meaningful Use incentive payments by users of the software. A five-year Corporate Integrity Agreement was required with stiff requirements relating to customer usage of the software. The case was the result of a *qui tam* action brought by a software technician who received approximately $30 million of the federal recovery.

**Life Care Centers of America, Inc.—$145 million**

Life Care Centers of America, Inc. (Life Care) agreed to pay $145 million to resolve FCA allegations that it knowingly caused its more than 220 skilled nursing facilities to submit false claims for rehabilitation services that were not reasonable, necessary, or skilled.[5] Specifically, the government alleged that Life Care falsely submitted higher levels of care than its patients needed in order to receive higher reimbursement and kept patients at the facility longer than needed, so the rehabilitation services could continue to be billed. Life Care was required to enter into a five-year Corporate Integrity Agreement. The case was brought to the attention of the government by two former Life Care employees who shared $29 million of the federal government's recovery.

**Freedom Health, Inc. and former COO—$32.5 million**

Freedom Health, Inc., a Medicare Advantage plan, its related corporate entities, and former chief operating officer (COO) collectively paid $32.5 million to resolve FCA allegations that

they submitted unsupported diagnosis codes to CMS, which resulted in a higher level of reimbursement.[6] It was also alleged that the plan made material misrepresentations regarding the scope and content of its network of physicians, specialists, and hospitals. The case was brought to the attention of the federal government by a former employee.

**Pain management physician—$20 million**
A pain management physician agreed to pay $20 million to resolve FCA allegations that he falsely billed federal healthcare programs by billing for surgical monitoring services that he did not perform and for medically unnecessary diagnostic tests.[7] Specifically, the federal government claimed that the physician billed for monitoring the neurological health of patients during surgery when he had a medical assistant doing the monitoring. The government further alleged that the physician billed for medically unnecessary balance tests, nerve conduction and electromyography procedures, and qualitative drug screens. The case was brought to the government's attention by three whistleblowers. In addition to the payment, the physician was sentenced to three years and two months in prison.

**Medically unnecessary services—$18 million**
A physician paid more than $18 million to resolve FCA allegations that he submitted claims for medically unnecessary biopsies and radiation therapy services, and radiation therapy services performed too frequently in contravention of medical standards. The government proved that more than 50% of the payments the physician received from Medicare were for services provided on days when he was not present in the clinic. The government also proved that the physician knew that a medical physicist had not performed the physicist services he had billed to Medicare. The case was brought to the attention of the government by a physician whistleblower.[8]

**Cardiac monitoring companies—$13.45 million**
AMI Monitoring Inc. (aka Spectocor); its owner, Joseph Bogdan Medi-Lynx Cardiac Monitoring LLC, and Medicalgorithmics, SA agreed to pay $13.45 million to resolve FCA allegations. The government alleged that the cardiac monitoring companies marketed a pocket ECG that provided three levels of cardiac monitoring services and consistently steered physicians to the more costly monitoring service, even though it was not medically necessary. The case was brought to the attention of the federal government by a former salesperson of Spectocor, who will share approximately $2.4 million of the federal government's recovery.[9]

**MedStar Ambulance Inc.—$12.7 million**
MedStar Ambulance Inc. agreed to pay $12.7 million to resolve FCA allegations that it routinely billed for transportation services that were not medically necessary and billed for higher levels of services than required by the patients' conditions, or services that were not actually provided. The case was brought by a former billing office employee who will share approximately $3.5 million of the federal government's recovery.[10]

**Urologist practicing at Gulfstream Urology—$3.8 million**
After 21st Century Oncology LLC paid $19.75 million to settle FCA claims in 2015,[11] a urologist practicing at Gulfstream Urology, which was a division of 21st Century Oncology, LLC, became the subject of FCA allegations. The urologist has agreed to pay more than $3.8 million to resolve FCA allegations that he ordered medically unnecessary tests performed on urine to detect genetic abnormalities associated with bladder cancer.[12]

Medicare does not cover the test unless it is ordered after a full urologic workup or there is reason to suspect a recurrence of cancer in a patient previously diagnosed with cancer. The urologist was the number one ordering physician in the country for this test and received $2 million in bonus payments for ordering the tests. The case was brought to the attention of the federal government through a *qui tam* action. The physician entered into a three-year Integrity Agreement with the OIG.

## Conclusion

As evidenced by the above cases, the government will continue to rely on those entrenched in the industry to bring allegedly fraudulent conduct to their attention. Therefore, despite temptation by some to overbill, the risks are high in an environment in which your colleagues are watching. Although egregious, all of these cases are teachable moments for healthcare executives and providers alike.


1. Department of Justice, Justice News, press release: "Justice Department Recovers Over $3.7 Billion From False Claims Act Cases in Fiscal Year 2017" December 21, 2017. Available at http://bit.ly/2mcgqX2
2. DOJ, Justice News, press release: "Shire PLC Subsidiaries to Pay $350 Million to Settle False Claims Act Allegations" January 11, 2017. Available at http://bit.ly/2jbbBNN
3. DOJ, Justice News, press release: "Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates" August 17, 2017. Available at http://bit.ly/2AQ04cg
4. DOJ, Justice News, press release: "Electronic Health Records Vendor to Pay $155 Million to Settle False Claims Allegations" May 31, 2017. Available at http://bit.ly/2sgG3v2
5. DOJ, Justice News, press release: "Life Care Centers of America, Inc. Agrees to Pay $145 Million to Resolve False Claims Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy Services" October 24, 2016. Available at http://bit.ly/2qUDaRe
6. DOJ, Justice News, press release: "Medicare Advantage Organization and Former Chief Operating Officer to Pay $32.5 Million to Settle False Claims Act Allegations" May 30, 2017. Available at http://bit.ly/2snKh0s
7. U.S. Attorney's Office, Eastern District of Kentucky, press release: "Pain Management Physician Pays $20 Million to Resolve False Claims Allegations" February 1, 2017. Available at http://bit.ly/2kVH6NK
8. U.S. Attorney's Office, Southern District of Florida, press release: "Dr. Gary Marder and the United States Consent to a Final Judgment of Over $18 Million to Settle False Claims Act Allegations" February 7, 2017. Available at http://bit.ly/2lcPPvG
9. DOJ, Justice News, press release: "Cardiac Monitoring Companies and Executive Agree to Pay $13.45 Million to Resolve False Claims Act Allegations" June 26, 2017. Available at http://bit.ly/2s29a1L
10. DOJ, Justice News, press release: "Medstar Ambulance to Pay $12.7 Million to Resolve False Claims Act Allegations Involving Medically Unnecessary Transport Services and Inflated Claims to Medicare" January 13, 2017. Available at http://bit.ly/2k7D0lh
11. DOJ, Justice News, press release: "21st Century Oncology to Pay $19.75 Million to Settle Alleged False Claims for Unnecessary Laboratory Test" December 18, 2015. Available at http://bit.ly/2FxTt9A
12. U.S. Attorney's Office, Middle District of Florida, press release: "Fort Myers Urologist Agrees To Pay More Than $3.8 Million For Ordering Unnecessary Medically Tests" February 1, 2017. Available at http://bit.ly/2kSFTXl

by Lynda S. Hilliard, MBA, RN, CCEP, CHC

# Preparing staff for change in leadership

***Lynda S. Hilliard*** *(lyndahilliard@hotmail.com) is Principal of Hilliard Compliance Consulting in Mount Shasta, CA.*

Change occurs constantly in organizations and we, as managers, should continually strive to prepare our staff to embrace change from all angles. One of the biggest stressors for staff is leadership change! Charismatic leaders who bring a wealth of industry experience and personal ideas to the job may build departments that reflect their personal style and their interpretation of the job to be done. However, when they leave, a void may be left, and it is up to the new leader to either maintain the status quo or change the structure, and possibly the focus, of the department.

Hilliard

So what do we do to help our staff when leaders decide to leave, either in a positive manner (e.g., promotions or retirement) or a negative manner (e.g., termination)? It's quite a dilemma, because we may not be prepared for the move ourselves. However, we want to leave our teams with the ability and agility to quickly respond positively to such a change, because we cannot dictate or predict what a new leader will do!

One of the best gifts a great leader can give to their department and staff is a core foundation for the operation of the business, so that staff can operate without day-to-day direction from a leader, for a period of time. It provides stability and eases fear of the unknown for staff. If this is a positive change, there is time for leadership to plan for a smooth transition, especially if the new leader has been identified. That planning can include a number of steps that can also be used in other types of change:

Develop a plan for the change. Involve middle management and staff as much as possible in building a temporary communication structure to span the period between leaders.

Explain, as much as possible, the rationale for the change. No need to dive into "deep" details, but don't leave staff in the dark:

- Develop a consistent message that is communicated across all levels of the organization by all managers.
- Communicate as early as possible, and continually keep staff in the loop of any changes to the plan.
- If possible, introduce the new leader to staff prior to your leaving the organization.
- Allow staff to ask questions and express themselves.

Change is critical, but change is manageable if the focus is on positive outcomes.

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by Denise Atwood, RN, JD, CPHRM

# Impact of state False Claims Acts

» Compliance professionals should become familiar with the legislation that establishes liability to the states for Medicaid false claims.

» If a state FCA meets the requirements set forth by the federal government, it may qualify for a Medicaid incentive under section 1909 of the Social Security Act.

» The federal Office of the Inspector General has a role in reviewing state false claims laws.

» If your state has an FCA, know how that impacts your organization's compliance efforts.

» If your organization does business in more than one state, determine which states have state FCAs.

***Denise Atwood*** *(deniseatwoodpllc@gmail.com) is owner of Denise Atwood, PLLC in Gilbert, AZ.* *bit.ly/in-DeniseAtwood*

Seasoned compliance professionals in healthcare are typically very familiar with the federal False Claims Act (FCA),[1] which prohibits healthcare providers from submitting claims for payment to the federal government that are false or fraudulent. Compliance professionals are also familiar with the civil monetary and criminal penalties under the FCA.[2] However, compliance professionals may be less familiar with state false claims acts that impact healthcare compliance activities in those states. It is important to establish both a compliance program and training that addresses both federal and state FCA requirements, as applicable. This article evaluates the impact of state FCA enforcement, in addition to federal FCA enforcement actions.

Atwood

## The role of the Office of the Inspector General

Section 1909 of the Social Security Act (SSA) was added by section 6031 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171) to create financial incentives for states to enact legislation that establishes liability to the state for false or fraudulent claims to the state Medicaid program.[3] The Office of the Inspector General (OIG) is amenable to reviewing a state's FCA draft or enacted legislation to determine if the state laws qualify for financial incentive. The OIG will review the state's FCA to see if it meets the following as described in the federal FCA:

- The state law must establish liability for false or fraudulent claims with respect to Medicaid spending [31 U.S.C. § 3729];
- Contain provisions that are at least as effective in facilitating and rewarding *qui tam* actions for false or fraudulent claims [31 U.S.C. §§ 3730-3732];
- Contain a requirement for filing the action under seal for 60 days for review by the state Attorney General [Section 1909(b)(3) of the SSA]; and
- Contain a civil penalty that is equal to or greater than the federal penalty amount [31 U.S.C. § 3729].[4]

The OIG and the Attorney General collaborate to determine whether the state FCA meets

the requirements set forth above and qualifies for an incentive under section 1909 of the SSA. Compliance professionals who develop and implement compliance programs in accordance with federal and state requirements can help their entities and organizations save a lot of money by preventing FCA allegations and the resulting civil money penalties.

## Impact of federal and state False Claims Acts

Many states enacted FCAs to establish civil liability to the states for individuals and entities that submit false or fraudulent claims under the state Medicaid program.[5] "If a state obtains a recovery as a result of a state action relating to false or fraudulent claims under the State Medicaid program, it must share the recovery with the Federal Government in the same proportion as the Federal medical assistance percentage."[6] For example, if the federal assistance percentage towards the state Medicaid program is 70%, then the state would retain 30% of the funds recovered, and the federal government would receive 70% of the recovery.

Congress added section 1909 to the SSA to encourage states to pursue civil Medicaid fraud; if a state has an FCA that was deemed to meet the requirements noted above, the federal medical assistance percentage will be decreased by 10% with respect to any amount recovered under a state action brought under such a law.[7] So in the example above, the state's Medicaid share would increase from 30% to 40%, while the federal government would be entitled to 60% instead of 70% of the recovery.

Table 1 lists states with federally deemed (approved) FCA laws that would permit the 10% state recovery increase.[8]

## Notable FCA settlements and judgments

Several notable FCA settlements and judgments in 2016 resulted in recoveries in the hundreds of millions of dollars, many of which included state Medicaid repayments. It is important for compliance professionals to stay abreast of these settlements so they can assist their organizations in remaining compliant with federal and state FCA requirements. Overviews of three healthcare fraud recoveries under the FCA are described below, involving a surgical device manufacturer, a pharmaceutical manufacturer, and a healthcare services company.

### Olympus Corporation

In 2016, under allegations that kickbacks were paid to doctors and hospitals in exchange for the purchase of endoscopes and surgical devices, Olympus paid $646 million in a global settlement, including $267.3 million in federal recoveries under the False Claims Act, $43.5 million in recoveries for state Medicaid programs, and $335.2 million in criminal penalties.[9] This case is an example of how the Anti-Kickback Statute (AKS) and the FCA are used jointly to assess civil and criminal penalties against an organization, in this case, a manufacturer. Additionally, for states that have deemed state FCAs, the motivation to recover additional monies for the state Medicaid program may be increased, because of the 10% increase in the recover percentage.

### Novartis Pharmaceuticals Corporation

According to the U.S. Department of Justice Fact Sheet (2009-2016), Novartis Pharmaceuticals Corporation paid multimillion dollar global settlements in 2010 and again in 2016:

> In 2010, Novartis paid $422.5 million for the first settlement, involving allegations Novartis marketed off-label use of an anti-epileptic drug and included $149.2 million recovered for federal programs, $88.3 million recovered for state

Table 1. State Laws Deemed by OIG as of October 2017

| | |
|---|---|
| **California** | https://oig.hhs.gov/fraud/docs/falseclaimsact/California.pdf |
| **Colorado** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Colorado.pdf |
| **Connecticut** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Connecticut.pdf |
| **Delaware** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Delaware.pdf |
| **Florida**<br>• Supplement 1<br>• Supplement 2 | https://oig.hhs.gov/fraud/docs/falseclaimsact/Florida.pdf<br>https://oig.hhs.gov/fraud/docs/falseclaimsact/florida-supplement.pdf<br>https://oig.hhs.gov/fraud/docs/falseclaimsact/florida-supplement2.pdf |
| **Georgia** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Georgia.pdf |
| **Hawaii** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Hawaii.pdf |
| **Illinois** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Illinois.pdf |
| **Indiana** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Indiana.pdf |
| **Iowa** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Iowa.pdf |
| **Louisiana** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Louisiana.pdf |
| **Massachusetts** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Massachusetts.pdf |
| **Michigan**<br>• Supplement 1<br>• Supplement 2 | https://oig.hhs.gov/fraud/docs/falseclaimsact/Michigan.pdf<br>https://oig.hhs.gov/fraud/docs/falseclaimsact/Michigan-supplement.pdf<br>https://oig.hhs.gov/fraud/docs/falseclaimsact/Michigan-supplement2.pdf |
| **Minnesota** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Minnesota.pdf |
| **Montana** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Montana.pdf |
| **Nevada** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Nevada.pdf |
| **New Hampshire**<br>• Supplement | https://oig.hhs.gov/fraud/docs/falseclaimsact/NewHampshire.pdf<br>https://oig.hhs.gov/fraud/docs/falseclaimsact/NewHampshire-supplement.pdf |
| **New Jersey** | https://oig.hhs.gov/fraud/docs/falseclaimsact/NewJersey.pdf |
| **New Mexico** | https://oig.hhs.gov/fraud/docs/falseclaimsact/NewMexico.pdf |
| **New York** | https://oig.hhs.gov/fraud/docs/falseclaimsact/NewYork.pdf |
| **North Carolina**<br>• Supplement | https://oig.hhs.gov/fraud/docs/falseclaimsact/NorthCarolina.pdf<br>https://oig.hhs.gov/fraud/docs/falseclaimsact/NorthCarolina-supplement.pdf |
| **Oklahoma** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Oklahoma.pdf |
| **Rhode Island** | https://oig.hhs.gov/fraud/docs/falseclaimsact/RhodeIsland.pdf |
| **Tennessee** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Tennessee.pdf |
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| **Vermont** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Vermont.pdf |
| **Virginia** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Virginia.pdf |
| **Washington** | https://oig.hhs.gov/fraud/docs/falseclaimsact/Washington.pdf |
| **Wisconsin**<br>• Supplement | https://oig.hhs.gov/fraud/docs/falseclaimsact/Wisconsin.pdf<br>https://oig.hhs.gov/fraud/docs/falseclaimsact/Wisconsin-supplement.pdf |

Medicaid programs, and $185 million in criminal fines and forfeitures. The second settlement, for $72.5 million, involved a cystic fibrosis drug which Novartis allegedly marketed for off-label use. The settlement included $43.5 million recovered for federal programs and $29 million recovered for state Medicaid programs. Novartis paid another $410 million global settlement in 2016 involving alleged kickbacks the company paid to specialty pharmacies to promote two drugs. The settlement included $306.9 million for the federal government, $83.1 million for state Medicaid programs, and $20 million in civil forfeitures.[10]

It is surprising that Novartis paid multi-million dollar settlements a few years apart for similar violations of marketing off-label drug use in addition to alleged kickbacks to promote Novartis pharmaceuticals. This demonstrates the importance of a compliance program that ensures adherence to the law, because most healthcare organizations could not sustain that kind of loss to the bottom line once in a decade, much less twice in six years.

**Tenet Healthcare Corporation**

In 2016, under allegations that four Tenet hospitals engaged in paying kickbacks in return for patient referrals, Tenet Healthcare Corp. paid $513 million in a global settlement, including $244.2 million in federal recoveries under the False Claims Act, $123.8 million in recoveries to state Medicaid programs, and $145 million by two Tenet subsidiaries under the terms of a guilty plea.[11] In an effort to combat healthcare fraud, the U.S. Department of Justice (DOJ) is proactive in posting convictions and settlements on the DOJ website. The transparency of the DOJ can be a challenge for the compliance professionals of those entities and also for the public image of the entity. The bottom line will invariably be impacted due to decreased patient volume and millions of dollars in lost revenue, in addition to the civil monetary penalties.

## Conclusion

In evaluating an effective compliance program, healthcare compliance professionals should ensure they review not only federal laws, but also state laws that govern healthcare entities and organizations. Review and implementation of state FCA requirements—regardless of whether they have been deemed by the federal government—should be included in any healthcare compliance program, because the consequences of violations and monetary penalties can be financially catastrophic to an entity or organization.

1. Department of Justice: The False Claims Act: A Primer [31 U.S.C. §§ 3729-3733]. Available at http://bit.ly/1Sckpg1.
2. Government Publishing Office: 18 U.S.C. § 287 (False, fictitious or fraudulent claims). Available at http://bit.ly/2CYQ6uR.
3. U.S. Department of Health & Human Services, Office of Inspector General: OIG Guidelines for Evaluating State False Claims Acts. Available at http://bit.ly/2FqbAOW.
4. HHS:OIG: "State False Claims Act Reviews" Available at http://bit.ly/2cbJ6IG.
5. Idem.
6. Idem.
7. Idem.
8. Ibid, Ref #4
9. U.S. Department of Justice: "Fact Sheet: Significant False Claims Act Settlements & Judgements Fiscal Years 2009-2016" Available at http://bit.ly/2mhVrSW.
10. Idem.
11. Idem.

by Sharon Parsley, JD, MBA, CHC, CHRC

# CMS Modifies MIPS in the CY 2018 Final Rule

***Sharon Parsley*** *(sharonparsley@q-a-g.com) is President & Managing Director of Quest Advisory Group, LLC, in Ocala, FL.*

March 31, 2018 marks the close of the submission period for Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Quality Payment Program (QPP) data gathered during the 2017 performance period. Beginning on January 1, 2019, the first payment adjustments under QPP will occur. For physicians and eligible clinicians who did not submit 2017 performance data, that will result in a negative 4% payment adjustment.


Parsley

As we know, MACRA includes two tracks, the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models (APM). CMS continued to refine both MIPS and APM in the calendar year (CY) 2018 final rule, which will affect the QPP 2018 performance period and impact clinician payments during 2020 and beyond. Interestingly, the final rule projections reflect that, of the 1,548,022 clinicians billing for Medicare Part B services, approximately 40% will be MIPS eligible, but only 11% and 15% will participate through an APM.

A few noteworthy provisions of the CY 2018 final rule for MIPS include:

1. Both positive and negative payment adjustments can be up to 5% for 2020.
2. An estimated 540,000 clinicians will be excluded from MIPS by virtue of a considerable increase in the "low volume threshold." If a clinician or group has less than $90,000 in Medicare Part B allowed charges or sees fewer than 200 Part B beneficiaries, that clinician or group is excluded.
3. Cost of care begins to factor into MIPS as it represents 10% of the final score for the 2020 payment year and increases to 30% during the 2021 payment year. On the other hand, the quality performance category decreases to 50% during the 2020 payment year and again to 30% for the 2021 payment year.
4. Solo practitioners and groups of fewer than 10 that would otherwise be excluded based on the low volume threshold can group together "virtually" irrespective of specialty and geographic location for MIPS participation.
5. Bonus points are earned by QPP participants for treating complex patients, demonstrating improvement in quality or cost performance categories, and for reporting performance data as a solo practitioner or small group practice. For 2018, QPP participants will need to earn a minimum of 15 points to avoid payment reductions in 2020. As a result, participants will be required to report multiple performance measures to avoid a negative payment adjustment.
6. An automatic exemption from submitting quality, cost, and improvement performance data was created for MIPS participants affected by natural disasters or public health emergencies.

A good overview of the rule is available at this link: *http://go.cms.gov/2lJwse4*

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by Bartt B. Warner, CVA and Thomas A. Warrington, Jr., CVA

# Stacked physician compensation: Keys to compliance

» Compensation paid to physicians is under constant scrutiny as the number of healthcare settlements continues to rise both in number and in settlement awards.

» Compensation paid to a physician must be commercially reasonable, consistent with fair market value (FMV), and not in violation of other laws and regulations designed to prevent fraud and abuse.

» Stacked compensation refers to taking the individual components of a physician compensation arrangement and adding them up to derive total compensation.

» If each individual component is consistent with FMV, that does not automatically mean the total stacked compensation is as well.

» By thinking through each component of a physician's agreement and asking the appropriate questions, hospitals and health systems can reduce the risk of enforcement actions for their physician arrangements.

***Bartt B. Warner*** *(Bartt.Warner@vmghealth.com) is a Director and* ***Thomas A. Warrington, Jr.*** *(Thomas.Warrington@vmghealth.com) is a Managing Director with VMG Health and both are based in VMG Health's Nashville office.*

Compensation paid to physicians is under constant scrutiny as the number of healthcare settlements continues to rise both in number and in settlement awards. There has also been a shift by *qui tam* relators and the government to include both physicians and medical practices in enforcement action cases. Recent settlements have demonstrated the severe financial implications of improper financial relationships as shown in the Table 1 on page 36.

## Staying within the law

But what does all this mean? The answer is that any compensation paid to a physician must meet several requirements. It must be commercially reasonable. In the preamble to the Stark Phase II interim final rule, CMS defined *commercially reasonable* as:

Warner

Warrington

> [A]n arrangement will be considered commercially reasonable in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential designated health services referrals.[3]

Physician compensation must also be consistent with fair market value (FMV).

Table 1: 2015 & 2016 Notable Healthcare Settlement Summary

| 2015 & 2016 Notable Healthcare Settlement Summary | | | |
|---|---|---|---|
| **Year** | **System** | **Settlement Reason** | **Amount** |
| 2015 | Citizens Medical Center[1] | Civil FCA allegations that it engaged in improper financial relationships with referring physicians. | $21.8 Million |
| 2015 | North Broward Hospital District[1] | Civil FCA allegations that it engaged in improper financial relationships with referring physicians. | $69.5 Million |
| 2015 | Columbus Regional Healthcare System[1] | Civil FCA allegations that they submitted claims to federal health care programs that violated the Stark Law and that misrepresented the level of services they provided. | $35 Million |
| 2015 | Tuomey Healthcare System[1] | Civil FCA judgment entered against it for illegally billing the Medicare program for services referred by physicians with whom the hospital had improper financial relationships. | $72.4 Million |
| 2015 | Tuomey Healthcare System[2] | Former Tuomey Healthcare System CEO (Ralph Cox) - illegal referrals | $1 Million |
| 2015 | Memorial Health, Inc., Memorial Health University Medical Center, Inc., Provident Health Services, Inc., and Memorial Health University Physicians[2] | Civil FCA allegations that they engaged in improper financial relationships with referring physicians that violated the Stark Law. | $9.9 Million |
| 2016 | Tenet Healthcare Corp. (Tenet)[2] | Allegations of illegal kickbacks paid to clinic owners in exchange for referring patients for labor and delivery to Tenet hospitals. | $514 Million |
| 2016 | Lexington Medical Center[2] | Hospital overpaid physicians and rewarded them based on their referral of patients to the facility. | $17 Million |

According to the International Glossary of Business Valuation Terms, *fair market value* is defined as:

> The price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arms-length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.[4]

Compensation paid to physicians must not be in violation of the Stark Law. According to the Office of Inspector General, "The Stark Law (42 USC § 1395nn) prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies."[5]

The Anti-Kickback Statute (AKS) also figures into physician compensation. According to the Office of Inspector General, "The Anti-Kickback Statute (42 USC § 1320a-7b(b)) prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business."[6]

And finally, physician compensation must not trigger the False Claims Act,[7] and other regulations designed to prevent fraud and abuse. According to the Office of Inspector General, "The False Claims Act (31 U.S.C. §§ 3729–3733) prohibits the submission of false or fraudulent claims to the Government."

Thus, it is crucial to understand the entire compensation package being paid to a physician in addition to the individual components.

## Stacked compensation

As the number of employed physicians increases and hospitals and health systems look for alignment strategies based on quality, the issue of "stacked" compensation is becoming more prevalent. Stacked compensation refers to taking the individual components of a physician compensation arrangement and adding them up to derive total compensation. For example, it is not uncommon for physicians to be paid for call coverage, clinical services, medical director/physician executive

services, quality, advance practice clinician oversight, and/or academic teaching and proctoring, among others. However, even if each individual component is consistent with FMV, does that automatically mean the total stacked compensation is as well? This is a crucial issue that must be considered by legal counsel and the compliance team when looking at complex compensation arrangements.

## Keys to compliance

When looking at stacked compensation, one should focus on the following items to ensure compliance and understand if the arrangement is consistent with FMV:

1. Are each of the individual components consistent with FMV and how was this determined?
   - Internal process by the hospital or health system. This method does not guarantee consistency with FMV, however, internal processes may be appropriate for low-risk arrangements.
   - Independent third-party valuation. The government has shown preference for this method.[8]
2. Is the arrangement and each component commercially reasonable?
   - Arrangement must make business sense absent consideration for referrals. This is the "why" of the arrangement.
3. Does the compensation arrangement comply with the healthcare laws and regulations?
4. Have you confirmed that the arrangement is not based on the volume or value of the physician's referrals?
5. Are the benefits and paid time off (PTO) package reasonable and consistent with industry norms?
6. One-time payments and bonuses such as signing, commencement, retention, relocation and various other bonuses are becoming more and more prevalent. Have these payments been considered when analyzing the total compensation paid to the physician?
7. Has the compensation package been tested using reasonability tests? In addition, have sensitivity models been performed/analyzed at various levels of productivity for physicians receiving productivity-based compensation?
8. How does the compensation compare to what other physicians in the same specialty receive in the market?
9. Are the overall hours reasonable and can the hours be worked without adversely affecting performance and/or other components?
10. Are each of the services separate and distinct, and are items paid on an hourly basis being tracked/documented?

According to Joseph N. Wolfe, Esq., the first three bullet points are crucial to defensibility in court. In addition, "Because these tenets of defensibility are found in most exceptions, physician compensation policies and procedures should take special care to document compliance with these three tenets, regardless of the exception that is ultimately relied upon."[9]

## Real world example

To fully understand this concept, let us look at real example of a pediatric surgeon employed by a large health system (see Table 2 on page 38):

At first glance, one may intuitively assume this physician is overpaid due to the high annual base guarantee. However, it is imperative to benchmark all metrics when analyzing the physician compensation to understand if the components are reasonably aligned. What Table 2 does not show is that this physician currently produces above the 90th percentile of market surveys for both work relative value

Table 2: Example of compensation for a highly productive pediatric physician

| Example: Highly Productive Pediatric Surgeon | | | |
|---|---|---|---|
| **Compensation Component** | **Notes** | **Compensation** | **Estimated Annual Hours** |
| Annual Base Guarantee | Base Guarantee or $75 per WRVU | $800,000 | 2,000 |
| Quality Incentive | Outcome based metrics | $50,000 | n/a |
| Medical Director | $175 per hour up to 240 hours per year | $42,000 | 240 |
| Call Coverage Compensation (1:5 Rotation) | Required to provide five (5) days per month uncompensated. Paid $1,000 per 24 hour shift after day five (5). Physician provides two (2) additional days per month. | $24,000 | 576 |
| **Total** | | **$916,000** | **2,816** |

WRVU = Work relative value units (a method for calculating the volume of work or effort expended)

units (WRVU) and professional collections. As a result, the compensation is *potentially* consistent with FMV. However, in situations such as these, FMV assessments are always recommended to ensure compliance. In addition, the hours listed above may warrant additional review to ensure the physician can reasonably work the hours and to confirm the physician is not receiving multiple streams of income during the same hour of service.

## Practical takeaways

1. Create a documented compliance program and ensure triggers are in place to determine when/if a valuation/FMV assessment is needed.
2. Analyze total hours worked and ask if it is reasonable for the physician to be paid for that amount of hours. Also, can the physician reasonably perform this amount of workload without negatively impacting other areas of the physician's practice?
3. Review each compensation component in the agreement to ensure the physician is not receiving multiple streams of income during the same hours worked. For example, a minimum amount of hours are required for physicians receiving base salaries. In essence, this time has already been paid for.
4. A highly productive physician will likely warrant a compensation-per-WRVU rate at or below the median percentile. (Note: An inverse relationship exists between compensation and compensation per WRVU—higher producing/earning physicians will indicate a lower compensation per WRVU.) Ensure benchmarking analyses are performed and review to see if compensation and productivity are reasonably aligned.
5. Review and document any instances of physician practice losses. It is important to detail why the losses are occurring. For example, when hospitals purchase physician practices, it is not uncommon for general overhead to be allocated to the physician practice profit and loss statement, which creates a loss on paper. In addition, many health systems will strip out the ancillary services post-transaction and move these services to the hospital. The loss of this technical revenue stream may result in physician practice losses. Another factor, which can create physician losses, is many health systems will negotiate stronger payer contracts for the hospital, while accepting lower rates for outpatient physician services. Each of these are the result of decisions the

hospital/health system makes as the owner of the physician practice, but may result in losses being implied at the physician practice level. Documentation is crucial for compliance.

6. Perform routine audits to understand if the services are still needed, hours are being effectively tracked, and compensation is being paid in accordance with the agreement. For example, a new hospital service-line medical director may be required to provide a certain number of hours per week or month while getting the program started. However, once the program is up and running, the time requirements may not be as burdensome and may need to be reduced. In addition, if the physician can earn compensation through quality incentives, those metrics should continually be reviewed to ensure they are appropriately structured to achieve the desired quality outcomes.
7. Document non-referral business rationale supporting compensation arrangements.

## Conclusion

The government has made it clear that healthcare organizations face large potential penalties for violations of healthcare laws and regulations. Therefore, it is imperative to ensure all physician compensation arrangements are consistent with FMV, both individually and in aggregate. By thinking through each component of a physician's agreement and asking the appropriate questions, hospitals and health systems can reduce the risk of enforcement actions for their physician arrangements.


1. The Department of Health and Human Services And The Department of Justice Health Care Fraud and Abuse Control Program: Annual Report for Fiscal Year 2015 (February 2016). Available at http://bit.ly/2D655SS
2. The Department of Health and Human Services And The Department of Justice Health Care Fraud and Abuse Control Program: Annual Report for Fiscal Year 2016 (January 2017). Available at http://bit.ly/2DHN1ML
3. Federal Register vol. 69, no. 59, p 16093: Preamble to the Stark Phase II interim final rule. March 26, 2004. Available at http://bit.ly/2Dmfyus
4. International Glossary of Business Valuation Terms: fair market value. Available at http://bit.ly/2mtqMTv
5. 42 USC § 1395nn: Limitation on certain physician referrals. Available at http://bit.ly/2AQvnDJ
6. 42 USC § 1320a-7b(b). (The Anti-Kickback Statute). Available at http://bit.ly/2siltcS
7. 31 U.S.C. §§ 3729–3733 (The False Claims Act). Available at http://bit.ly/1Sckpg1
8. OIG: Corporate Integrity Agreement for Halifax Hospital Medical Center Appendix A. March 10, 2014. Available at http://bit.ly/2Dt058U
9. Joseph N. Wolfe and Wesley R. Sylla: "Physician compensation compliance: Can your plan survive Stark Law scrutiny?" *Compliance Today*, March 2016.

by Frank Ruelas

# Emails from unknown senders

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

This month's Security Awareness Reminder (SAR) is related to the receipt of emails from unknown senders. When receiving email from unknown senders, one should take note, especially if the received email contains links or attachments. These links and attachments could contain harmful programs that could compromise the security and privacy of your computer system.

Ruelas

Given the risk of compromising the privacy and security by introducing a harmful program onto the organization's computer system, the following reminder is provided for your consideration and use.

## Suggested SAR text

"When receiving an email, take a moment to identify the sender of that email. If the sender is unknown to you and the email contains links or attachments, please take a moment to validate the sender, the reason for the email, and the nature of the links and attachments. These quick and easy steps can significantly help maintain the privacy and security of our network by reducing the risk associated with clicking on links and opening attachments from unknown senders of emails."

## Why this reminder matters

The use of email is very popular and often the communication channel of choice between people. Instead of calling a person by phone, most people opt to send that person an email. Consequently, it is very common for people to get quite a few emails during the day. Unless a person makes the effort to review their email box regularly, a person can easily end up with several dozen emails stacked up in the inbox waiting for attention. This in turn may prompt people to go through their emails with little thought as to their origin in the effort to clean up their inbox.

One strategy that is used by hackers to try to compromise an organization's computer system is to send emails that people may not recognize as coming from an unknown sender, hoping a recipient will then click on a link or on an attachment that ends up creating a computer security incident.

> ...please take a moment to validate the sender, the reason for the email, and the nature of the links and attachments.

Understanding how this method of attack makes use of email and the tendency that people have to go quickly through their emails, the stage is set for a successful attack on a computer system by someone clicking on a link or attachment that was sent by a computer hacker.

By raising awareness of this ever-present threat of an email-based attack, advising people to exercise care in the review of emails, and providing guidance on what users are to do when they receive a suspicious email, organizations can increase their chances of preventing a computer security incident.

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- October 1–4, 2018 • Dallas, TX
- October 15–18, 2018 • Nashville, TN
- November 12–15, 2018 • San Diego, CA
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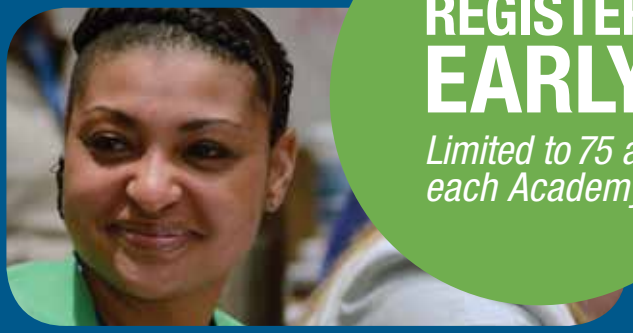

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by Gary W. Herschman, Melissa L. Jampol, and Tristan A. Potter-Strait

# Navigating Medicare Secondary Payer compliance and False Claims Act liability

» The Supreme Court's recent decision in Escobar expands the potential for Medicare Secondary Payer Act (MSP) enforcement through the False Claims Act.

» The MSP impacts healthcare providers, insurers, employers, beneficiaries, and other parties.

» Medicare requires timely reimbursement of conditional payments.

» Non-compliance with MSP requirements can result in double damages.

» Providers need appropriate internal controls to monitor potential overpayments in a timely manner to avoid potential exposure under the MSP and FCA.

***Gary W. Herschman*** *(gherschman@ebglaw.com) and* ***Melissa L. Jampol*** *(mjampol@ebglaw.com) are both Members of the Firm in the Health Care and Life Sciences practice, in the Newark, NJ and New York offices of Epstein Becker Green.* ***Tristan A. Potter-Strait*** *(tpotterstrait@ebglaw.com) is an Associate in the Health Care and Life Sciences practice in the Newark office of Epstein Becker Green.*

Herschman

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The Medicare Secondary Payer Act (MSP) places certain responsibilities on insurers, employer health plans, and healthcare providers. Non-compliance with the MSP can result in monetary penalties and government enforcement action. Currently, the MSP is garnering attention as an enforcement tool under the False Claims Act (FCA).[1] This article gives a general overview of the MSP, discusses requirements for compliance, describes recent MSP enforcement actions under the False Claims Act (FCA), and gives some key takeaways to reduce potential liability.

## The Medicare Secondary Payer Act basics

The MSP affects providers, employer-sponsored group health plans (GHPs), liability and no-fault insurers, workers' compensation funds and plans (collectively, non-group health plans, or NGHPs), and Medicare beneficiaries. Generally, the MSP:

- Requires that Medicare be a secondary payer if a beneficiary carries certain types of employer sponsored health plans;[2]
- Prohibits the Centers for Medicare and Medicaid Services (CMS) from making payments for Medicare-covered services if payment has been made, or can reasonably be expected to be made, by a another payer;[3] and
- Allows CMS to make "conditional payments" to the beneficiary if there is a delay in reimbursement from another entity for a covered service.[4]

Notably, Congress also enacted a parallel MSP provision that applies to state Medicaid plans.[5] Special rules

apply to Medicare beneficiaries covered under a GHP,[6] and Medicare is generally the secondary payer for these covered services when a beneficiary is entitled to Medicare.

In an effort to assist primary payers and providers in determining Medicare's payer status, CMS established a Coordination of Benefits (COB) system that collects beneficiary coverage data. The Benefits Coordination & Recovery Center (BCRC) administers the COB by ensuring the accuracy of the Common Working File (CWF), a CMS database that stores information regarding MSP data and investigations. CMS shares this data with other payers to ensure proper claim submission to Medicare.

## Conditional payments

Medicare will make a conditional payment to a beneficiary if there is a delay in payment by the primary payer to keep the beneficiary from experiencing a gap in coverage.[7] Subsequently, Medicare may pursue reimbursement of conditional payments from:

- A beneficiary or other party, if both a primary and conditional payment were received;
- A primary payer, if a conditional payment was made pursuant to liability insurance settlements, disputed claims under group health plans, workers' compensation plans, or no-fault insurance; and
- The beneficiary or provider, if the filing of an improper claim resulted in a conditional payment, unless the claim was a result of false information provided by the beneficiary and the provider complied with certain regulatory procedures.

These conditional payments must be reimbursed to Medicare within 60 days of receipt of payment. If a primary payer or provider fails to pay back the conditional payments, CMS may assess double damages.

Both beneficiaries and their fiduciary agents, such as attorneys, can be sued for recovery of improperly retained conditional payments. In one such case, a Medicare Advantage (MA) plan operated by Humana made a conditional payment to a beneficiary injured in a motor vehicle accident.[8] The beneficiary sued several insurance companies for payment, resulting in a settlement and the disbursement of settlement funds to the beneficiary's attorney. Humana issued a demand letter to the beneficiary, seeking reimbursement for its conditional payment, which it alleged was partly contained in the settlement amount. When the beneficiary failed to pay, Humana commenced a lawsuit against both the beneficiary and the beneficiary's counsel to recover the funds. On a motion to dismiss by the beneficiary's attorneys, the court ruled that the MSP allowed the MA plan to pursue recovery of conditional payments and double damages against beneficiary's counsel, as "plain language fails to limit the parties against whom suit may be maintained" and that there is a private right of action that a MA can use to recover conditional payments pursuant to 42 USC §1395y(b)(3)(A).[9]

If a primary payer or provider fails to pay back the conditional payments, CMS may assess double damages.

## MSP requirements and liability for providers and primary plans

The MSP also requires that GHPs, NGHPs, and providers report certain beneficiary

information to CMS. Non-compliance with these reporting requirements results in a minimum fine of $1,000 a day per unreported beneficiary and, potentially, double damages.

**Group health plans (GHPs)**

Generally, a GHP is sponsored by an employer to provide healthcare to employees and their families.[10] These include self-insured plans that may be administered through a third-party administrator (TPA) and plans arranged by employers through a health insurer. The MSP requires that GHPs with 20 or more employees report certain information to CMS to avoid payment conflicts (although smaller companies have certain limited reporting obligations). These plans are considered Responsible Reporting Entities (RREs) and must report all active covered individuals to Medicare. An active covered individual is defined as:

- Those between 45 and 64 years of age who are covered through the GHP, based on their own or a family member's current employment status;
- Those 65 and older who are covered, based on their own or their spouse's current employment status;
- All individuals covered under a GHP who have been receiving kidney dialysis or have received a kidney transplant due to end-stage renal disease (ESRD); and
- All individuals covered under a GHP who are under 45, are known to be entitled to Medicare, and have coverage in the plan, based on their own or a family member's current employment status.[11]

GHP RREs have multiple reporting options, but the basic option requires a GHP RRE to submit an MSP Input File containing information about each active covered individual, as outlined in the CMS manual. The GHP RRE reports through registering on the Coordination of Benefits Secure Website (COBSW).[12] The GHP may submit a Query Only Input File, which helps the GHP assess if potential employees are covered by Medicare. GHPs must be careful to obtain detailed information from their employees (including information about family members) to comply with this requirement.

**Non-group health plans (NGHPs)**

Although reporting requirements among GHPs are largely uniform, the same cannot be said for NGHPs. Thus, this article will not explore the nuances of each NGHP's reporting priority and specific guidance.

NGHPs are generally liability insurance plans (including self-insurance), no-fault insurance, and workers' compensation laws or plans.[13] The intent behind the NGHP reporting requirements is that if a Medicare beneficiary is injured and another payer (such as a workers' compensation plan) is responsible for paying for the medical treatment of the beneficiary, then the other party should be the primary payer. Unlike GHPs, there is no blanket requirement that all NGHPs register with Medicare, but those that have reportable information must register at least a quarter before submitting a report. NGHPs are required to submit a report when there is an ongoing responsibility for medical bills (ORM) or there is a total payment obligation to the claimant (TPOC).

An ORM must be reported when there is ongoing compensation to a party for medical care associated with a claim. ORM reports do not include dollar amounts, but just the fact that payments are being made for ongoing medical expenses, and the start and end dates. Additionally, an ORM report should include information about the cause of illness, injury, or incident associated with the

claim so that Medicare can determine if the NGHP, Medicare, or another payer is responsible for the claim.

TPOC reports are made when the sum of a total settlement, judgment, award, or other payment obligation is established. There are various mandatory reporting thresholds depending on the type of insurance and the date of payment.[14] NGHPs should be well versed in the intricacies of these requirements and the six detailed CMS reporting manuals issued on December 15, 2017.[15]

**Healthcare providers**

Healthcare providers have defined responsibilities under the MSP, although these responsibilities are less onerous than those placed upon GHPs and NGHPs. Generally, providers must implement certain procedures to determine each patient's Medicare eligibility status and submit claims to the proper insurer for reimbursement. These procedures include asking patients their Medicare eligibility status, checking the Common Working File, and creating and maintaining an internal database that stores information on each patient's insurance coverage. When inquiring about a patient's insurance coverage, providers are encouraged to use a CMS questionnaire found on the CMS website.[16] Providers must also submit an Explanation of Benefits (EOB) form with each claim to Medicare to ensure proper billing.[17] Providers should inquire as to whether the reason the patient is being seen for treatment is prompted by an injury that would be covered by an NGHP provider, such as an automobile accident, fall, or injury in the workplace.

When inquiring about a patient's insurance coverage, providers are encouraged to use a CMS questionnaire found on the CMS website.

If a provider submits an improper claim to Medicare but receives a conditional payment, the provider must reimburse Medicare within 60 days of receiving the payment. The provider will not be penalized if the provider maintains an internal database that stores information on each patient's insurance coverage and the provider can show that the claim was submitted as a result of false information provided by the beneficiary or someone acting on the beneficiary's behalf.[18] However, if a provider does not reimburse such a conditional payment within the timeframe mandated in a Medicare demand letter, the provider can face civil monetary penalties, such as paying interest on any outstanding payment and being subject to double damages.[19]

## Recent FCA enforcement actions involving MSP

The Supreme Court's 2016 decision in *Universal Health Services, Inc. v. United States ex rel. Escobar* expands the potential for MSP enforcement.[20] In *Escobar*, the Supreme Court ruled that an implied false certification action can survive if the defendant made a misrepresentation "about compliance with a statutory, regulatory, or contractual requirement [that is] material to the Government's payment decision." Through the implied false certification theory of liability, both relators and the government have a potentially powerful tool to regulate non-compliance

with several regulations and statutes, including the MSP. Three recent decisions illustrate a potential rise in MSP-related FCA cases, especially in the wake of *Escobar*.

**Incorrect billing**

In *United States ex rel. Jersey Strong Pediatrics, LLC v. Wanaque Convalescent Center et al.*,[21] which is still pending in the District of New Jersey, a *qui tam* relator alleges that Wanaque Convalescent Center billed only Medicare/Medicaid for services rendered to patients admitted to its skilled nursing facility and failed to bill any third party, resulting in overpayments triggering MSP and FCA liability. In its amended complaint, the relator detailed eight instances of allegedly incorrect billing where the patient's medical record only listed Medicare or Medicaid as payer, even though the patient had multiple forms of insurance.[22]

The defendants filed a motion to dismiss the amended complaint, arguing that false claims were not submitted, because private insurance plans did not cover the services rendered, resulting in Medicare or Medicaid becoming the primary payer for the specific services. The defendants further contended that the relator's allegations lacked the heightened materiality standard set forth in *Escobar*, claiming that the relator merely cited to federal regulations that the relator deemed "material" to the government's decision to reimburse, rather than providing specific facts that any claim for payment has been rejected as being non-compliant with the MSP or any other regulation.[23] The relator responded that non-compliance with the MSP satisfies the "materiality" standard set by *Escobar*.

The court denied the motion to dismiss, noting that the government has a great interest in ensuring strict compliance with the MSP, such that compliance with the MSP is "material" to the government's decision to render payment. The court found that the amended complaint alleged sufficient detail to put the defendants on notice, sufficiently pleaded knowledge, and that the relator sufficiently pleaded that "MSP laws are material to the government's decision to pay Medicare/Medicaid claims in this context."[24]

Thus, still at issue while the case moves forward is whether the defendant may be liable under the FCA for violations of the MSP due to submitting allegedly improper claims to Medicare or Medicaid as the primary payer and impliedly certifying those claims as compliant with all federal laws and regulations.[25]

> ...the government has a great interest in ensuring strict compliance with the MSP...

**60-day repayment window**

In *Kane ex rel. United States v. Healthfirst, Inc. et al.*,[26] the United States and the State of New York filed complaints-in-intervention (the complaint), alleging that the defendant, Healthfirst, a private, non-profit insurance program with contracts with New York hospitals, issued electronic remittances to certain providers relating to Medicaid patients. Although the remittances should have stated that Medicaid could not be billed as a secondary payer for certain covered services, due to a computer "software" glitch, they failed to include that information, resulting in improper payment by Medicaid for claims which triggered MSP and FCA liability.[27]

The relator alleged that the defendant violated the 60-day window mandate by reimbursing Medicaid more than 60 days

from the time the relator compiled the list of possible overpayments. In its ruling denying defendant's motion to dismiss the complaint, the district court concluded that the 60-day window for reimbursement commenced when the provider has been put on notice of a potential overpayment, noting that allowing an individual or entity to commence repayment only after definitively identifying an overpayment would be incompatible with the legislative history and intent of the FCA. Subsequently, this case settled for $2.95 million.[28]

**Automobile insurance**

A third FCA case involving the MSP has a twist, as it involves the intersection of MSP law with New Jersey state automobile insurance law. In *Negron ex rel. United States v. Progressive Casualty Insurance Co. et al.*,[29] the relator purchased an auto insurance policy from Progressive, which gave her the choice of selecting a "health first" policy or a "personal injury protection (PIP)" policy as her primary insurer. Under a health first policy, the enrollee's private health insurer is the primary payer for medical bills resulting from an automobile accident. The relator's primary insurance was Medicare; however, Medicare and Medicaid recipients are not eligible for this type of insurance coverage, as Medicare and Medicaid are treated as secondary payers in such situations.[30]

A few months later, after the relator was involved in a car accident, Medicare conditionally paid for a claim that should have been reimbursed by the auto insurance policy. The relator brought a FCA action against Progressive and its New Jersey subsidiary, stating that the insurer had failed "to make reasonable and prudent inquiries to ensure compliance with the MSP Act" and that Medicare had improperly paid her bills as the primary payer.[31] Subsequently, the insurer moved to dismiss the complaint. In denying the motion to dismiss, the court found that the practice of allowing Medicare and Medicaid beneficiaries to select the "health first" policy was a violation of the MSP, because it allows Progressive to remain willfully ignorant of a beneficiary's primary plan coverage. The court chided the auto insurance company for its lack of controls. Specifically, the court looked at the underwriting process, which should have involved some investigation into the beneficiary's eligibility for Medicare and Medicaid. It also noted that the claims adjustment process should have involved an identical investigation to determine the appropriateness of a "health first" or PIP policy for each beneficiary.[32]

The court stated that Medicare should not pay conditionally for the services rendered to the relator just because the auto insurance company eventually paid Medicare back, and found that this manipulation of the "conditional payment" provision of the MSP ignores the requirement that a conditional payment is only to be made if prompt payment is not made by a primary payer. Ignoring this requirement allows the defendants to "receiv[e] an interest free loan from the government on claims they are obligated to pay and were always obligated to pay."[33] As such, the court found that there was a "sufficient allegation [in the complaint] demonstrating economic loss to plead that the claims were false or fraudulent." Subsequently, after the U.S. Department of Justice and the State of New Jersey intervened, the defendants settled the case for $2 million.[34]

Although *Negron* involves New Jersey state auto insurance laws, the court's findings are instructive for healthcare providers. The burden of investigating a patient's health insurance coverage is squarely on the shoulders of the provider, and merely

allowing a patient to elect certain coverage without more inquiry may not be a sufficient defense against FCA liability based upon MSP violations.

## Practical recommendations for providers

Given the recent trend in MSP and FCA enforcement, providers should consider the following practical recommendations so as to avoid liability:

- Implement adequate controls when submitting reimbursement claims to Medicare and Medicaid to ensure correct payer status.
- Actively investigate each patient's healthcare coverage to determine if the patient carries a primary policy or if another party is responsible, prior to submitting a claim for reimbursement.
- Reassess the patient's primary payer coverage at each encounter.
- Conduct random internal billing audits to ensure MSP compliance.
- Educate any case management/billing staff on the MSP and potential liability issues.

Once an overpayment is identified, providers are on notice that next steps involve confirming an overpayment and beginning the refund process as necessary. As a result, providers need appropriate internal controls to monitor potential overpayments in a timely manner to avoid potential exposure under the MSP and FCA laws.

1. For more updates on MSP enforcement, see http://bit.ly/2DrGhF6.
2. 42 USC § 1395y(b)(2)(A)(i); 42 CFR § 411.20 .
3. 42 USC § 1395y(b)(2)(A)(ii); 42 CFR § 411.20 .
4. 42 USC § 1395y(b)(2)(B); 42 CFR §§ 411.21 & 411.24
5. 42 USC § 1396a(a)(25); 42 CFR §§ 433.135-140
6. 42 USC § 1395y(b)(1); 26 USC § 5000(b)(1)
7. 42 USC § 1395y(b)(2)(B); 42 CFR §§ 411.21 & 411.24
8. *Humana Ins. Co. v. Paris Blank LLP*, 187 F. Supp. 3d 676 (E.D. Va. 2016)
9. Id. at 681
10. 26 USC § 5000(b)(1)
11. CMS: Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA) Section 111: MSP Mandatory Reporting: GHP User Guide 7-2—7-3 (v5.0 2017). Available at http://go.cms.gov/2DrY5h1
12. CMS: COB Secure Web site (COBSW). Available at http://bit.ly/2DhlT6c
13. 42 USC § 1395y(b)(8).
14. CMS: MMSEA Section 111 MSP Mandatory Reporting: NGHP User Guide Ch. III (v5.3 2017). Available at http://go.cms.gov/2zIX58k
15. Id.
16. CMS.gov: Your Billing Responsibilities. Available at http://go.cms.gov/2AUYPZj
17. Medicare Secondary Payer Manual, Ch. 3 § 30.5.B.
18. 42 CFR § 489.20.
19. 42 CFR § 489.24.
20. *Universal Health Services, Inc. v. U.S.*, Supreme Court decision: 136 S. Ct. 1989, 1996 (2016).
21. *United States ex rel. Jersey Strong Pediatrics v. Wanaque Convalescent Ctr.*, No. 14-6651-SDW-SCM, 2017 U.S. Dist. LEXIS 150566 (D.N.J. Sept. 18, 2017).
22. Id. at *2.
23. See id. at *9-10.
24. Id. at *7-9.
25. Id. at *7-8.
26. *Kane ex rel. United States v. Healthfirst, Inc. et al.*, 120 F. Supp. 3d 370 (S.D.N.Y. 2015).
27. Id. at 375-77.
28. Department of Justice, Justice News press release: "Manhattan U.S. Attorney Announces $2.95 Million Settlement With Hospital Group For Improperly Delaying Repayment Of Medicaid Funds" August 24, 2016. Available at http://bit.ly/2bBBH59.
29. *Negron ex rel. United States v. Progressive Cas. Ins. Co. et al*, No. 14-577(NLH/KMW), 2016 U.S. Dist. LEXIS 24994 (D.N.J. Mar. 1, 2016).
30. Id. at *5-*9.
31. Id. at *27.
32. Id. at *7.
33. Id. at *8.
34. DOJ, Justice News press release: "Two Insurance Companies Agree To Pay More Than $2 Million To Resolve False Claims Act Allegations" November 14, 2017. Available at http://bit.ly/2CVW8bA

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by Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC

# We interrupt your research compliance program!

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

Interruptions—life's temporary pauses that cause us to stop or take a break from our activity. Research compliance seems to have many of these types of breaks. In 2018, we have to face numerous interruptions for new areas of change. Consider the 2018 Common Rule implementation and what you did to prepare for it. Remember the action items and the list to get your team ready? You had new standard operating procedures, new elements of the informed consent, and the upcoming single Institutional Review Board (IRB) to consider. I remember when asking the question, "Did you check the box?" was an easy answer. With another interruption, we are challenged with keeping up.

Willenberg

Last December, the Food and Drug Administration (FDA) announced the availability of the guidance entitled, "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions." These types of interruptions are not uncommon in the research compliance world.

By modifying the policy, the FDA thought they were helping CMS in determining whether or not an IDE device should be covered (reimbursed) by CMS. It is up to us in the research compliance offices to discern the new rules, because there are rules for CMS that are not necessarily followed by commercial insurance plans or Medicare Advantage Plans. A site must know not only the category designation, but whether the Medicare contractor wants more than the CMS approval available online. Yet another interruption in your normal flow to meet a rule!

2018 will be a busy year for our pharmaceutical sponsors in clinical research. The new General Data Protection Regulation (GDPR) will become effective in all European Union (EU) Member States, so any sponsor doing clinical research must understand the key elements. The GDPR will strengthen the rights of individuals to be better informed about how their data is to be used and set new standards and obligations on using data. Consent, transfer of data, and accountability of data are important in the GDPR for sponsors moving forward. Another interruption?

> I remember when asking the question, "Did you check the box?" was an easy answer.

A pause for a staffing adjustment or a monitor change can seem trivial when you consider the disruptions we must confirm to meet new guidelines or rules imposed by others. "We interrupt your regularly scheduled compliance program to bring you a special bulletin" is just part of the research compliance administrator's every day work life!

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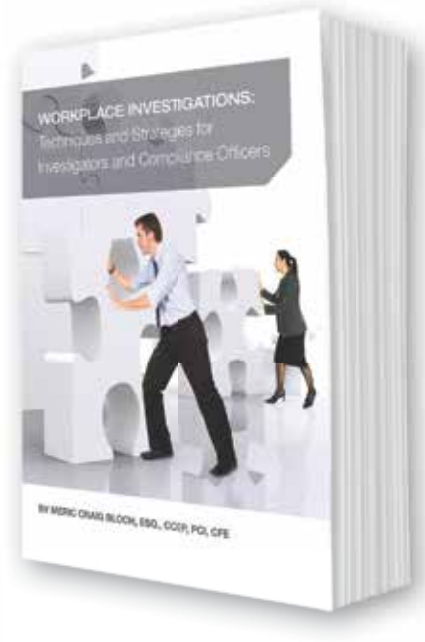


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by Alaina Underberg, MHSA, CCRP and Christina Head, MHSA

# How to open oncology clinical trials: Staying compliant

» Regulatory tasks in healthcare, especially in clinical research, are a necessary but laborious job that encompasses all aspects of daily operations.

» Good Clinical Practice (GCP) is a universal set of principles that are recommended and essential in the field of research.

» The IRB and the research site are responsible for ensuring patient's rights are protected when conducting human research.

» To be in accordance with FDA regulations, it is of utmost importance to maintain regulatory integrity by ensuring clinical trial requirements are met.

» It is important to have a structured process throughout all phases of opening and maintaining oncology clinical trials.

***Alaina Underberg*** *(underberga@sjchs.org) is Research Business Manager and* ***Christina Head*** *(warrenc@sjchs.org) is Oncology Clinical Initiatives Analyst at Nancy N. and JC Lewis Cancer & Research Pavilion at St. Joseph's/Candler Health System in Savannah, GA.*

Many areas of business and government are heavily saturated in regulatory requirements throughout their daily operations. The field of research—especially in oncology—is no exception, and regulatory requirements are present in every aspect of conducting clinical research. Regulatory compliance can be very cumbersome and resource intensive, encompassing all phases from opening a new trial, to approval from the Institutional Review Board (IRB), assigning a principal investigator, managing the consent process, and from enrolling patients to study close-out. In fact, the regulatory burden is so complex that most research sites struggle with the daily management of regulatory compliance. In a survey conducted in 2015 by a joint Initiative from the American Society of Clinical Oncology (ASCO) and the Association of American Cancer Institutes (AACI), 47% of respondents indicated a lack of adequate staff to handle regulatory burdens, and 41% lacked adequate staff for monitoring regulatory compliance.[1] It is of utmost importance to maintain regulatory integrity in accordance with the federal guidelines to ensure clinical trial requirements are being met.

Underberg

Head

In oncology clinical research, regulations are put forth and ultimately overseen by the Food and Drug Administration (FDA). The FDA requires oversight by an IRB that has the authority to review protocols at the site level and approve or disapprove research from being carried out at a particular institution. The main purpose of the IRB is to ensure that patient rights are protected.[2] IRBs and research sites must adhere to the principles of Good Clinical Practice (GCP), which is universally recognized as a critical requirement in conducting research involving human subjects.

The FDA developed the Bioresearch Monitoring (BIMO) program to safeguard the human research subjects involved in FDA-regulated clinical trials.[3] Multiple steps are followed throughout the life of a cancer clinical trial in order to comply with the regulations set forth by the FDA. According to the National Cancer Institute's (NCI) Education in Palliative and End-Of-Life Cancer for Oncology Care, 40,000 to 60,000 cancer patients will enroll in clinical research trials annually.[4] Clearly, it is important for this high volume of human research subjects to be overseen by regulatory professionals that are meticulous with the various responsibilities associated with oncology regulatory compliance.

## Steps to opening oncology clinical trials

After the clinical trial has been activated at the National Cancer Institute (NCI) level for research site participation, in most cases, the site's regulatory professional is responsible for preparing all the required study documents for submission to the IRB. The NCI's National Clinical Trials Network (NCTN) studies include submission of the following information:

- Financial disclosure forms
- Form 1572
- Current medical licenses
- Physicians' curriculum vitaes (CV)
- Active Cancer Therapy Evaluation Program (CTEP) ID numbers
- Recruitment materials
- College of American Pathologists (CAP) certificate
- Clinical Laboratory Improvement Amendments (CLIA) certificate
- Informed Consent form (ICF)
- Study protocol
- Investigational drug brochure (IB)
- Submission letter

First, the principal investigator and each sub-investigator must complete a study-specific financial disclosure form that mandates disclosure of any financial interests held by investigators that could potentially affect the study outcome. The research site is responsible for informing the sponsor within 60 days of any changes that could result in compromised integrity of the study data. Next, Form 1572 needs to be completed by the principal investigator and submitted to the sponsor group. Form 1572 acknowledges and documents the investigators qualifications and commitment to comply with FDA regulations. This form is also used to determine whether the research site is appropriate to perform the study.[5]

The research site is also responsible for obtaining current CVs for all investigators, along with their current medical licenses, for submission to the IRB. Qualifications for new investigators can be provided to the IRB by the regulatory professional or by the credentialing office. Each investigator must have an active CTEP ID number, which is renewed annually via the Registration and Credentialing Repository (RCR) portal on the Clinical Trials Support Unit (CTSU) website.

It is also important that the IRB have the most current CLIA and CAP certificates on file. The CAP Laboratory Accreditation Program accredits the entire range of laboratory test disciplines using a scientific checklist tool. The CLIA is used to ensure compliance through laboratory standards that are scientifically validated.[6] Next, the Informed Consent form (ICF) must be updated to include the research site's approved boilerplate language which, in legal terms, is a phrase used in uniform language or often considered "standard terms." The ICF is used to maintain compliance by providing the patient with critical information to make an educated decision whether to volunteer for the study or not.

The submission letter, the investigational drug brochure, and the recruitment materials must be included in the IRB submission packet. The submission letter is a formal letter from the research site to the IRB of record on letterhead that includes a list of the documents submitted for IRB approval. In order to adhere to the GCP guidelines, all recruitment materials used to recruit study participants (including flyers, advertisements, websites, etc.) must be submitted and approved by the IRB prior to use.[7] Next, the investigational drug brochure, which contains a combination of clinical and non-clinical data in reference to the investigational drug and its effect on human subjects, is submitted only if the study contains an investigational drug. Lastly, the complete packet will be submitted to the IRB and reviewed by the board members. A ballot vote will be taken to determine whether the IRB thinks the study should be approved or disapproved based on the overall safety of the patient.

## Response from the IRB

Once the IRB has made its final decision, the research site will be notified with an official letter granting its approval or disapproval to open the study. Approved studies are maintained throughout the life of the study, which includes keeping up with all amendments, updates, and any notifications released by the sponsor group. Per FDA requirements, which include data collection and documentation submission, studies are renewed annually by the IRB. This gives the IRB the opportunity to review the study in its entirety in order to maintain patient safety. It is necessary to keep the regulatory compliance documents in an organized and secure location that is easily accessible. In the event of an FDA audit, the research site will be asked to provide the FDA inspector with the regulatory and patient case documents.

## Importance of regulatory compliance

Considering the rigorous nature of regulatory compliance in oncology clinical research and the significance of an FDA audit, it is crucial that all documents are accurately submitted to the IRB for review in order to be in accordance with rules and regulations. The process of completing the various tasks and required forms can last several weeks and can involve multiple professionals from all areas of the oncology research site. Forms that are incomplete, lack information, or contain incorrect information can significantly delay opening the trial, which may affect the availability of necessary advanced oncology treatment trials for the patient population. It is essential for oncology research sites to have adequate regulatory and administrative professionals who are knowledgeable in oncology research, FDA guidelines, and compliance in order to remain compliant in a heavily regulated environment.


1. Julia M. Vose, Laura A. Levit, Patricia Hurley, et al: "Addressing Administrative and Regulatory Burden in Cancer Clinical Trials: Summary of a Stakeholder Survey and Workshop Hosted by the American Society of Clinical Oncology and the Association of American Cancer Institutes." *Journal of Clinical Oncology*; vol. 34, no. 31 (November 2016). Available at http://bit.ly/2EPv9iq
2. U.S. Food and Drug Administration: Recruiting Study Subjects - Information Sheet. January 2016. Available at http://bit.ly/2ASnttn
3. U.S. Food and Drug Administration: Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Inspections for Clinical Investigators. June 2010. Available at http://bit.ly/2D1CWfQ
4. National Cancer Institute: Education in Palliative and End-Of-Life Care for Oncology Care, Self-Study Module 10: Clinical Trials. Available at http://bit.ly/2FwA60I
5. U.S. Food and Drug Administration: Information Sheet Guidance for Sponsor, Clinical Investigators, and IRBs: Frequently Asked Questions- Statement of Investigator (Form FDA 1572). May 2010. Available at http://bit.ly/2mueBFY
6. College of American Pathologists: Laboratory Accreditation Program. Available at http://capatholo.gy/2mueASq
7. Northwestern Office for Research: Recruitment Materials and Guidelines. Available at http://bit.ly/2qVVoBO

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by Rose T. Dunn, MBA, RHIA, CPA, FACHE, FHFMA, CHPS

# Physician supervision of assistants: What must be countersigned?

» When researching the regulations, do not assume that all regulations relevant to physician assistants will be in a single regulatory source.

» When creating a policy, be certain to research federal, state, and accrediting agencies.

» The agreement between a supervising physician and the physician assistant should include the oversight details and be consistent with the medical staff rules and regulations.

» Clarity can be enhanced with definitions for the terms used. This is especially true when using the term "record."

» Specialty societies can assist you with identifying relevant regulations that may apply to your situation.

***Rose T. Dunn*** *(Rose.Dunn@FirstClassSolutions.com) is Chief Operating Officer of First Class Solutions, Inc., a healthcare consulting firm in St. Louis, MO.* *bit.ly/in-RoseTDunn*

Does each entry by a physician assistant (PA) need to be countersigned by the supervising physician? The answer is, yes and no! In this article, I will discuss the research challenges I encountered when I attempted to answer that question for a health information management director in Pennsylvania. I stated that the answer may be yes and no, because there may be state regulations that modify the findings for this question or, to further complicate answering this simple question, there may be federal regulations that preempt the state regulations. So, let's discuss the first challenge.

## What is a record?

The first challenge I encountered was the use of the term "record." Some regulations referred to the supervising physician's responsibility to sign the record. However, nothing I found helped me determine if "record" meant "each entry." Signing a record, from a health information management perspective, means a "one-time" event. However, one could interpret "record" as each recording of an event (i.e., each entry). The effort of signing each entry is substantially different for the supervising physician.

Dunn

## Finding the rules

Some states may have separate legislation that does not appear in the regulations that govern physician assistants (PAs). For Pennsylvania, the Pennsylvania Medical Practice Act[1] and the Osteopathic Medical Practice Act[2] include a limited period during which the supervising physician must review and countersign physician assistant entries. However, if I had not found these Acts, I would have relied on the Pennsylvania Code, Subchapter D, which has no "probationary period," for lack of a better term.

The Pennsylvania Code, Chapter 18[3] states that the supervising physician shall monitor and supervise the activities of the physician assistant and *review documentation prepared* by the physician assistant (emphasis added). Additionally, the Code states the supervising physician shall countersign the patient *record* completed by the physician assistant within a reasonable amount of time. This time period may not exceed 10 days. As mentioned above, I found no definition of "record" in the regulations and the phrasing of this regulation may imply a one-time signature of the entire record. From an accrediting or auditing perspective, however, I would question how the supervising physician can prove they reviewed the documentation if they do not countersign each entry.

In short, digging into your state regulations will require you to also look elsewhere for refined regulatory expectations. A good source for that "hidden" information is your state society for physician assistants.

## Agreement

Many states require that there be a contract or agreement that outlines the responsibilities of the PA and the supervising physician. Unless otherwise specified by your state, you may wish to take a cue from Pennsylvania and incorporate language such as the following:

- 100% of the physician assistant's entries will be reviewed and such review will be demonstrated by the supervising physician's countersignature within 10 days for the following terms:
  - The first 12 months of a PA's practice post-graduation and after obtaining licensure;
  - The first 12 months of a PA's practice in a new specialty;
  - The first 6 months of a PA's practice in the same specialty under a new primary supervisor (unless the new primary supervisor was registered as a substitute supervisor for at least 6 months under another written agreement).
- If, after the required timeframe listed above, the supervising physician wishes to deviate from the 100% chart review, the supervising physician must complete and submit a written agreement change form, including specific details regarding how patient records will be selected for review and how often patient records will be reviewed. Deviation from 100% review of patient records within 10 days will require board approval. The supervising physician will need to continue to perform 100% review of patient records within 10 days until the board of directors approves the amended written agreement.[4]

Your state or organization may require the board's approval to allow a supervising physician to limit his documentation reviews. The board may question why the physician is not interested in overseeing the work done by the PA.

Nothing should preclude the supervising physician from transitioning to the lower percent of record reviews and other regulations applicable to your environment and state. Medicaid billing requirements may require a supervising physician to continue to monitor (and co-sign) 100%. According to the Pennsylvania's Society of Physician Assistants, the typical interpretation of demonstrating the supervising physician's oversight is through the countersignature, whereby the supervising physician countersigns each PA's entry.

Additionally, your organization's and your medical staff's malpractice liability coverage insurer may require the 100% entry co-signature effort. If CMS and/or your accrediting body (The Joint Commission, National Integrated Accreditation for

Healthcare Organizations [NIAHO], or Healthcare Facilities Accreditation Program [HFAP]) conducts a review that finds that the supervising physician has deviated from the written agreement's stated sampling volume, then that citation may be publicly posted on the Hospital Inspections site of the state Department of Health and it may be reported to the state Medical Board.

Finally, the agreement between the supervising physician and PA will include other specified duties, such as the performance of part or all of a patient's medical history and physician examination, regular visits to assess the patient's progress, and other activities (e.g., on-call responsibilities).

## Accrediting bodies

The Joint Commission states, "the organized medical staff is responsible for establishing and maintaining patient care standards *and oversight* of the quality of care, treatment provided by practitioners privileged through the medical staff process (emphasis added)."[5] Anyone who has experienced an accreditation survey knows The Joint Commission will expect the medical staff members to demonstrate their oversight through their documentation—hence, countersignature of each entry as suggested above, or as the Pennsylvania Code says, "maintenance of records evidencing patient and supervisory contact by the supervising physician."

## Medicare

In addition to covering PA services that are billed incident-to a physician's care, Medicare now covers PA services billed separately under a PA's own national provider identification (NPI) number,[6,7] provided the following conditions are met:

- They are considered physicians' services when furnished by a physician;
- They are performed by a person who meets the definition of a physician assistant;
- They are not otherwise excluded from coverage by law;
- They are performed under the "supervision of a physician"; and
- State law allows physician assistants to perform the services.

Medicare also covers services and supplies furnished incident to a physician assistant's covered services.

To satisfy Medicare requirements, the PA must work with a physician supervisor who is primarily responsible for the overall direction and management of the PA's professional activities and for ensuring that the services provided are medically appropriate. The physician supervisor need not be present when the PA furnishes a service, unless state law provides otherwise. If the physician supervisor is not present, he/she must be immediately available to the PA for telephone consultation.[8]

Medicare also states that in order to meet the "direct supervision" requirement, the supervising physician or non-physician practitioner (NPP) must be immediately available, meaning physically present, interruptible, and able to furnish assistance and direction throughout the performance of a procedure. It does *not* mean that the physician or NPP must be present "in the room." CMS removed the physical boundary requirement in the definition of direct supervision to allow the supervising practitioner greater flexibility in location while still meeting the requirement to be immediately available.[9]

It may be appropriate to reiterate some of the above Medicare billing limitations in the agreement between the physician assistant and the supervising physician.

## Other requirements

If the supervising physician chooses to transition from 100% review to a small sample, he/she must continue to (i.e., is required to) sign:

1. **The hospital inpatient admission order** written by a non-physician practitioner (NPP), PA, or Resident as required by Medicare Conditions of Payment (IPPS Rule).[10] [CMS Manual System, Transmittal R234BP; 3/10/2017.]
2. **The comprehensive history and physical** (H&P) because of the Medicare Conditions of Participation for hospitals requirement that "there must be evidence in the chart" that the patient is under the care of an MD/DO. This has led many hospitals to require a co-signature on the admission H&P prepared by a PA.[11] CMS regulations require that Medicare and Medicaid patients admitted by non-MD/DO practitioners be under the care of an MD/DO, evidence of which must be in the patient's medical record. If a hospital allows these non-MD/DO practitioners to admit and care for patients, as allowed by state law, the governing body and medical staff would have to establish policies and bylaws to ensure that the requirements of 42 CFR § 482 are met.
3. **The discharge summary** as required by Medicare Conditions of Participation for hospitals.[12] In accordance with hospital policy and 42 CFR part 482.12(c)(1)(i), the MD/DO may delegate writing the discharge summary to other qualified healthcare personnel to the extent recognized under state law or a state's regulatory mechanism. CMS expects the person who writes the discharge summary to authenticate, date, and time their entry and, additionally, the MD/DO responsible for the patient during his/her hospital stay to co-authenticate and date the discharge summary to verify its content. The discharge summary requirement would include outpatient records.
4. **The Medicare home health certification and recertification**, during which the PA/NPP may perform and document the required face-to-face encounter, but the "certification" requires a physician's signature.[13,14]

## Medical staff rules and regulations

Which elements and specifically which entries must be co-signed should be clearly spelled out in your medical staff rules and regulations. The Joint Commission requires the hospital to "define the types of entries in the medical record made by non-independent practitioners that require countersigning, in accordance with law and regulation." [RC.01.02.01] Therefore, at a minimum, the rules and regulations should require countersigning of the above four documents when those entries are created by a physician assistant.

If the hospital board of directors permits the limited countersignatures, it may be appropriate to incorporate a process whereby the supervising physician countersigns the above four items when present in the hospital inpatient and outpatient records *and* also signs an attestation document that states that he/she has reviewed the PA's services and entries in the record. By signing the document, they confirm their agreement with the treatment and services provided.

## Emergency department services

As for Emergency department encounters managed by the PA, these encounters need to be assessed in light of your state's regulations and those services that the state allows PAs to do incident-to or under the supervision of a physician.

## Summary

Due to regulatory quagmire and operational challenges to the above, the organization's legal counsel, compliance officer, and/or lead physician advisor should collaborate on policy and procedure development. Remember, the organization's policies may always be more restrictive than the state and federal requirements.

*Disclaimer: The content of this article should not be considered to be legal or billing advice and does not create an attorney-client relationship. If you need legal advice, please contact an attorney directly.*


1. Pennsylvania General Assembly: Medical Practice Act of 1985 (2013 Act 100), November 27, 2103. Available at http://bit.ly/2Do045w
2. Pennsylvania General Assembly: Osteopathic Medical Practice Act (2013 Act 101). November 27, 2103. Available at http://bit.ly/2BtS8Cl
3. Pennsylvania Code, Subchapter C & D, Physician Assistants. Available at http://bit.ly/2p95myQ and http://bit.ly/2kBgmjI
4. Pennsylvania Acts 100 and 101. Available at http://bit.ly/2zcIhuR
5. The Joint Commission: Organized Medical Staff Structure-MS Chapter. Overview and Standard MS.03.01.01. 2017 Hospital Accreditation Standards.. ISBN# 9781599409580
6. Health First Network: Frequently Asked Questions (FAQ's) and General Medicare Guidelines on Billing for Non-Physician Extender Visits. Available at http://bit.ly/2BXJuf4
7. Texas Medical Association, Direct and Incident to Billing. Available at http://bit.ly/2BYqYmy
8. Ibid, Ref #4
9. Medicare Supervision Requirements, Updated May 2011. Available at http://bit.ly/2Bk0okt
10. CMS: Admission Order: IPPS Rule "Additional Clarification of Guidance" January 30, 2014 Available at http://go.cms.gov/2CUcWzw
11. CMS: State Operations Manual, Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, revised November 17, 2017. Available at http://go.cms.gov/2CSTd2R
12. Idem, Discharge Summary: State Operations Manual, Appendix A
13. MLN Matters, Number MM8441: Home Health: Available at http://go.cms.gov/2DqFktO
14. Tricia Marriott: "Maximizing Utilization of PAs and NPs: Rules, Realities, and Reimbursement." Conference presentation, September20, 2016. National Association Medical Staff Services.

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by Dale Sanders, DO, DHA; and Tom Ealey

# Safety is the law: Occupational safety compliance

» Safety management and compliance are multi-faceted, and all facets are important.
» The enforcing agency (state or federal) can examine the entire safety culture and operation.
» Policies based on legal requirements must be written for ease of communications and training.
» Employees have a right to be whistleblowers, without fear of retaliation.
» There are significant negative consequences from safety failures for both employee and employer.

***Dale Sanders*** *(sandersdl@alma.edu) is a professor at Alma College in Alma, Michigan and Director of the Health Care Administration program.*
***Tom Ealey*** *(ealey@alma.edu) is a professor at Alma College in Alma, Michigan, and has decades of experience in healthcare consulting and administration, including regulatory compliance and risk management.*

Prior to 1970, workplace safety was somewhat ad hoc—employers responded to state regulations, workers compensation costs, liability concerns, and contract language. In 1970, the federal Occupational Safety and Health Act (OSH Act or the Act) was passed and the Occupational Safety and Health Administration (OSHA)[1] was created.[2]

The Act allows a state agency to supersede OSHA if the state agency has regulations more stringent than OSHA.[3] Employers should be aware of which agency is the authorized enforcement agency and the details of the regulations.

For editorial purposes we will refer to OSHA and OSHA regulations. The first step for the organization is to determine which agency enforces safety practices in your state. We will focus on the federal regulations, but each organization should build a reference collection of applicable federal and/or state regulations.

## The healthcare scene


Sanders

As modern medicine developed, so did modern safety practices and especially infection controls. Workplace safety became a political issue and was formalized into law in 1970. The next wave of regulation came during the AIDS/HIV crisis, when universal precautions and related practices were formalized into law.


Ealey

The AIDS/HIV crisis created a new concern—working in healthcare can have lethal consequences. There was a necessary and quick improvement in medical safety practices, and these practices were quickly codified into the blood-borne pathogen standards.

With more than 40 years since the passage of the OSH Act and about 30 years since universal precautions were codified, every health organization should be in a best practices state of operations. Time pressures, resource pressures, and just the daily rush of practice operations may put safety on a back burner. Constant efforts should be made to review and refresh safety practices.

## The General Duty clause

This is the "everything else" section of the law that covers the types of safety issues applicable to all employers, regardless of industry (Section 5.(a)).[4] These regulations cover everything from trip-and-fall to electric shock to burn hazards, and all other common means of workplace injury (e.g., falling objects, vehicles, lifting injuries, ladder issues, pinching and cutting injuries).

Ever walk into a room and find an employee using an office chair as a step ladder? Probably yes. Ever seen the multi-plug turned wiring octopus? No doubt. The employer is always responsible for bad outcomes.

Liability for general duty violations follows this checklist:

1. A hazard exists
2. The hazard is likely to cause harm
3. The employer knew or should have known of the hazard
4. An incident was foreseeable
5. Workers were exposed to the hazard
6. Injury occurs and is reported to OSHA

With the General Duty clause, the recognition of a hazard is always established if the employer knew about the hazard. An employee, supervisor, or a compliance officer may put the organization on notice.

This section interacts with the local fire and building codes as well as with the Americans with Disabilities Act (ADA). If leasing, be certain responsibility for fire and building codes are clearly assigned. Know if your facility is accredited with any relevant accreditation standards. Your workers compensation and general liability carrier may also have guidelines and standards.

## Mandatory postings

Federal and state safety agencies require the postings of regulatory notices. Your advertising mail and email will likely have a steady stream of ads for the mandatory posters in your state. Not to make you uneasy, but the posters will include 800 call-the-feds numbers and whistleblower information.

And speaking of whistleblowers, retaliating against an employee who files a complaint is a very serious offense.

## Rights and responsibilities

This section is straightforward: Employees have rights and employers have responsibilities.[5] Employees have a right to a safe workplace, a healthy workplace, hazardous materials warnings, access to Safety Data Sheets (SDS, formerly MSDS), training and updates, personal protective equipment, necessary supplies, a right to complain, and a route to being a protected whistleblower.

Employers have the responsibility to provide all of the above, keep required records and file required reports, respond to incidents and mitigate damages, abate known violations, and refrain from retaliating against whistleblowers. Beyond all of this is a "duty to supervise," the employer is responsible for failures to perform.

## Safety enforcement

An organization may never see an OSHA inspector. Or one walks through the door tomorrow. OSHA has a very broad enforcement mandate, access rights to your facility, permission to speak with your employees (and you may not retaliate), and power to review your paperwork, including required policies and procedures.

Two responses to an OSHA visit are critical—first, cooperate and second, call your lawyer. Cooperate unless your lawyer tells you to stop. The enforcement agency is enabled to levy penalties, and penalties can go all the way to criminal prosecution (although this is somewhat rare).

Safety enforcement actions are public record and may end up in the local newspaper. Not the sort of brand enhancement the organization is seeking.

**Workplace violence**

Almost monthly we turn on the news to a gruesome workplace shooting spree. OSHA requires each employer to have a workplace violence plan in place, with the requisite employee training.

If your facility has narcotics, or even if someone might think your facility has narcotics, there is an armed robbery risk. Minimizing cash on hand is a good practice. Protocols must be set, hardware (security cameras) put in place, and employees trained, because the unthinkable is thinkable.

**Ergonomics**

OSHA has an ergonomics safety standard aimed at reducing the incidents of work-related musculoskeletal disorders (MSDs), both accidental injury incidents and repetitive motion injuries. Management has a responsibility to analyze each job and determine the risks.

Healthcare is notorious for back injuries suffered while lifting and positioning patients and for slip-and-fall accidents on highly polished floors. OSHA requires engineering controls, work practice controls, and personal protective equipment, all appropriate to the site. Appropriate training is required, and there should be a feedback loop. Injuries should be analyzed with an eye toward preventing future injuries.

## Blood-borne pathogens

Universal precautions became a major issue during the HIV/AIDS crisis, and by the late 1980s, universal precautions were in place as law.

Blood-borne pathogens are infectious microorganisms in human blood that can cause disease in humans. The practice has a very definite duty to protect employees from these hazards, and also patients from secondarily acquired infections.

On a typical day, a healthcare facility is rushed; on a non-typical day, chaos ensues. Clinical staffers are almost always rushed, phones are ringing, computers are beeping, and patients are getting impatient. It is certainly easy to miss putting on a pair of gloves. Or pass the hand washing sink.

Universal precautions are designed primarily to protect your employees, with a secondary emphasis on protecting patients by preventing cross contamination. And there is a lot more to universal precautions than hands and gloves.

**The regulations**

Regulations and informational materials for the entire OSH Act and especially blood-borne pathogens are readily available online,[6] as are state-specific regulations for states, which supersede federal regulations.

The Centers for Disease Control (CDC) has recommendations and research available, and recommends "standard precautions" that are more conservative than universal precautions. The regulations sort bodily fluids and wastes into two categories: (1) blood and blood products, and (2) other potentially infectious materials (OPIM).

The blood category includes blood, components of blood, and products made with blood. OPIM is defined by OSHA as:

> …semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body (sic) fluid that is visibly contaminated with blood, and all body fluids in situations

where it is difficult or impossible to differentiate between body fluids;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

As the CDC points out in standard precaution protocols, since it is nearly impossible to know if OPIM contains any blood, effectively *all of these should be treated as infectious at all times.*

Human sweat is not considered OPIM unless a known infection is present.

### Work process (engineering) controls

Management must design work process controls, train employees to use them, and supervise their use. Hand sanitation is a typical work process control. A critical control is the sharps injury prevention program, the controls designed to prevent needle sticks and other percutaneous injuries.

Also crucial to the controls are personal protective equipment (PPE). The employer is responsible for having the proper equipment available at all times, for training, and for supervising the staff and physicians.

**Exposure control plan**

Having determined the employees who have occupational exposure by job category, the practice must prepare an exposure control plan and train the employees on the plan protocols. In many practices, the common exposures come from bleeding, splashing, and needle sticks, but other events may occur.

The plan should cover all anticipated employee exposures and be broad enough to cover unusual incidents. The plan should include a feedback loop—all incidents should be analyzed in light of patterns of incidents and possible points for improvement. Employees must be trained to report all exposures immediately, and supervisors must be trained in proper responses. Physicians are also subject to these protocols.

**Hepatitis B**

There is a significant risk of transmission of Hepatitis B pathogens during an exposure incident.

All employees in the exposed categories should be vaccinated during their initial work period. The vaccination is highly effective and need not be repeated. Appropriate records should be maintained.

The opioid crisis is creating new concerns, particularly inadvertent exposure to fentanyl, which can be fatal.

**New worries**

The opioid crisis is creating new concerns, particularly inadvertent exposure to fentanyl, which can be fatal. If there is any possibility of such exposure in your practice, protocols must be developed and staff and physicians *must* be trained.

**Policy development**

Why not just photocopy the law and pass it out to physicians and staff? Besides being too long, the law does not exactly read like poetry.

Policy and procedure statements need to be: (1) written in plain English, (2) useful for training, (3) customized to your organization,

and (4) clear enough to be useful for supervision and discipline.

Statements should be customized to the specific risks of your practice, because each type of practice has different work effort, different ancillaries, and different potential hazards.

Organizations with a surgical component, invasive procedure, or trauma care should use accreditation agency standards (e.g., surgical hand scrub procedures). Practices with imaging and/or lab facilities must be aware of all special regulations targeted at these units.

Government jargon and bureaucratic language are not helpful here; what is required are plain descriptions of what the rules are for performance in your particular setting.

**Training**

There may be a notion floating around that anyone more than a few months out of school already knows about universal precautions, so your new hires need no training. Not so. Initial training should take place as close as possible to the "on-boarding" date and should be integral to the orientation process. At the very least, a tour of safety logistics (e.g., red bags, sharps containers, spill kits) should take place very early on. Annual training sessions should be conducted with materials and attendance records kept on file.

## Relentless supervision and performance auditing

The only way to measure performance is "eyes on," spending time in clinical areas, watching the ebb and flow of patients, and watching the performance of staff. Another source of input is patient satisfaction surveys. Many patients and families are very aware of proper precautions and failures in performance.

Formal performance audits can be structured to measure more precisely daily compliance with safety regulations. The best situation is a culture of compliance, where staff and physicians reinforce compliance with each other.

## Annual compliance reviews

A review and assessment is required every year, and would be good compliance practice in any case. Scheduled reviews should include:

- assessing overall program design and effectiveness,
- scanning regulators websites for new regulations or interpretations,
- reviewing policies and procedures (e.g., up-to-date? readable? thorough? outcomes?),
- studying injury logs with emphasis on negative trends, and
- evaluating the effectiveness of training programs and training attendance logs.

Many patients and families are very aware of proper precautions and failures in performance.

Inputs should be solicited from clinical supervisors, and clinical supervisors should be evaluated for effectiveness. Injury logs and employee complaints should be sorted into departments and analyzed for causation. Injury trends will require further study and sometimes remedial action.

Employees who were subject to the exposure control plan, such as employees who suffered needle sticks, should be interviewed and their records reviewed to test the performance of the plan.

Necessary changes and updates should be prepared, reviewed through the chain of command, and implemented with appropriate

communications to employees and incorporation into future training sessions.

## Conclusion

This is a complex topic with many operational and regulatory risks. Organizations must focus on the most basic of the seven elements (below) to assist management in addressing the full range of implementation options for health care facilities, regardless of size and resources:

- Standards of conduct and policies and procedures
- Designation of compliance officers
- Conducting effective training
- Effective lines of communication
- Auditing and monitoring
- Establishing disciplinary guidelines
- Responding to detected offenses and developing corrective action initiatives

The practice of medicine has inherent dangers as well as many of the same dangers as other businesses. There is an affirmative duty for employees to meet the requirements, whether from OSHA or a state affiliate.


1. U.S. Department of Labor, Occupational Safety and Health Administration website: https://www.osha.gov
2. About OSHA. Available at http://bit.ly/2DJutM6
3. U.S. Department of Labor, Office of State Plans: Frequently Asked Questions. Available at http://bit.ly/2mIWll6
4. OSHA General Duty clause available at http://bit.ly/2D3xLwM
5. U.S. Department of Labor, OSHA Administration: Job Safety and Health. Available at http://bit.ly/2D1sIw9
6. CDC, The National Institute for Occupational Safety and Health: Bloodborne Infectious Diseases: HIV/AIDS, Hepatitis B, Hepatitis C. Available at http://bit.ly/2FsHxWO

by Eric Hummel, MS CS, InfoSec

# Building a security program: It's not just IT

» Executive leadership must be invested in the security program.
» Create a security program led by a compliance officer who has been trained in cybersecurity.
» Build the governance structure first.
» Propose a realistic budget.
» The security program consists of a set of projects led by domain leaders (HR, Facilities, IT, Administration, Clinical, etc.).

***Eric Hummel*** *(eric.hummel@qipsolutions.com) is Chief Technology Officer at QI Partners, LLC in Rockville, MD.*

As the saying goes, "To a hammer, all problems look like a nail." Most healthcare companies start their Health Insurance Portability and Accountability Act (HIPAA) security program by assigning responsibility and accountability to a manager of Information Technology (IT). This creates a bias within the organization that security compliance is an IT issue. In reality, much of security does not directly involve IT. The result is that non-IT risk gets overlooked, and the IT team takes on a security enforcement duty that is both uncomfortable and ineffective.


Hummel

The need for security compliance is *not* going away. It is rapidly taking on increased importance in all organizations. Losses are starting to become significant and threats are increasing. Security is an ongoing requirement for all organizations in the 21st century. A security program needs to be built for efficiency and longevity. It needs to manage risk in a way that also meets the compliance requirements of HIPAA and state laws. This makes the choice of an organizing principle for your security program much more important.

## Managing risk

Merging the twin requirements of HIPAA compliance and the need to manage risk in medium or small healthcare organizations is challenging at best. The compliance side demands that a thoroughly documented program be in place that meets certain minimum requirements. The risk side of security needs to meet the real threats of ransomware and data breaches that harm reputation and bottom line. In many communities, expertise is neither affordable nor available to plan and lead in this complex situation. But, these are compatible requirements, particularly when managed as a single program.

Left searching for cost-effective options, organizations reflexively turn to their IT staff, assigning the Chief Information Officer (CIO) or an IT manager the new responsibility for security compliance. This person is proficient in technology and possibly technical data security, but they are rarely experienced in organizational risk management. Beyond having the added burden of planning, execution, and continuous monitoring of risk and compliance, they also must lead a program that encompasses workflows throughout the

organization. Internal IT professionals should be focused on ensuring complex security aspects such as data loss prevention or security event and incident monitoring. However, things like business associate agreements and better staff background checks will likely be out of their experience range. Even though cybersecurity may seem like an IT issue on the surface, security compliance is process oriented, and risks come from all directions, not just IT.

Security is a risk management process, not an IT function. Like other business or medical risks, security should be viewed as a process to minimize potential losses by controlling sources of risk. IT is one source of risk, but there are many others that may be more important:

- Human error is a major source of risk that IT may be poorly suited to address.
- The physical layout and security features of a clinic can help or hinder security.
- Effective staff training is both needed and key to reducing human error.
- Clinical and operations staff are key stakeholders and have vast knowledge that is needed when planning for disaster or emergency operations.

These are all functions of security risk management.

Ultimately, all of these risks, whether IT, HR, clinical, financial, legal, or administrative, should be the concern of the entire organization (see sidebar).

If planned correctly, compliance will be the natural result of a comprehensive security program led by someone who understands both the risk management methodology required for security and the HIPAA compliance documentation requirements.

## What is the best strategy and who should lead?

First and foremost, support for security must come from executive leadership. Security involves resources and time. Understanding business risk is in executive management's domain. Compliance is also a business risk. Merging these two risk objectives makes sense if the resulting program is managed for both. Managing them separately is a recipe for frustration and disaster. Setting up a process for assessing and reporting risk and compliance to the C-level leaders permits them to make intelligent allocation of resources and realistic expectations of schedule. Their full-throated support is a key factor for success.

One should look at security and HIPAA compliance as a series of ongoing projects that need to be managed. Individual projects, such as security training, business associate contracts, or encryption, can be assigned to the appropriate lead, but the overall strategy for controlling business risk should remain with executive leaders who are good at motivating, guiding, and measuring projects. Identifying and training the leader who will understand both HIPAA and security risk is key to keeping a single program. The logical choice for this role in a smaller organization is the compliance officer.

**Security Stakeholders**

Executive management
Administrative operations
Clinical staff
Human Resources
Information Technology
Physical Plant
Finance
Risk and Compliance

## Risk: From threat to loss

In the language of cybersecurity, "risk" is the expected "loss" due to materialized "threats." Where threats meet "vulnerabilities," an "impact" can occur, resulting in loss. Losses are most easily quantified in terms of dollars, but other values are relevant in healthcare.

The security program must identify threats and vulnerabilities, then develop security controls that close or mitigate the vulnerabilities. Controls can also be used to limit the impact of materialized threats and to minimize the ultimate loss (see figure 1).

## Compliance, governance, and risk

Security projects come in all different sizes with various objectives. The first project for an organization with very little security experience is to build security governance. Policies, roles, responsibilities, documentation, and the decision-making process are the core of governance. Much of this can be accomplished quickly and is essential to the rest of the program.

Having a good decision-making process is useless without good information to inform decisions, and this fits neatly with compliance. One of the first jobs of the new governance program is to identify the information that is needed for anticipated decisions. Baseline data about your organization should be available. How many staff? How are they trained? How many devices? What data is "business critical"? Where is it stored? Is it backed up? What is shared with business associates? What are their security practices? By delegating responsibility for accurate information to those who are already engaged in a business domain (e.g., HR, Finance, or IT), the load is spread out, and the data may be easier to collect. This is also the time for planning the collection of compliance documentation.

A good security organization structure is critical. We advise organizations of all sizes to have a security team or committee led by an executive and staffed by the leads of each business domain. It should be tasked with:

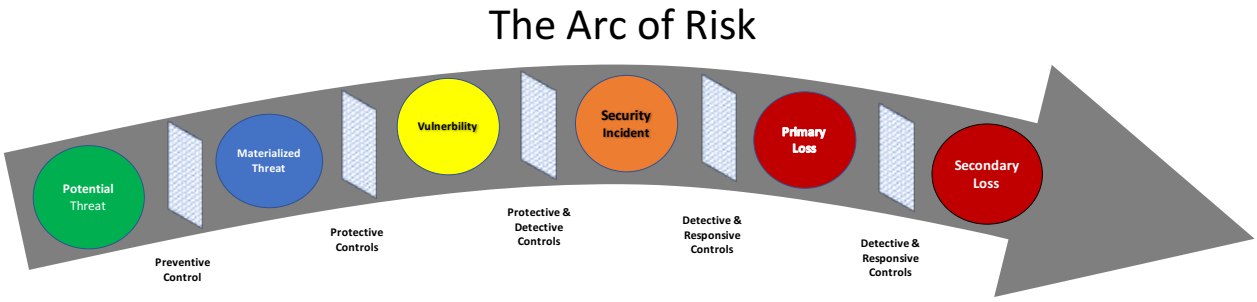
- creating, maintaining, and documenting the security program;
- ensuring that significant risks to the business are identified and understood;
- requesting and justifying a budget for security;
- assigning responsibility for projects and tracking execution;
- reporting progress on risk minimization; and
- preparing the organization to respond to security incidents and breaches of patient privacy.

The business domain leaders should be responsible for:

- collecting the necessary inventory and compliance documentation specific to their domain;
- leading the security projects that are within their domain; and
- delegating work to staff where appropriate.

Once organized, the starting point for the program should be to convene the security

Figure 1: The Arc of Risk



team to execute a startup process in roughly this order:

1. Assess the current state of security in the organization
2. Understand the legal requirements that must be met
3. Adopt organizational policies for security and privacy
4. Assign roles and responsibilities for security
5. Document a policy enforcement process
6. Circulate and train staff on security policies
7. Assess risk and prioritize security projects
8. Assign responsibility for project to business domain staff
9. Track progress of projects

### Full toolbox

Effective information security requires you to use all the tools in the shed, not just the hammer. Instead of making security a responsibility of one business domain, management of the security program needs to be distributed across the organization and led from the top. Breaking down the responsibility for controlling risk to smaller projects spreads out the effort and engages staff in security. A natural outcome of the process described is continuous improvement of the security program and the capacity to control threats as they increase. Having everyone aware and participating will be the future norm as cyber threats become ever more prevalent. The result will be 360-degree visibility and the integration of security into all business domains.

by Tynan O. Kugler

# Regulatory compliance: Physician needs assessments are an integral step

» Physician needs assessments (PNAs) are evolving to play an expanding and dynamic role with respect to fair market value (FMV) and commercial reasonableness (CR) opinions.

» As the healthcare industry shifts from volume to value, a historical approach to PNAs based solely on physician-to-population metrics may no longer be sufficient.

» Modern PNAs should consider market specifics relative to healthcare transformation because communities are transitioning at various speeds.

» PNA findings are important to consider in determining whether a particular transaction is commercially reasonable.

» Justification for a hospital's recruitment or physician affiliation strategy is a research-intensive, yet critically important, exercise to support regulatory compliance

***Tynan O. Kugler*** *(tkugler@pyapc.com) is a Principal at PYA, P.C., and is based in Atlanta, GA.*

Hospitals have traditionally performed physician needs assessments (PNAs) or medical staff manpower studies to answer a series of questions related to local community healthcare requirements: What will the demand and need for physicians and advanced practice providers (APPs) be? What will the supply of physicians and APPs be? Is there a gap between demand and supply? If so, what do the studies suggest can be done?

Kugler

PNAs typically involve identification of the hospital's Stark-defined service area[1] and determination of the physician full-time equivalent supply and demand within that market to quantify overall physician need by specialty. Adjustments may be made to account for provider attrition, population health considerations, APPs, and hospital market share, among other considerations. Further, qualitative information shared by key stakeholders through executive interviews and/or physician practice surveys may be used to refine quantitative results.

From a compliance perspective, payment to recruited physicians and APPs—in a Stark-compliant manner[2]—used to be a primary driver to complete PNAs. The constantly shifting environment of healthcare has propelled PNAs into a much more dynamic role. Though still used in large part for recruiting purposes, PNAs have expanded their footprint to become an integral part of a larger picture. They are now consistently interwoven with both commercial reasonableness (CR) opinions and fair market value (FMV) assessments.

PNAs alone are no longer sufficient in a recruitment exercise. Today, physician contracts must also be commercially reasonable, and meet Stark and other regulatory

requirements for FMV. Market trends are furthering PNAs' role in strategic recruitment initiatives for hospitals and physician practices and may be used in tandem with CR and FMV.

To understand the evolving role that PNAs serve in today's markets, it is important to understand the underlying concepts that not only drive PNAs, but also are changing along with them. PNAs can be quite complicated; they require applying potentially imperfect ratios to an often-changing community of providers within a defined service area, but are generally driven by the laws of supply and demand.

## Understanding the drivers of today's markets

The PNA can provide valuable insights regarding the current demand for providers in a community, the supply available, and the business case for hiring certain individuals.

### Demand

According to the Association of American Medical Colleges (AAMC), a variety of factors impact demand for medical services.[3] These factors include population demographics (e.g., an aging U.S. population), the expanded use of integrated care delivery models, efforts to control costs of care, an increased number of individuals with chronic conditions, uncertainties around immigration reform, the use of telehealth services, and technological advances.

Market demand is not evenly distributed across the U.S. Though traditional PNAs often use a set of physician-to-population figures to calculate market-specific demand, other factors often come into play. Much like the Dartmouth Atlas Project[4] has proven that health expenditures and outcomes differ across the country, the same can be said about the demand for physician services. Some communities have specific health needs that require different levels of physician and APP support. The competitive landscape of healthcare providers in a particular market may also impact the demand for physicians of different specialties.

A modern approach to PNAs must not only account for the factors that have historically influenced demand, but also must consider other critical industry dynamics. Specifically, as the healthcare industry evolves from one based on payment for the volume of services provided to one that rewards the value of services provided, reliance on traditional physician-to-population metrics must be balanced by other factors, such as patient panel size (i.e., the number of patients one doctor can manage) and physician sub-specialization. Further, qualitative data (e.g., wait times to obtain a first appointment with a physician, whether physicians do or do not accept Medicare and Medicaid) also help inform demand. It is imperative that modern PNAs do a better job of appropriately identifying demand for specific markets, because not all communities are experiencing the same transformation at the same speed.

### Supply

Much like the changes to physician demand, several factors will continue to influence the supply of physicians over the next several years. The AAMC has projected physician supply for the next 10+ years based on a variety of factors and scenarios. Each scenario projects growth in physician totals until 2025, but one may argue that the growth rate is not high enough to meet the increasing demand.

Macro trends in physician supply are influenced by changes to graduate medical education (GME), shifting trends in physician work hours, and an aging workforce. At a micro level, hospitals are trying to lay the groundwork for improved population health, which requires more primary care providers (PCPs) to manage the population

effectively. And, much like demand, the supply of physicians is not evenly distributed across all markets and communities. The shortage of supply in rural communities is well-documented and has been a challenging battle for healthcare providers.[5]

The market has begun to adjust to this issue and, in recent years, responded to the short supply of physicians with an increase in APP entrants to the marketplace. For example, in the *2017 Review of Physician and Advanced Practitioner Recruiting Incentives*, Merritt Hawkins, a national healthcare search and consulting firm, indicated that advanced practitioners were third on the list of their most requested recruiting assignments.[6] This influx of APPs has lightened the burden in some ways, though it does not completely fill the gap between consumer demand and provider supply. These APPs assist the existing population of PCPs and certain other specialists, thereby lessening the patient load, but they are unable to perform all the tasks of physicians.

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The laws regulating the physician recruitment environment have also changed. Medicare's release of the 2016 Physician Fee Schedule contained new exceptions for compensation arrangements.[7] Hospitals can now assist in the recruitment of APPs for physician practices. These changes in the final rule help alleviate some of the strain on the system, but they create additional complexities for PNAs to consider.

## Confirming commercial reasonableness

The supply-and-demand discussion above lays the groundwork for the crux of the matter. When a hospital develops a recruitment plan, it is important to carefully document the supply and demand in the hospital's service area, with an understanding of the various complexities noted above. Traditionally, the PNA may have been the sole step for determining physician need within a service area; following the PNA, the hospital could move on to recruiting. However, determining the surplus or deficit of physicians by specialty should not be the final step when making recruitment decisions. Discoveries from the PNA should be applied to determining the CR of provider recruitment.

Consider a PNA as the due diligence for justifying certain recruiting decisions as well as a critical component of a CR opinion. CR essentially asks if the transaction or financial arrangement makes "business sense" to the recruiting entity in the absence of patient referrals. The PNA plays a pivotal role, because the information it uncovers regarding supply-and-demand characteristics of a market and population can help establish the CR of a proposed arrangement. If the information discovered in a PNA does not support an identified need (e.g., results show a surplus of physicians in a certain specialty), the CR of the recruitment strategy that the hospital wants to pursue may be unsupported.

## Does the arrangement meet fair market value?

Once a hospital has performed a PNA and used this to inform the CR of its recruiting strategy, there are still additional regulatory considerations. As the hospital begins to recruit and engage potential physicians to fill any deficits, the contract must also meet the Stark Law criteria for FMV—compliant

physician compensation cannot be determined in a manner that takes into account, directly or indirectly, the volume or value of any Medicare designated health services (DHS) referrals or other business generated by the physicians to the entity that will employ them or to other affiliated entities.[8]

Financial assistance for physician recruitment must adhere to Stark requirements. Just as the PNA gives backing to the CR assessment, so too it proffers backing and justification for proposed recruitment contracts with regard to FMV.

When determining the FMV of an arrangement, proper documentation and support is vital—especially when dealing with arrangements that may fall under scrutiny. A PNA performed by an independent third party can be used to inform arrangements with highly compensated physicians or provide support in a situation where a physician's employment results in initial financial loss for the hospital while the physician builds his/her practice.

## A research-intensive process

PNAs, CR analyses, and the determination of FMV compensation are strongly intertwined. Much research is required to thoroughly and accurately conduct a PNA, especially given the transition from volume-based to value-based healthcare. Without a PNA or similar validation of provider need in a community, an assessment of the CR and FMV of an arrangement may be incomplete. It is critically important to conduct PNAs with CR and FMV in mind to fully develop and justify a hospital's recruitment and/or affiliation strategy.

*The author would like to thank PYA Consulting Senior Aaron Elias for his assistance in the development of this article.*

1. 72 Fed. Reg. 51050 (September 5, 2007).
2. Ibid.
3. Association of American Medical Colleges: The Complexities of Physician Supply and Demand: Projections from 2013 to 2025, Final Report. March 2015. Available at http://bit.ly/1OUvrli.
4. The Trustees of Dartmouth College: The Dartmouth Atlas of Health Care. Available at http://bit.ly/2DHWSCd.
5. National Rural Health Association Policy Brief: "Health Care Workforce Distribution and Shortage Issues in Rural America" January 2012. Available at http://bit.ly/2FuKsOT.
6. www.merritthawkins.com.
7. 80 Fed. Reg. 71376 (November 16, 2015).
8. 69 Fed. Reg. p. 16096 (March 26, 2004).

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## False Claims Act 2017 report card: $2.4 billion recovered

*by Joan W. Feldman (page 23)*

- Don't assume that a whistleblower complaint cannot be brought against your organization.
- Address compliance concerns promptly, so they don't fester and result in a *qui tam* action.
- The government will continue to rely on individuals to bring cases to their attention, motivated by sharing in a federal monetary recovery.
- Providing medically unnecessary services to patients is typically not an isolated event.
- The government is likely to increase the use of tools that identify outliers.

## Impact of state False Claims Acts

*by Denise Atwood (page 29)*

- Compliance professionals should become familiar with the legislation that establishes liability to the states for Medicaid false claims.
- If a state FCA meets the requirements set forth by the federal government, it may qualify for a Medicaid incentive under section 1909 of the Social Security Act.
- The federal Office of the Inspector General has a role in reviewing state false claims laws.
- If your state has an FCA, know how that impacts your organization's compliance efforts.
- If your organization does business in more than one state, determine which states have state FCAs.

## Stacked physician compensation: Keys to compliance

*by Bartt B. Warner and Thomas A. Warrington, Jr. (page 35)*

- Compensation paid to physicians is under constant scrutiny as the number of healthcare settlements continues to rise both in number and in settlement awards.
- Compensation paid to a physician must be commercially reasonable, consistent with fair market value (FMV), and not in violation of other laws and regulations designed to prevent fraud and abuse.
- Stacked compensation refers to taking the individual components of a physician compensation arrangement and adding them up to derive total compensation.
- If each individual component is consistent with FMV, that does not automatically mean the total stacked compensation is as well.
- By thinking through each component of a physician's agreement and asking the appropriate questions, hospitals and health systems can reduce the risk of enforcement actions for their physician arrangements.

## Navigating Medicare Secondary Payer compliance and False Claims Act liability

*by Gary W. Herschman, Melissa L. Jampol, and Tristan A. Potter-Strait (page 42)*

- The Supreme Court's recent decision in Escobar expands the potential for Medicare Secondary Payer Act (MSP) enforcement through the False Claims Act.
- The MSP impacts healthcare providers, insurers, employers, beneficiaries, and other parties.
- Medicare requires timely reimbursement of conditional payments.
- Non-compliance with MSP requirements can result in double damages.
- Providers need appropriate internal controls to monitor potential overpayments in a timely manner to avoid potential exposure under the MSP and FCA.

## How to open oncology clinical trials: Staying compliant

*by Alaina Underberg and Christina Head (page 52)*

- Regulatory tasks in healthcare, especially in clinical research, are a necessary but laborious job that encompasses all aspects of daily operations.
- Good Clinical Practice (GCP) is a universal set of principles that are recommended and essential in the field of research.
- The IRB and the research site are responsible for ensuring patient's rights are protected when conducting human research.
- To be in accordance with FDA regulations, it is of utmost importance to maintain regulatory integrity by ensuring clinical trial requirements are met.
- It is important to have a structured process throughout all phases of opening and maintaining oncology clinical trials.

## Physician supervision of assistants: What must be countersigned?

*by Rose T. Dunn (page 56)*

- When researching the regulations, do not assume that all regulations relevant to physician assistants will be in a single regulatory source.
- When creating a policy, be certain to research federal, state, and accrediting agencies.
- The agreement between a supervising physician and the physician assistant should include the oversight details and be consistent with the medical staff rules and regulations.
- Clarity can be enhanced with definitions for the terms used. This is especially true when using the term "record."
- Specialty societies can assist you with identifying relevant regulations that may apply to your situation.

## Safety is the law: Occupational safety compliance

*by Dale Sanders and Tom Ealey (page 62)*

- Safety management and compliance are multi-faceted, and all facets are important.
- The enforcing agency (state or federal) can examine the entire safety culture and operation.
- Policies based on legal requirements must be written for ease of communications and training.
- Employees have a right to be whistleblowers, without fear of retaliation.
- There are significant negative consequences from safety failures for both employee and employer.

## Building a security program: It's not just IT

*by Eric Hummel (page 68)*

- Executive leadership must be invested in the security program.
- Create a security program led by a compliance officer who has been trained in cybersecurity.
- Build the governance structure first.
- Propose a realistic budget.
- The security program consists of a set of projects led by domain leaders (HR, Facilities, IT, Administration, Clinical, etc.).

## Regulatory compliance: Physician needs assessments are an integral step

*by Tynan O. Kugler (page 72)*

- Physician needs assessments (PNAs) are evolving to play an expanding and dynamic role with respect to fair market value (FMV) and commercial reasonableness (CR) opinions.
- As the healthcare industry shifts from volume to value, a historical approach to PNAs based solely on physician-to-population metrics may no longer be sufficient.
- Modern PNAs should consider market specifics relative to healthcare transformation because communities are transitioning at various speeds.
- PNA findings are important to consider in determining whether a particular transaction is commercially reasonable.
- Justification for a hospital's recruitment or physician affiliation strategy is a research-intensive, yet critically important, exercise to support regulatory compliance.

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| 4 | 5<br>WEB CONFERENCE:<br>*How Corporate Culture Impacts Compliance - And What to do About it!*<br>**BASIC COMPLIANCE ACADEMY**<br>New York, NY | 6 | 7 | 8<br>WEB CONFERENCE:<br>*Corporate Integrity Agreement Developments- Understanding the Government's Expectations*<br>CHC Exam | 9<br>**REGIONAL CONFERENCE**<br>Washington, DC | 10 |
| 11 | 12<br>**HEALTHCARE PRIVACY BASIC COMPLIANCE ACADEMY**<br>San Francisco, CA<br>**RESEARCH BASIC COMPLIANCE ACADEMY**<br>San Francisco, CA | 13<br>WEB CONFERENCE | 14 | 15<br>WEB CONFERENCE<br>CHPC Exam<br>CHRC Exam | 16 | 17 |
| 18 | 19 | 20 | 21<br>WEB CONFERENCE:<br>*Those Skills They Never Told You a Compliance Officer Needs to Have* | 22<br>WEB CONFERENCE:<br>*Deploying Research Compliance Analytics: Turning an Audit into an Asset* | 23 | 24 |
| 25 | 26<br>WEB CONFERENCE:<br>*The Medical Record and Its Role in Litigation* | 27 | 28<br>WEB CONFERENCE:<br>*Medical Device Security: To Be Or Not To Be Prepared-That Is The Question* | 29 | 30 | 31 |

## April 2018

| Sunday | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday |
|---|---|---|---|---|---|---|
| 1 | 2<br>WEB CONFERENCE:<br>*Fundraising & Patient Privacy* | 3 | 4 | 5 | 6 | 7 |
| 8 | 9<br>**BASIC COMPLIANCE ACADEMY**<br>Chicago, IL | 10 | 11 | 12<br>CHC Exam | 13 | 14 |
| 15<br>**2018 COMPLIANCE INSTITUTE**<br>Las Vegas, NV | 16 | 17<br>CHC,CHRC & CHPC Exam | 18 | 19 | 20 | 21 |
| 22 | 23 | 24<br>WEB CONFERENCE:<br>*Paying Employed Physicians to Supervise Advanced Practice Clinicians* | 25 | 26 | 27<br>**REGIONAL CONFERENCE**<br>New Orleans, LA | 28 |
| 29 | 30<br>WEB CONFERENCE:<br>*HIPAA & The Medical Practice: Requirements for Privacy, Security and Breach Notification* | 1 | 2 | 3 | 4 | 5 |

### REGIONAL CONFERENCES

March 9 · Washington, DC
April 27 · New Orleans, LA
May 4 · Columbus, OH
May 11 · New York, NY
May 17–18 · San Juan, PR
June 1 · Philadelphia, PA
June 8 · Seattle, WA
June 15 · Orange County, CA
September 7 · Boston, MA
September 14 · Minneapolis, MN
September 21 · Kansas City, MO
September 28 · Indianapolis, IN
October 5 · Pittsburgh, PA
October 11–12 · Honolulu, HI
October 19 · Denver, CO
October 26 · Chicago, IL
November 2 · Louisville, KY
November 9 · Scottsdale, AZ
November 16 · Nashville, TN
November 30 · San Francisco, CA
December 7 · Houston, TX

### BASIC COMPLIANCE ACADEMIES

April 9–12 · Chicago, IL
May 7–10 · Anaheim, CA
June 11–14 · Scottsdale, AZ
July 23–26 · Seattle, WA
August 6–9 · Washington, DC
September 10–13 · Las Vegas, NV
October 1–4 · Dallas, TX
October 15–18 · Nashville, TN
November 12–15 · San Diego, CA
December 3–6 · Orlando, FL
December 10–13 · Orlando, FL

### HEALTHCARE PRIVACY BASIC COMPLIANCE ACADEMIES

March 12–15 · San Francisco, CA
July 23–26 · Seattle, WA
October 15–18 · Nashville, TN
December 3–6 · Orlando, FL

### RESEARCH BASIC COMPLIANCE ACADEMIES

March 12–15 · San Francisco, CA
December 3–6 · Orlando, FL

### 22ND ANNUAL COMPLIANCE INSTITUTE

April 15–18 · Las Vegas, NV

### RESEARCH COMPLIANCE CONFERENCE

June 3–6 · Austin, TX

*Dates and locations are subject to change.*

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| ATTENDEES | TRACKS | SPEAKERS | SESSIONS |

***FOLLOW A TRACK:***

General Compliance/Hot Topics • Long-Term Care • Privacy & IT Compliance
Physician Compliance • Compliance Lawyer • Auditing & Monitoring
Internal Audit • How to Succeed as a Compliance Professional • Quality of Care
Advanced Discussion Groups • Industry Immersion NEW

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