HCCA HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

April 2016

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The keys to more effective internal investigations

an interview with Marita Janiga

Executive Director of Investigations
National Compliance, Ethics & Integrity Office
Kaiser Permanente

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QUESTIONS? catherine.stollenwerk@corporatecompliance.org




by Roy Snell, CHC, CCEP-F

Government enforcement vs. compliance programs in the global economy

Please don't hesitate to call me about anything any time.
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We talk a lot about the government's oversight of business. It gets a lot of negative press. But imagine, if you will, an environment in which the government does not enforce the rule of law. Or imagine countries in which the government owns most businesses. Countries that own most businesses have similar problems to those countries with little to no enforcement. What is the difference between businesses self-regulating and governments self-regulating? I would say the difference in independence is near zero. The conflict of interest would be a very strong deterrent to self-regulation.

Snell

Countries with little to no enforcement of the rule of law are not big players in the global economy. It hurts their economy because players in the global economy would rather do business where the rule of law is enforced by an independent entity free from conflict. There are benefits to being a well-regulated country. Civilized society depends on it. Economic success depends on it. So which is the most advanced country in the world with regard to regulatory enforcement for business? It is an interesting question that could be argued many ways.

What could be better than the government running around trying to catch bad players? What is the most effective way to prevent, find, and fix ethical and regulatory missteps on a real time basis? I would argue that it is the country with the most compliance officers and compliance programs. They would have a material edge. Compliance programs catch problems much more often and much earlier than government enforcement.

> What is the most effective way to prevent, find, and fix ethical and regulatory missteps on a real time basis?

Players in the global economy are attracted to business opportunities in trusted countries. Government enforcement and regulations are inefficient and haphazard. Countries that own most businesses are not much better off than countries where business is self-regulated.

Enforcement folks just can't be everywhere all the time. It's a post-mortem approach. Enforcement is not very effective at prevention. Therefore it stands to reason that countries that head off regulatory problems on a real-time basis with in-house compliance programs are going to be the most trusted. Countries with the most businesses with compliance programs will be the most successful in the global economy.

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

> People might be surprised to learn how much a certificate of appreciation and a $2 pin contributes to engagement.

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ARTICLES

Compliance TODAY

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VOLUME 18, ISSUE 4

Supreme Court: Implied certification and the FCA

On February 1, 2016, *Modern Healthcare* reported, "More than a dozen major healthcare organizations and associations have jumped into a Supreme Court case over the validity of a legal theory now used to bring many fraud lawsuits against them.

"The case has the potential to reduce—or increase—the number of False Claims Act suits brought against healthcare providers and other companies, depending on which way the high court rules."

According to the article, the Supreme Court case, *Universal Health Services v. United States ex rel Escobar*, centers on "situations in which whistle-blowers allege providers have submitted false claims to government programs by failing to follow certain regulations." The article notes that providers may on occasion be "held liable even if the government never explicitly stated that following a regulation was a condition of payment, and even if the provider never explicitly vouched that it had complied with the regulation."

For more: http://bit.ly/21GCKtk

Compliance profession is fast-growing

A recent article in the *Mississippi Business Journal* reported that the compliance officer job "has been around a relatively short time so it isn't that well known, but its ranks are growing.

"Roy Snell, CEO of the Society of Corporate Compliance & Ethics, a non-profit professional membership organization, said the corporate compliance officer's role 'is to implement a compliance program to prevent, find, and fix ethical and regulatory problems' using familiar tools such as audits, risk assessments, investigation and education."

According to the article, "Snell said the profession has grown in just 20 years from practically zero to tens of thousands of compliance officers with vastly different functions. And with more and more federal and state rules and regulations cascading down on businesses, the demand for compliance professionals will snowball."

For more: http://bit.ly/1QtRPql

Increased enforcement, fraud, and abuse regulations in 2016

Bloomberg/BNA recently reported that 2016 healthcare compliance challenges would include, "an increase in False Claims Act cases and increased enforcement actions against corporate executives." The article further noted that 2016 "will also ring in more fraud and abuse regulations from the government, as well as an increase in the government's use of civil monetary penalties."

The *Bloomberg/BNA* article also reported, "The Department of Health and Human Services Office of Inspector General is scheduled to release revisions to three fraud and abuse rules by spring 2016…"

For more: http://bit.ly/1Rsf7de

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

Regulatory News

CMS: First-ever home health patient experience of care star ratings released

On January 28, 2016, the Centers for Medicare and Medicaid Services (CMS) announced its release of "the first patient experience of care star ratings on Home Health Compare (*medicare.gov/homehealthcompare/search.html*). Known as Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) Survey star ratings, these measures evaluate patients' experiences with home health agencies.

"Home Health Compare is the agency's public information website that provides information on how well Medicare-certified agencies provide care to their patients. The HHCAHPS Survey star ratings report patients' experiences of care ranging from one star to five stars using data from patients (or the family or friends of patients) that have been treated by the agency. Five stars is the highest rating and reflects the best patient experience. There are over 11,000 agencies with data on Home Health Compare, and about 6,000 of them now have patient care experience star ratings."

CMS press release:
http://go.cms.gov/1q5JCjk

CMS fact sheet:
http://go.cms.gov/1ME5awU

Administrative Law Judge rules in favor of OCR enforcement of HIPAA Privacy Rule

A February HHS-OCR press release announced, "A U.S. Department of Health and Human Services Administrative Law Judge (ALJ) has ruled that Lincare, Inc. (Lincare) violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and granted summary judgment to the Office for Civil Rights (OCR) on all issues, requiring Lincare to pay $239,800 in civil money penalties (CMPs) imposed by OCR. This is only the second time in its history that OCR has sought CMPs for HIPAA violations, and each time the CMPs have been upheld by the ALJ.

"Lincare is a provider of respiratory care, infusion therapy, and medical equipment to in-home patients, with more than 850 branch locations in 48 states. OCR's investigation of Lincare began after an individual complained that a Lincare employee left behind documents containing the protected health information (PHI) of 278 patients after moving residences. Evidence established that this employee removed patients' information from the company's office, left the information exposed in places where an unauthorized person had access, and then abandoned the information altogether. Over the course of the investigation, OCR found that Lincare had inadequate policies and procedures in place to safeguard patient information that was taken offsite, although employees, who provide health care services in patients' homes, regularly removed material from the business premises. Further evidence indicated that the organization had an unwritten policy requiring certain employees to store protected health information in their own vehicles for extended periods of time. Although aware of the complaint and OCR's investigation, Lincare subsequently took only minimal action to correct its policies and strengthen safeguards to ensure compliance with the HIPAA Rules."

For more:
http://1.usa.gov/1L6ygos

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Questions? jennifer.parrucci@corporatecompliance.org

HCCA *conference news*

Regional Compliance Conferences

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September 16 | Minneapolis, MN
September 23 | Overland Park, KS
September 30 | Indianapolis, IN
October 7 | Pittsburgh, PA
October 13–14 | Honolulu, HI
October 21 | Denver, CO
November 4 | Louisville, KY
November 11 | Scottsdale, AZ
November 18 | Nashville, TN
December 2 | San Francisco, CA
December 9 | Houston, TX

If you have any questions, email beckie.smith@hcca-info.org or visit www.hcca-info.org/regionals for more info.

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

HCCA *website news*

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

Top pages last month

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

Number of website visits last month

64,602

Resources

HCCA has more than just expert videos to help compliance professionals. Under the *Resources* section of the website, there is also a *Library* of compliance material, *Surveys* from HCCA, and complimentary *Pamphlets & Whitepapers* in multiple languages.

We also continue to add new resources. Our two newest sections are *Podcast*, where HCCA employee Kortney Nordrum talks to compliance professionals about compliance issues, and a *Compliance Dictionary*, explaining common terms in the Compliance profession. Visit our website to explore these materials on your own.

Video of the Month

What are some of the risks of Facebook for health care providers?

See this and other videos about risks with social media at: *http://bit.ly/votm-ct-2016-04*

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

HCCA *social media news*

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

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

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

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

Join us on LinkedIn—a business-oriented network with more than 300 million active users. With more than 22,000 members, our LinkedIn group fosters more than 50 new discussion posts every week. One recent highlight:

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

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

Facebook — *www.facebook.com/hcca*

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

Pinterest — *www.pinterest.com/theHCCA*

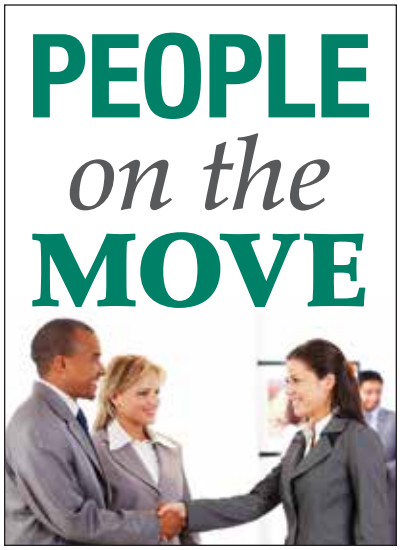
Check out our Pinterest boards for *HIPAA*, *ICD-10*, *ACA*, *Compliance Videos*, and using *Technology & Social Media* in healthcare, as well as map-boards for our major conferences (highlighting local restaurants, sights, and things to do in each of our conference cities). Our "infographics of the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

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

▶ **Terry Deyoung** has been named Director of Quality Improvement & Risk Management, Patient Advocate, HIPPA & Corporate Compliance Officer at Fairbanks Hospital Treatment Center in Indianapolis, IN.

▶ **Dawn Geisert**, of Troy, MI has been named Senior Vice President and Chief Compliance Officer for Beaumont Health in southeast Michigan.

▶ North Shore Medical Center's Compliance and Privacy Officer **Oksana Baczyk**, RN, CHC, received the President's Award for her outstanding work and accomplishments throughout the year. The award was presented in December 2015 by North Shore Medical Center (Miami) CEO Manny Linares.



▶ **Jeff White** has been appointed to the National Hospice and Palliative Care Organization (NHPCO) Regulatory Committee for a two-year term. He is the Chief Compliance Officer at The Elizabeth Hospice in San Diego, CA.

▶ The Joint Commission has appointed **Ronald M. Wyatt**, MD, MHA, to the newly created position of Patient Safety Officer, reflecting the organization's commitment to promoting a safe and high-quality healthcare system with a goal of zero patient harm.

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

▶ If you've received a promotion, award, or degree; accepted a new position; or added a new staff member 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@hcca-info.org*.

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

Compliance Today needs you!

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

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

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

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Marita Janiga
Executive Director of Investigations
National Compliance, Ethics & Integrity Office
Kaiser Permanente
Oakland, CA

an interview by Lynda S. Hilliard, CHC, CCEP

Meet Marita Janiga

*This interview with **Marita Janiga** was conducted in January by HCCA member **Lynda S. Hilliard** (lyndahilliard@hotmail.com), Principal at Hilliard Compliance Consulting in Mount Shasta, CA.*

LH: Please introduce yourself and what career path led you to this position within Kaiser Permanente?

MJ: When I was in college, women were being recruited for positions that had traditionally been open almost exclusively to men, such as the military and law enforcement. My mom, a school teacher, encouraged me to think about nontraditional careers, something that she would have liked to have been able to do herself, but many career paths simply weren't an option when she attended college. My dad was also very supportive of me reaching for the stars and told me that I could do anything that a guy could do.

Federal law enforcement was of particular interest to me. I was both curious and athletic, and I loved to solve problems, attributes that I thought would be important qualities for a special agent. I was recruited by the Naval Criminal Investigative Service (NCIS) to become a special agent and, in 1986, after going through a rigorous application process, I was fortunate enough to be hired and I left for the Federal Law Enforcement Training Center in Glynco, Georgia to attend Criminal Investigator Basic Training. It truly was a life changing experience for me and I was hooked. I loved every aspect of doing investigations: digging through boxes of documents to find that smoking gun, interviewing witnesses and

subjects, presenting cases to prosecutors, writing affidavits, executing search warrants, and testifying in court.

I couldn't really see myself ever doing anything else. But, as the saying goes, all good things must come to an end, so in late 2007, after 22 years, I retired from my federal law enforcement career as the Special Agent in Charge of the U.S. Department of Labor's Office of Inspector General, Office of Labor Racketeering & Fraud Investigations in the San Francisco Region. I knew there had to be life after my first career, but I didn't think it could ever measure up to my law enforcement days.

After taking a short time off, a friend from the FBI, with whom I'd worked on healthcare cases over the years, encouraged me to apply for a position at Kaiser Permanente in the Compliance department, which I did. I was hired in 2008 and I've never looked back. I was immediately struck by the professionalism of the team—the investigators were top notch, as was the data analytics team with their cutting-edge capabilities. We had certainly begun using data in our healthcare fraud cases in the government, but having the capabilities of the fraud control analytics team right at my fingertips was amazing. One of my first cases after coming on board at Kaiser Permanente involved an individual suspected of frequenting one of our Emergency Departments to seek drugs. We had three names with slight variations and some demographic data. I engaged the fraud control data analytics team and within a few hours, the number of names that were suspected of being used by one individual had expanded from three to more than 40, and the number of Emergency Departments frequented by the individual had also increased significantly. I knew I was really going to enjoy my second career, possibly even as much as my first!

I knew there had to be life after my first career, but I didn't think it could ever measure up to my law enforcement days.

LH: Please describe how the Investigations Department is integrated within the Kaiser Permanente Compliance Program?

MJ: Kaiser Permanente has a National Compliance, Ethics & Integrity Office, and within that office there is a Fraud Control function that is made up of multiple teams, including Investigations, which I lead. As the head of Investigations, I report directly to our Senior Vice President and Chief Compliance & Privacy Officer Vanessa Benavides. Within my team there is our National Special Investigations Unit (NSIU) that is comprised of a director, three senior managers, two fraud analysts, and 11 senior investigators. There is also the Hotline Operations team, which has two managers and five compliance consultants who triage cases, oversee the compliance case management system, prepare reports, and perform an assortment of other tasks to support the compliance community across our entire organization. To put that into perspective, there are more than 600 people throughout Kaiser Permanente who support Compliance. That probably seems like a huge number, but Kaiser Permanente takes compliance very seriously, and we have to considering we have 38 hospitals and approximately 620 medical offices and other outpatient facilities, 510 pharmacies, and 187,00 employees including 18,500 physicians, all supporting our 10.2 million members—so compliance is a big job.

LH: Does your position have direct interaction with the board of directors?

MJ: I have responsibility for reports to the board that keep them apprised of the status of our overall fraud control program. I prepare an annual report for the board that details our work plan initiatives and our associated accomplishments for the previous 12 months. This report includes our efforts to prevent, detect, and investigate fraud, waste, and abuse. On a quarterly basis, I prepare a report detailing our significant investigations to ensure that board members are aware of all investigations of high importance to the company. I report directly to the board on specific investigations when requested by the senior vice president and chief compliance and privacy officer.

Now with the IWA, we have a standardized process and everyone has agreed on who will take the lead on various types of investigations.

LH: Does your position interact with the Kaiser Permanente Internal Audit department and/or any other fraud/waste and abuse detection functions?

MJ: My team interacts and collaborates with multiple departments and functions at Kaiser Permanente, both inside and outside of our Compliance department. In particular, we interact with other risk management units, such as internal audit and SOX, and with finance, revenue cycle, IT, operations, legal, HR, and very importantly, our internal compliance data analytics team.

One example of how our collaboration with other detection functions has been beneficial is our Investigations Working Agreement (IWA). A number of years ago, all functions within Kaiser Permanente that conduct compliance-related investigations, including Internal Audit, came together to develop the Investigations Working Agreement, whereby we put in place a central case management system as well as a standardized process for conducting investigations. Prior to the IWA, different investigations groups were bumping into each other investigating the same allegations. Now with the IWA, we have a standardized process and everyone has agreed on who will take the lead on various types of investigations.

Another example of interaction and collaboration is with our internal compliance data analytics team, who we work hand in glove with. The data analytics team performs data mining and analysis specifically designed to detect fraud, waste, and abuse, and conducts dynamic data studies using various analytic tools to identify anomalous patterns that raise red flags for further review and analysis. These red flags often result in leads for investigators to pursue.

And our collaboration goes beyond the risk management units and data analytics team. To engage the entire organization, we partner with our compliance training team, which we call our Learning and Awareness team, to make sure our annual compliance training focuses on the highest level risks and what our workforce can and should do to help mitigate these risks. We also work closely with our communications team, and in fact, that team is embedded with our National Compliance, Ethics & Integrity Office, meaning we have a dedicated resource, which I know is a luxury many organizations don't have.

LH: How does your department develop compliance program-related goals? And how do they connect to the overarching compliance program goals?

MJ: Every year senior compliance leaders, with input from partners in other departments, create an annual compliance work plan, which is presented to the board. The work plan and initiatives are based on Kaiser Permanente's internal assessments of risk areas, as well as guidance from external regulators such as the Office of Inspector General (OIG). After the compliance work plan has been reviewed and approved, leaders of functional areas and teams, including me for Investigations, develop goals to support the work plan, and those goals are cascaded throughout the compliance organization as appropriate. Transparency is extremely important. Everyone needs to understand how their work supports the overall goals, and how other teams, departments, or functions play a part. The last thing we want to do as an organization is duplicate efforts or exhaust our operations departments by submitting multiple requests for the same information.

LH: Are there key industry or other national resources you use for reviewing and benchmarking your data?

MJ: In terms of benchmarks for NSIU, we utilize resources such as the National Health Care Anti-Fraud Association's (NHCAA) biannual anti-fraud management survey. This is a tool to help health plans compare the structure, staffing, funding, operations, and results of their anti-fraud efforts to those of similar companies and the industry as a whole. Kaiser Permanente participates in the survey and this year I'm a member of the survey committee to revise and update the questions to ensure we are eliciting the correct information to help organizations determine if they are in or out of range with industry norms. We use this benchmarking data to make certain we are maintaining a best in class investigations team. For Hotline Operations benchmarking, we refer to key industry reports from Navex Global to review how we compare against the many variables contained within the report. For example, the types of calls reported, visibility of callers to the hotline, investigation outcome ranges or rates, call volume per 1,000 employees, etc.

LH: Do you work on any special infrastructure projects, or are you always heads-down with investigations?

MJ: Yes, based upon the outcomes of our compliance work plan, I lead one or more company-wide initiative a year. In 2015, we landed on the Medical Identity Fraud Project to help mitigate fraud that is typically committed in Emergency Departments by individuals using fictitious identities as a way to seek narcotic drugs. According to the CMS, more than 40 people die each day from overdoes of prescription painkillers. It's truly a national epidemic. The goal of this project was to heighten awareness and provide guidance on how to report suspected medical identity fraud. What we did was form a workgroup that had representation from my team, the regional compliance fraud leaders, select hospital compliance officers, the communications team, and the data analytics team. The project focused on our Emergency Departments, which, based on our experience, is the most likely venue to be frequented by an individual using a fictitious identity to seek narcotics. During the course of our project, we went to the hospitals and met with Emergency Department staff, including physicians, nurses, registration clerks, and security personnel to determine how we could most effectively spread awareness about this issue and to learn more about what tools would help them identify and report suspected medical identity fraud. During these collaborative, in-person meetings we gained insights and discovered nuances that we probably would not have uncovered if these meetings had been held via conference calls.

One result of our findings was a redesign our Fraud Alert posters. These posters of alleged medical identity fraud suspects are created by senior investigators and placed in our Emergency Departments in an area only viewable by staff. The posters contain photos we've captured of alleged suspects from our video surveillance cameras, as well as a list all of the different aliases and addresses that we know of at that time. And this can be a long list. With the help of our data analytics team, we recently put together a profile of a person who used more than 40 different aliases at multiple Kaiser Permanente hospitals in our Northern California region. This, by the way, results in the same number of medical records being generated, which can lead to serious patient safety concerns if the person provides false medical information, such as allergies, conditions, or past surgeries, at every Emergency Department encounter.

We also designed a recognition program to reward observant staff members who report suspected medical identity fraud. We give these employees a certificate of appreciation and a coffee mug or pin. These things are just tokens, but they make employees feel good about their contributions, and they serve as visible reminders to the rest of their team members that one of their colleagues is a "star," and who doesn't want to be a star? It's a great way to keep operations and compliance connected and the program has been very well received! We also recently developed a short video that we will be rolling out, along with a training deck, to our hospital officers to use in their Emergency Departments to raise awareness across our organization. We have worked closely with our communications partners every step of the way. Having communications embedded with compliance is optimal for an effort such as this.

LH: What professional and personal skills do you feel are integral to succeeding as an Investigations Executive Director?

MJ: To effectively lead an investigations program, it is imperative to be well connected, not only inside of your organization, but also externally, and to continue to build and expand those relationships yourself and through the people you hire. When hiring, I focus on bringing highly skilled investigators onto the team who have varied law enforcement and healthcare fraud experience. These senior investigators bring their contacts and connections to the team—and the effect is exponential. These relationships are crucial in the fight against healthcare fraud.

To effectively lead an investigations program, it is imperative to be well connected, not only inside of your organization…

When I came to Kaiser Permanente, I brought with me a number of external contacts in law enforcement and U.S. Attorney's Offices in the areas where I was assigned. For instance, I had been active in the National Healthcare Anti-Fraud Association (NHCAA) during my federal career, attending many of their annual training conferences, which have different tracks so attendees can focus on areas specific to their particular work. This is a great way for any organization, large or small, to learn how to become more adept at combating fraud in healthcare and to make valuable contacts in this area. NHCAA offers a certification called AHFI® (Accredited Health Care Fraud Investigator), which members of my team have earned. I'm now on the NHCAA Board of Directors, which was a great honor for

me, and I can tell you that I've called upon my contacts to collaborate and to compare and discuss issues many times, as have they me. While other health plans are our competitors in the marketplace, in the world of fraud detection, prevention, and investigation, we're all on the same side.

Kaiser Permanente is also a founding member of the Medical Identity Fraud Alliance (MIFA), and I am on their board. MIFA provides leadership, education, and awareness to drive the development of best-in-class technologies and influence changes to regulation, policies, and laws to help reduce medical identity fraud. We also have Kaiser Permanente compliance folks who actively participate in the Healthcare Fraud Prevention Partnership (HFPP) sponsored by CMS. HFPP's purpose is to exchange information between public and private partners in order to be more informed and better detect and reduce healthcare fraud. Kaiser Permanente is a member of the analytics design team. These are just a few of the organizations with whom we participate, along with, of course, HCCA.

LH: One of the key concerns from compliance officers recently is how to improve the effectiveness of their investigations. For those in smaller organizations what tips would you give to make their investigations more effective, and what could they do to maximize their investigative resources?

MJ: I'd suggest taking a look at your landscape and doing some brainstorming with other risk management partners in your organization to identify a couple of areas where you can make an immediate difference. For me, I find that when I put process around what it is I want to do, and I reach out to my colleagues with expertise that I can leverage, I begin to make progress. It may be an awareness program similar to what we did with the Medical Identity Fraud Project, where you heighten awareness and recognize individuals for their involvement. People might be surprised to learn how much a certificate of appreciation and a $2 pin contributes to engagement, which pays off for our investigators, because we now have "feet on the street" helping us do our job.

Another area to focus on to help maximize investigative resources is technology and data analytics. Using data and analysts to focus the investigations is a time saver, and if you can automate that work, so much the better. While Kaiser Permanente has access to sophisticated technology, smaller organizations can see similar benefits using everyday tools such as Microsoft Excel to conduct data studies to uncover outliers. Sometimes all it takes is a conversation with the right data analytics or IT person to uncover a real passion for this work, and before you know it, a small team has been formed to help. After all, investigations can be fun—at least I think so!

From an external perspective, joining industry associations and alliances such as HCCA and NHCAA, is a great way to broaden your sphere of contacts and learn about how other organizations are mitigating risks and implementing best practices. And look to the millennials in your life to show you the ropes on Twitter and other social media sites. More and more companies and industry groups are actively using Twitter, Facebook, LinkedIn, and the like to provide forums for real-time information and interactions. I even noticed that HCCA has a Pinterest group. Now I can look for decorating ideas and view compliance videos all from the same site!

LH: Please let us know more about you. What types of hobbies and/or relaxation activities do you enjoy? How do you decompress after a stressful day at the office?

MJ: I'm smiling as I answer this question, because I don't have very many hobbies, and

I keep telling myself that I need to develop some! Along with my career, I did manage to raise a family and looking back, I sometimes wonder how I did it. I love spending time with my family. Both of my children have graduated from college, so my husband and I have a bit more carefree time now. I love to travel and have both lived overseas as a child and traveled as an adult to many wonderful and some exotic locations. I also enjoy cooking when I can find the time. As for decompressing, I don't wait until the end of the day for that. I am up very early in the morning to exercise. I like to start my day off in that fashion, with my workout behind me and feeling relaxed and ready to go! If I waited until the end of the day, I'm afraid I'd find too many excuses not to do it.

LH: Thank you, Marita for sharing your story with us.

by Catherine Boerner, JD, CHC

Medicare Compliance Reviews

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

It is good to keep your Compliance Committee informed regarding enforcement actions and results of Department of Health and Human Services Office of Inspector General (OIG) audit reports. The best place to provide information for hospitals is to report on the OIG's Medicare Compliance Reviews to ensure you have controls in place. It is always helpful to take a practical approach that everyone in the room can understand. Presenting compliance risks, based on what is happening in audits of other organizations, can help engage Compliance Committee members. This approach also encourages committee members to ask questions about risk areas and get answers regarding how your organization would perform in a similar audit. For example, you can present the five most-recent Medicare Compliance Review results reported on the OIG website, which may include the following audit reports:

Boerner

1. Medicare Compliance Review of Nebraska Methodist Hospital for 2012 and 2013. (A-07-15-05073), December 2015.
2. Medicare Compliance Review of University of California, Davis, Medical Center for 2011 through 2013. (A-09-14-02036), November 2015.
3. Medicare Compliance Review of Sierra View Medical Center. (A-09-14-02039), November 2015.
4. Medicare Compliance Review of Boca Raton Regional Hospital, Inc., for 2011 and 2012. (A-04-14-07048), October 2015.
5. Medicare Compliance Review of Moses H. Cone Memorial Hospital for 2012. (A-04-14-04023), August 2015.

It might be helpful to break down the OIG report results in a table (see Table 1) to help with the discussion.

Table 1: Comparison of Medicare Compliance Reviews

	Correct Claims/ Total Claims	Inpatient Claims with Errors	Inpatient Over-payments	Outpatient Claims with Errors	Outpatient Over-payments
Nebraska Methodist Hospital	119 / 138	17	$86,000	2	$25,000
UC Davis Medical Center	130 / 231	92	$1,884,700	9	$545,802
Sierra View Medical Center	5 / 30	23	$228,969	2	$569,095
Boca Raton Regional Hospital, Inc.	161 / 211	50	$514,449[1]	0	$0
Moses H. Cone Memorial Hospital	152 / 225	70	$430,418[2]	3	$27,172

1. "On the basis of our sample results, we estimated that the Hospital received net overpayments of at least $2,628,112 for the audit period. This overpayment amount includes claim payment dates outside of the 3-year recovery period. Of the total estimated overpayments, at least $282,259 was within the 3-year recovery period and as much as $2,345,853 is outside the 3-year recovery period."
2. "On the basis of our sample results, we estimated that the Hospital received overpayments of at least $1,826,464 for the audit period." "Our audit covered $9,598,982 in Medicare payments to the Hospital for 1,349 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 225 claims with payments totaling $1,990,430."

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by Joan Feldman, Esq. and William Roberts, Esq.

Communicating protected health information via text messaging

» Many individuals depend on text messaging to communicate with clinicians.
» Text messaging can improve communication and patient outcomes.
» Providers must assess risk before sending PHI via text message.
» Risks exist with using text messaging in the clinical setting.
» Providers can mitigate risk when text messaging with patients.

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There is no doubt that we are now fully immersed in a world where communications are rapid fire and electronic. Approximately three-quarters of the U.S. population own phones that can receive text messages. Some 83% of American adults own cell phones and three-quarters of them (73%) send and receive text messages. The Pew Research Center's Internet & American Life Project asked those texters in a survey how they prefer to be contacted on their cell phone: 31% said they preferred texts to talking on the phone and 53% said they preferred a voice call to a text message. Another 14% said the contact method they prefer depends on the situation.[1]

In fact, many individuals have abandoned their landlines and rely exclusively on mobile or cellular phone technology. For obvious reasons, communicating with patients at their place of employment is not always possible or welcomed by either the patient or their employer, and mail service is only fine if you have a few days to communicate your message. Although some patients prefer to receive information from their provider via voicemail, many patients prefer to receive healthcare-related information via text messaging as a means to having reciprocal communication in real time.


Feldman


Roberts

According to the United States Department of Health and Human Services, there is a "substantial body" of evidence that demonstrates that text messaging can improve clinical outcomes, improve patient compliance (including medication and appointment reminders), and reduce risky behavior.[2] As a result, more and more providers are eager to embrace text messaging as a means of communicating directly with their patients. Texting may be an extremely effective way to communicate with a patient, but if you are a healthcare provider or acting on behalf of a healthcare provider, communicating with a patient by text is not always advisable, because there are potential privacy and security risks associated with communication via text messaging.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations require healthcare providers to implement reasonable safeguards to protect the privacy and security of patient health information, regardless of the information's form or format. This obligation under HIPAA extends to patient information contained in text messages sent or received by the healthcare provider. Therefore, providers who use text messaging must conduct a risk analysis to determine where the electronic protected health information (ePHI) it is texting is primarily created, received, and maintained on mobile phones (text messages may also reside on workstations or cloud-computing servers or be embedded into patient medical records).

Upon identifying text messages as a location of ePHI, HIPAA directs a healthcare provider to identify reasonably anticipated threats to such ePHI and evaluate the likelihood and potential impact of such threats. Examples of such threats in the context of text messaging include:

- Access of ePHI by an unauthorized or unintended recipient (e.g., text message sent to incorrect patient or third party)
- Theft or loss of the mobile device
- Improper disposal of the device
- Interception of transmission of PHI by an unauthorized person (i.e., hacking).

Recent statistics included in the Department of Health and Human Services' reports to Congress on HIPAA breaches show that misdirecting the transmission of ePHI or the loss or theft of mobile devices are among the most common incidents leading to a HIPAA breach, along with a growing prevalence of hacking and interception of transmission as causes of breaches.

Although the federal privacy rules neither explicitly prohibit text messaging as a means of communicating with patients, nor prescribe how it can be done to remain compliant, there is an overriding expectation under the law that such communications should be sent in a secure and private manner. Even though technology is currently available in the marketplace that allows a more secure format for communicating via text messaging, not all providers, especially providers with limited resources, can afford the current technology. Moreover, even with the secure platform technology, privacy and security risks remain, as they do with all forms of patient communication.

Given the value of real-time text messaging with patients, with or without the security technology, we do not recommend that providers forego communicating via text messaging. However, if text messaging will be used as a form of communication with patients, we do offer the following recommendations and/or guidelines with respect to reducing your privacy and security risks:

- Develop a written policy so staff are aware of who can communicate with patients via text messaging, the indications for text messaging, and the content that is appropriate to communicate via text messaging;
- Contemporaneously record in the patient's medical record the information that was texted to the patient. Specifically, the date, time, content, and person who text messaged the patient should be documented. It is our understanding that cellular carriers do not maintain the text messaging data as long as the retention periods most healthcare providers are required to comply with; therefore, documentation of the text messaging content in the medical record is essential for risk management, auditing, and reimbursement purposes;
- Obtain the patient's written consent prior to communicating through text messaging to confirm that they are willing to receive information via text messaging. Have the written authorization specify the type

of information that the patient is willing to receive by text message. For example, appointment reminders, messages to call the provider, and other content specific information;
- Require that all texting be done on password-protected mobile devices, both on the sending and receiving end;
- Send a confirmatory text message to make sure that the patient is able to receive the text message. To be sure that it is the patient who is texting back, you have the option of asking the patient to text back an agreed upon code;
- Do not send any ePHI that is highly sensitive (e.g., HIV-related confidential information, drug and alcohol information, psychiatric information) through a cellular phone that does not have the secure text messaging platform discussed above. We are also of the opinion that laboratory results and pathology and radiology reports or results should not be sent via text;
- Make sure that before phones are retired, all PHI is deleted;
- Consider requiring mobile devices used for text messaging to be equipped with remote wiping technology in the event the device is lost or stolen; and
- Ensure that data breach policies and privacy and security training programs address the use of mobile devices and text messaging.

Conclusion

We expect, as with most technological advances that, in due time, more secure text-messaging technologies will be more affordable or considered standard technology in all cellular or mobile phones. Until such time, we recommend that you take an inventory of staff that are currently using text messaging to communicate with patients and, if it is a practice that is currently being used, develop a policy that takes into consideration the foregoing recommendations.

1. Aaron Smith: Americans and Text Messaging. Pew Research Center. Available at http://pewrsr.ch/1WX8qUk
2. Department of Health and Human Services: Using Health Text Messages to Improve Consumer Health Knowledge, Behaviors, and Outcomes: An environmental scan. May 2014. Available at http://1.usa.gov/21GN846

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THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

by Nancy J. Beckley

#HCCAci—What happens in Vegas, stays in Vegas! (Whoops! Except your Tweets!)

Nancy J. Beckley *(nancy@nancybeckley.com) is President of Nancy Beckley & Associates LLC, a rehab compliance consulting firm in Milwaukee, WI.*
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It's another year, another HCCA Compliance Institute, and another TweetUp! It is no secret that the social media platform of choice at the CI is Twitter (*#HCCAci*), but this year, there is an opportunity to try some different social media apps in addition to tweeting all the live action.


Beckley

How about getting the Periscope app and going live (be sure to be in the back of the room and whisper) during one of the keynotes? Your Twitter followers who aren't at the CI get a chance to see a quick, live segment. Line up some colleagues with the Periscope app beforehand, and let them know that you will be "up scope" for live reports from the CI. Be sure to connect your Periscope and Twitter accounts, so your Twitter followers will be notified that you are "up scope." As you are live on Periscope, you will see the Twitter handles of everyone who is joining the live feed scrolling up. Be sure to set the app to record for later viewing, and also to take a practice run before hitting Vegas.

If you are looking for a "What happens in Vegas, stays in Vegas" opportunity, you might want to try the Snapchat app. Snapchat leaves it up to the user to take a quick screen shot in order to memorialize the chat before it self-destructs. Poof! Practicing your timing on this might be in order if you are looking to use this feature. (See the February *Connectivity* column).

As you get ready to pack your bags, be sure to download HCCA's Compliance Institute app and set up your laptop or tablet with TweetDeck so you can organize a *#HCCAci* column. Then check out the latest HCCA postings on Pinterest (*www.pinterest.com/thehcca*). Whether you are at the CI or not, we all can join in by watching the Twitter feed and following the official *#HCCAci* hashtag on Twitter, or alternatively via TweetDeck, where it is easy to organize a dedicated *#HCCAci* column.

> If you are looking for a "What happens in Vegas, stays in Vegas" opportunity …try the Snapchat app.

Once again I ask you to join me at the official *#HCCAci* TweetUp on Monday evening, where we will all be watching the Twitter feed, counting the tweets, and hoping for a door prize. I am wondering if *@walter_johnson1* will win big again? What are the odds?

P.S. Exhibitors, don't forget to tweet us about your door prizes and booth numbers. Vegas, baby! @nancybeckley

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by Kyle A. Vasquez, JD, LLM

Embracing 340B reform: What's in store for 2016?

» Congress and federal agencies continue to implement policies that directly impact the 340B Program.

» 2016 promises to be a busy year for covered entities managing 340B Program compliance.

» Stakeholders need to dedicate resources to stay informed of and quickly adapt to regulatory updates to ensure ongoing 340B Program compliance.

» Prior audit results, the Mega-Guidance, and reports by the OIG and GAO can guide an evaluation of your 340B program and identify risk areas.

» Stakeholders should consider reaching out to members of Congress and HRSA to present ideas on how to drive compliance and efficiency in the 340B Program.

Kyle A. Vasquez *(kvasquez@polsinelli.com) is a healthcare regulatory attorney with Polsinelli PC, and is based in Chicago. He devotes a significant portion of his practice to the 340B Program, reimbursement, certification and compliance matters.* *bit.ly/in-KyleVasquez*

2015 promised to be a big year for the Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program (340B Program). Members of Congress, MedPAC, the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), and the U.S. Government Accountability Office (GAO) continued to scrutinize the program. A federal orphan drug case was decided, proposed guidance was released, and Congress attempted to write new 340B legislation. This flurry of activity caused stakeholders to wonder, "What does the future hold for 340B?"

Vasquez

HRSA attempted to pacify regulators' concerns through more audits and the development of a comprehensive set of proposed regulations (Mega-Reg). However, a recent orphan drug decision by the U.S. District Court for the District of Columbia (the Court) found that HRSA lacked certain 340B Program rulemaking authority and threw a wrench in HRSA's plans.[1] HRSA spent the earlier part of 2015 repackaging its Mega-Reg into proposed interpretive guidance (Mega-Guidance), but yet another decision by the Court in favor of drug manufacturers could impede HRSA's ability to finalize its Mega-Guidance.[2]

Now, here we are in 2016, and stakeholders are still wondering, "What's next for 340B?" Although the Mega-Guidance was a step in the direction of 340B Program reform, it appears that the 340B provider community will have to focus its attention on not only the Mega-Guidance, but also on other proposals by Congress, the Centers for Medicare & Medicaid Services (CMS), and potentially other agencies. Compliance team members and their advisors will have to closely follow a number of different developments throughout the year, and will need to properly position themselves to quickly adapt to what could be significant legislation, rulemaking, and guidance.

This year promises to be a thrilling and challenging one for 340B stakeholders. Below is a recap of the recent legislative and agency actions that pertain to the 340B Program, a

discussion of potential changes on the horizon, as well as a discussion of key compliance takeaways raised by these changes.

Bipartisan Budget Act of 2015

In March 2015, the House Energy & Commerce Committee attempted, but ultimately suspended its effort, to include 340B overhaul language in the 21st Century Cures Bill (Cures Bill). This effort caused an uproar in the 340B community. Ultimately, the Committee removed the draft 340B language from the Cures Bill.

Then, in late 2015, with virtually no notice, Congress and the White House took aim at hospital reimbursement in the Bipartisan Budget Act of 2015 (the Budget Act), by including a significant change to the way hospitals will be paid for off-campus department services beginning January 1, 2017.[3] Specifically, Section 603 of the Budget Act reduces reimbursement to new off-campus sites to that of physician offices or ambulatory surgery centers, effective January 1, 2017. Section 603 applies only to off-campus sites that were not billed to Medicare as hospital departments prior to November 2, 2015.

Off-campus hospital departments are currently eligible for 340B if they are reimburseable cost centers of the main hospital. In 340B, these are commonly referred to as "child sites." Because Section 603 of the Budget Act changes the way off-campus child sites are reimbursed under Medicare, Congress may have taken a significant jab at the future of child site 340B eligibility.

The impact that this law will have on 340B child sites remains to be seen, because it will largely depend on whether Congress enacts any changes to the Budget Act and how CMS operationalizes Section 603. For example, if CMS requires off-campus departments that were developed after November 2, 2015 to enroll as Medicare Part B free-standing clinics, this may effectively render such sites ineligible for 340B, because they presumably would no longer be reimbursable cost centers on the Medicare cost report, as required under the 340B Program.

This development could render newly developed, acquired, or converted off-campus hospital departments ineligible for 340B. The Budget Act may also impact 340B eligiblity associated with expansion of existing hospital departments. Worst case scenario, covered entities would need to use non-340B drug purchasing accounts to acquire drugs for ineligible off-campus locations. CMS is expected to publish proposed rules on this issue in mid-2016 with a final rule anticipated in fall 2016.

The impact that this law will have on 340B child sites remains to be seen, because it will largely depend on whether Congress enacts any changes to the Budget Act and how CMS operationalizes Section 603.

One thing is clear—Congress is taking aim at 340B, so it is critical to monitor and take part in Congressional activity. Congress may wait to see if HRSA's Mega-Guidance stands on its own two feet. If it doesn't, stakeholders should expect Congress's involvement. Rumors are already circulating that the House Energy and Commerce Committee has reached out to stakeholders in a few key 340B topic areas to seek input that would assist the Committee staff with developing draft legislation.

Mega-Guidance

HRSA issued its highly anticipated Mega-Guidance on August 28, 2015. Stakeholder reaction was immense—HRSA received 1,273 comments during the 60-day comment window.[4] HRSA has committed to reviewing and considering all comments when issuing its final Mega-Guidance. According to HHS's Fall 2015 Rulemaking Agenda, the final Mega-Guidance is expected in September 2016.[5] Time will tell if the Mega-Guidance is finalized in 2016, or if legal challenges will block further developments.

Although HRSA proposed numerous substantive changes to the 340B Program in its Mega-Guidance, there are a few key aspects that participants (i.e., covered entities) should keep top of mind as we begin 2016. HRSA and its auditors are already showing signs that the Mega-Guidance is influencing their analysis and findings during audits. Although not ideal financially and administratively, using the Mega-Guidance as an informal and conservative roadmap may be a useful approach to facilitate compliance during these uncertain times. Below are a few critical highlights from the proposed Mega-Guidance with editorial commentary included for clarity.

Patient definition changes

The bulk of HRSA's proposed changes appear in a new, six-part patient definition that replaces the current three-part test. HRSA's proposal includes: (1) a site of care standard, (2) a billing standard, (3) a prescription standard, (4) a classification standard, (5) a medical record standard, and (6) a scope of care standard. It appears that HRSA applied lessons it learned during the hundreds of audits it conducted over the last three years in an attempt to eliminate a number of loopholes that covered entities relied on to expand their respective 340B programs, although many times inadvertently.

Site of care standard

Under the site of care standard, HRSA would require a patient to receive care at the covered entity or a covered entity-registered child site. HRSA's proposal would eliminate the existing "referral for consultation" exception found in its current patient definition. In practice, the referral for consultation language is useful to covered entities with 340B contract pharmacies, because current contract pharmacy guidance, software limitations, and other operational challenges may prevent covered entities from restricting access to 340B in contract pharmacies to patients who physically receive their prescription from an eligible covered entity location. This is particularly true with covered entities that do not e-prescribe 100% of the time. This issue arises during HRSA audits time and time again.

A conservative solution for such entities would be to restrict eligible 340B prescriber lists to those practitioners who spend 100% of their time at the covered entity. An alternative would be to find a way to implement a location match within a hospital's EMR/contract pharmacy software. Either solution will likely reduce the overall financial return of contract pharmacies, but this may be a reality that covered entities need to accept to stay out of HRSA's crosshairs during an audit. Remember, audit findings generally require a corrective action plan that includes more comprehensive audit work and mandatory manufacturer repayments that are time intensive and costly.

Billing standard

Under HRSA's proposed billing standard, only employed or contracted physicians would be eligible to write orders/prescriptions for 340B drugs, and only if the covered entity's contract with the practitioner permits the covered entity to bill on the practitioner's behalf. Under HRSA's proposal, active medical staff privileges would not be an insufficient nexus.

This proposal would have a number of significant consequences, some that have very few alternatives. For example, many states have corporate practice of medicine laws that prevent hospitals from employing or contracting directly with physicians. The proposed billing standard could effectively eliminate 340B programs in those states. For this reason alone, many expect changes to the billing standard in the final Mega-Guidance.

Also, the billing standard creates significant compliance challenges. Currently, covered entities generally manage a list of practitioners who are eligible to write 340B prescriptions, and this list is shared with software vendors and other third-parties that manage the covered entity's contract pharmacy network. The development and accurate maintenance of this list is a constant struggle, due to the frequent additions to and departures from the medical staff. The billing standard would add another level of complexity by requiring covered entities to individually assess whether the covered entity can bill on behalf of a physician. This analysis would involve reviewing each practitioner's arrangement with a covered entity (hopefully, in a written contract) and consideration of complex reassignment laws that dictate whether someone else can bill for a practitioner's services (assuming HRSA intends the billing standard to mean billing for professional services). The potential margin for error here appears to be great.

Finally, many covered entities aren't in the business of employing or contracting with physicians, and many of these covered entities are those who rely on the 340B Program to stay open (e.g., rural hospitals). Covered entity access to 340B savings would be significantly reduced by the billing standard.

Prescription standard

In its prescription standard, HRSA would require the patient to receive a drug that is ordered or prescribed by a practitioner who meets the billing standard above. Again, this would eliminate the ability to refer patients outside of the organization for follow-up care and fill resulting contract pharmacy prescriptions using 340B drugs.

HRSA's proposal also notes that under the prescription standard, an individual would not be a patient if the only relationship with the covered entity is the dispensing or infusion of a drug. This proposed change would have significant consequences on the nation's cancer care network.

HRSA's proposal also notes that under the prescription standard, an individual would not be a patient if the only relationship with the covered entity is the dispensing or infusion of a drug. This proposed change would have significant consequences on the nation's cancer care network. To adhere to the proposed prescription standard in the infusion space, and in order to qualify the resulting infusion drug for 340B, covered entities would need to: (1) ensure that every infusion patient has a provider-to-patient encounter prior to the patient receiving an infusion, (2) ensure that the provider-to-patient encounter is with a provider who meets the new billing standard previously discussed, and (3) ensure that the infusion order is written by a practitioner who meets the billing standard.

To operationalize this in the chemotherapy setting, covered entities may consider employing or contracting (e.g., through a professional services agreement) with medical oncologists and designing patient flow processes in a manner that results in each patient seeing a covered entity medical oncologist prior to beginning an infusion regimen. This may be costly and certain markets may not support employment of or professional services agreements with medical oncologists.

Classification standard

Under the proposed classification standard, HRSA would restrict 340B to those situations where a patient received *outpatient* care. HRSA proposes to eliminate eligibility of inpatient discharge prescriptions—prescriptions filled at retail pharmacies after a patient is discharged from an inpatient bed. Again, this would have a significant financial impact on covered entities, particularly their contract pharmacy networks. More important, this change would create a tremendous compliance burden that, in many cases, may not be overcome.

Currently, software vendors and third-parties that help administer covered entity contract pharmacy models may not have the capability to determine if the basis for filling a prescription with 340B drugs in the contract pharmacy setting was due to an inpatient stay. These vendors would need to quickly adapt and accept additional data feeds from covered entities. The data feeds would need to include inpatient indicators that would disqualify prescriptions from 340B or exclude inpatient utilization from data feeds altogether, so drugs are only qualified based on outpatient activity. Needless to say, covered entities, contract pharmacies, and third-party vendors are not pleased with this proposal, and many argue that it doesn't recognize that discharge prescriptions are truly outpatient prescriptions and are, therefore, in line with the intent of the 340B Program.

Key patient definition takeaways

Below are a few critical takeaways to consider when assessing the impact of HRSA's proposed patient definition on your organization:

1. Patients must be treated in qualified outpatient area of a covered entity before receiving a 340B drug.
2. Covered entities would need to build additional contract pharmacy filters to prevent 340B utilization for prescriptions written outside of the organization (i.e., no more referrals for consultation).
3. Covered entities would need to restrict 340B utilization to: (A) patients who had a provider-to-patient encounter with a practitioner who is either employed by or under contract with the covered entity such that the covered entity could bill on behalf of the practitioner; and (B) prescriptions written by the employed/contracted practitioners.
4. Covered entities would need to have all infusion patients examined/treated by an employed or contracted practitioner, and the infusion order must originate from the employed or contracted practitioner.

Manufacturer repayments and HRSA self-disclosures

One consistent issue that covered entities continue to struggle with is whether a certain instance of non-compliance must be reported to HRSA and/or manufacturers. In recent years, Apexus, HRSA's prime vendor, offered a material breach tool to help covered entities determine if an event must be reported to HRSA. However, Apexus did not define "material," but it offered covered entities various options on how to identify a material breach.[6] This has led to some uncertainty in the community, and many covered entities have asked for additional clarity from HRSA.

HRSA did not address a materiality standard in its Mega-Guidance. Instead, HRSA indicated that a covered entity must notify

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HRSA and each manufacturer of all instances of 340B drug diversion. This suggests that HRSA is considering eliminating the materiality discussion and requiring providers to report all instances of non-compliance.

In a different breath and in the context of group purchasing organization (GPO) prohibition violations and split-billing software commentary, HRSA recognized that covered entities and manufacturers routinely work together to identify and correct errors in purchasing through a credit and rebill process. HRSA encourages this as a tool to resolve matters of non-compliance and did not mention whether such events must be disclosed to HRSA.

Read together, the commentary seems to suggest the credit-and-rebill process does not require a self-disclosure, but when a credit and rebill is not possible and a repayment is required, the details of the event must be reported to HRSA, regardless of how material the event is. However, this won't be clarified until the final Mega-Guidance is issued.

Key manufacturer repayment and HRSA self-disclosure takeaways

HRSA's Mega-Guidance suggests that:

1. Covered entities should continue to work with their wholesalers on routine credit and rebill processes to resolve inaccurate purchases. Such events may not require a self-disclosure to HRSA.
2. When a credit and rebill is not possible, a manufacturer repayment must be initiated, and the repayment should be reported to HRSA. Until the final Mega-Guidance is released, covered entities may still choose to rely on their internally established material breach policies that outline when a matter must be reported to HRSA.
3. Manufacturers may forgive proposed repayments below a *de minimus* amount, provided the facts comply with the federal Anti-Kickback Statute.

Duplicate discounts and Medicaid managed care

Historically, HRSA deferred to covered entities on whether Medicaid managed care organization (MCO) patients could receive 340B-priced drugs. As a result, covered entities typically treat MCO patients similar to other privately insured patients—covered entities provide 340B drugs to those who meet HRSA's patient definition and bill the MCO at its usual and customary rate. In duplicate discount terms, covered entities carve-in these patients, because they are providing the patients with 340B drugs.

In the Mega-Guidance, HRSA proposes: (1) that covered entities make site-by-site carve-in or carve-out determinations for each MCO and update HRSA's Medicaid exclusion file to identify the MCOs that covered entities carve-in; and (2) a mandatory carve-out for MCO patients in the contract pharmacy setting unless an exception is met.

The main compliance considerations under the first MCO proposal are the ability to identify all applicable MCOs that a covered entity works with, and the need to report all MCOs in the Medicaid Exclusion File. Identifying MCOs is a challenge, so effectively carving in MCOs will be difficult for covered entities.

The second MCO proposal raises additional challenges. Currently, it's common for covered entities to carve-in MCO patients in the contract pharmacy setting pursuant to contract language between the covered entity and its pharmacies. If HRSA finalizes its proposals, covered entities would need to review and modify their existing contract pharmacy agreements to accommodate the mandatory carve-out (i.e., no longer provide 340B drugs to MCO patients) *unless* the parties have a written agreement with the State Medicaid agency/MCO that outlines how the parties will prevent duplicate discounts with an alternative carve-in. Assuming most covered

entities would comply with the mandatory carve-out, this proposal would reduce the scope of covered entity contract pharmacy programs. Again, this will also present challenges with identifying and properly excluding Medicaid MCO patients from covered entity 340B programs.

The complexities of the above issues are further exacerbated by CMS' Medicaid Covered Outpatient Drug Final Rule (AMP Rule) published on February 1, 2016.[7] Pursuant to the Affordable Care Act, CMS continues to push states and MCOs to take steps necessary to collect rebates on drugs provided to MCO patients, except in instances where covered entities and contract pharmacies provide 340B drugs to MCO patients. Further, CMS implemented a Medicaid fee-for-service (FFS) actual acquisition cost (AAC) plus professional dispensing fee reimbursement policy in the AMP Rule that applies to covered entities and their contract pharmacies, excluding specialty and physician-administered drugs. States are required to submit State Plan Amendments (SPA) to describe how they will reimburse covered entities for drugs going forward, including how they will comply with the new AAC requirement.

Covered entities will have to monitor the interaction between the AMP Rule and the Mega-Guidance as the rules conflict in a few instances. For example, on one hand, CMS is requiring states to reimburse covered entities and their contract pharmacies at AAC which, on its face, seems to promote carving in FFS patients so the state gets the best bang for their buck. On the other hand, HRSA's proposed Mega-Guidance suggests a presumption that covered entities carve-out Medicaid FFS patients from their contract pharmacy programs. In light of the above, covered entities need to work with their respective Medicaid agencies to develop cohesive Medicaid 340B reimbursement models to submit to CMS.

Key duplicate discount/MCO takeaways

Covered entities, contact pharmacies, and other 340B vendors should:

1. Prepare to identify and register all MCOs in the exclusion file if the Mega-Guidance is finalized and the covered entity continues to provide 340B drugs to MCO patients (applies only to patients within the four walls of the hospital or registered child sites).
2. Review existing contract pharmacy agreements and practices to assess the implications of a mandatory MCO carve-out in the contract pharmacy setting.
3. Consider approaching MCOs regarding alternative arrangements that would permit a covered entity to carve-in MCO patients in the contract pharmacy setting.

Conclusion

Back to the question of "What's next for 340B?" From a high level, it appears that the program will likely remain intact, because it has the general support of many key members of Congress. Reform will be the focus for the foreseeable future. It is important that covered entities voice their concerns and requests for consideration, but more importantly, covered entities need to continue to synthesize the various proposals to logically refine their programs in a manner that ensures compliance. Prior audit results, the Mega-Guidance, and reports by the OIG and GAO are indicative of target areas that covered entities should prioritize and address.

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

Healthcare quality: What does it mean?

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As I was thinking about what topic to write about this month, I pondered the term "Quality." I've heard it used in several contexts recently that led me to ask: What is healthcare quality? I googled "healthcare quality" and not surprisingly, the Agency for Healthcare Research and Quality (AHRQ), and the National Quality Forum (NQF) were at the top of the search results. As the federal agency responsible for improving the quality of the country's healthcare system, the AHRQ provides resources for healthcare professionals as well as patients. The NQF, a national organization whose mission is to "improve health and healthcare quality through measurement,"[1] plays a key role in measurement standard setting. Both organizations utilize the Institute of Medicine's (IOM) widely accepted definition of what quality healthcare should look like. This definition is in the form of six characteristics of quality care and their corresponding metrics: safe, effective, patient-centered, timely, efficient, and equitable.[2]

Abbondandolo

So how does this equate to how patients and staff in healthcare organizations define or understand quality? To a patient, it could be their perception of the care or experience they had while receiving services in a facility, that their needs were met, or the outcome of treatment was positive. To healthcare professionals, it could be the understanding they have of their participation in a particular quality initiative, the results of their organization's participation and reporting of quality measures as part of governmentally mandated programs, clinical outcomes, or simply the daily operations of their Quality department. Is any one or all of these correct? Yes and yes.

So I will leave you with a thought: In conjunction with your Quality department, conduct a one-question, open-ended survey to staff at different levels within your organization: "What is healthcare quality?"

> …conduct a one-question, open-ended survey to staff… "What is healthcare quality?"

I'm sure you will probably receive various responses based upon the role, perception, or even knowledge each individual has within the organization or their view of the organization. This is a great exercise to help build or foster the relationship with your Quality staff and identify some great educational opportunities. Both departments can join forces to educate staff on the role of their respective departments, various quality initiatives the organization participates in and reports on, and how individuals and departments within the organization play a part in the process. I would definitely enjoy hearing the results from those of you who complete the survey and any ideas that are developed from the analysis of the results.

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by Paul P. Jesep, JD, MPS, MA

Is the compliance officer practicing law without a license?

» Make clear distinctions between Legal and Compliance functions in policies and procedures.
» Know when being a compliance officer ends and becoming an attorney begins.
» If the organization is too small to have an attorney on staff, consider putting one on retainer.
» Within the department budget, permit the compliance officer to selectively use outside counsel.
» Engage the board to decide whether Legal and Compliance could be combined in limited cases, using an attorney on staff to serve in both roles, with safeguards to maintain the distinction.

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U.S. Senator Charles Grassley lamented during an investigation into a healthcare company regarding the combined roles of general counsel and chief compliance officer, "It doesn't take a pig farmer from Iowa to smell the stench of conflict in that arrangement."[1]

Jesep

Hence, it's with good reason organizations should exercise caution in how Legal and Compliance are handled. Never allow internal organizational politics or legal gamesmanship to compromise honest, objective decision-making.

Lawyers and compliance officers have distinct roles. Attorneys are zealous advocates and protectors, while compliance officers identify and prevent bad outcomes and are motivated, in part, by fairness and transparency. Yet, some organizations increasingly find the lines between law and compliance blurred, though complementary in many cases. If this inevitable conflict isn't apparent, it should be a red flag for the organization to do a careful analysis.

Practicing law without a license

No day passes in an organization where law and regulation isn't a factor. There's a growing, subtle pressure for compliance officers not only to ensure the law is followed, but also to conduct some level of legal research and analysis. It can spill over into contract reviews, revising bylaws, board education on the state's non-profit law, or writing memos of understanding with social service agencies, among other things.

Compliance officers should be on the board's Compliance Committee for obvious reasons, but serving on the Governance Committee may be a different matter. Whether bylaws are revised; how non-profit law is interpreted; or the language used in the meeting minutes to reflect discussions, formal motions, and actions taken, historically falls to the attorney serving on the board or the general counsel on staff who often is the de facto secretary.

Issues can arise over something as innocuous as using another non-profit's form when establishing a relationship if referring a patient for care, without realizing the document is intended to protect the other entity, not yours. Should the form or agreement have been vetted by a lawyer?

If a translation service is used for non-English speaking patient-consumers, were

sufficient HIPAA safeguards crafted into the contract? In doing so, does it constituent practicing law? It depends on the state.[2,3]

Most states have an "unauthorized practice of law" statute. Generally, practicing law without a license means providing legal advice, misrepresenting oneself as an attorney, sometimes drafting documents for someone else, and acting on behalf of an entity or person in court or judicial proceedings. In some cases, compliance officers, particularly those without the benefit of counsel on staff or retainer, probably have wandered into the area of practicing law and not realized it.[4]

Increasingly, state bar associations are aggressively alleging and attempting to stop individuals and companies from even selling legal templates, arguing unauthorized practice of law.[5] Not surprisingly, there is push back with counter-charges of monopoly to the detriment of the consumer (or, potentially, a small organization), where a competent professional without a law license can read the law or regulation just as well. To be clear, legal and compliance roles are distinct for a reason. In addition, compliance officers have repeatedly demonstrated their value, necessity, and unique training independent of lawyers.[6]

Designing creative, informative educational campaigns to keep people engaged with and informed about compliance, as one of many examples, is not a legal function. Reviewing or drawing up an employment contract for physicians should not be done by a non-lawyer, though there is likely to be necessary input from the compliance officer and Human Resources department.

Lawyers in a compliance role

In 2014, Mitratech Holdings released a white paper, "At the Intersection of Legal and Compliance," documenting five key trends and showing how the two disciplines, for good or ill, are intersecting.[7] Respondents included the non-profit, healthcare, insurance, and manufacturing sectors. According to the Mitratech findings, the "legal department owns the enterprise compliance function in 40% of respondents' organizations and owns a portion of compliance functions in another 24%."[8]

The survey also found law and compliance were becoming "more tightly intertwined" and Legal departments were "consistently staffing up to meet" compliance requirements. The findings further noted a "wide variability" existed in the nature of legal and compliance relationships.[9]

Be mindful that lawyers offer a client or their organization the benefit of attorney-client privilege. In serving in a mixed capacity, however, it is necessary to carefully decide what should be privileged communication. Knowingly attempting to place everything in this category is unethical and potentially illegal. This also requires some staff training regarding the hybrid role.

Combined Legal and Compliance functions

Understandably, the government encourages a distinction between legal and compliance matters. Realistically, resources will drive how that's done, and certain allowances by the government, within reason, may be made for a documented justification for overlap. The larger the organization with sufficient financial resources, the harder it is to make the case.

In April 2015, the Office of Inspector General for the U.S. Department of Health and Human Services issued "Practical Guidance for Health Care Governing Boards on Compliance Oversight," which underscored the distinctions between the legal and compliance functions.[10] The Guidance also recognized that compliance is an organic process and "one size doesn't fit all," especially when resources are at a premium.

A combined role or having the benefit of each discipline at an early stage can contribute significantly to prudent decision-making. Compliance must never be subordinate to a legal strategy. Outside counsel may still need to be brought in (should there be a hybrid role) for certain issues in the interest of objectivity, transparency, and making sure legal strategy never undermines the ethical culture an organization must nurture.

If in the off-chance you retain someone with the sole focus of compliance who is a licensed attorney, be respectful. He/she is still held to a different, often higher standard, once the person touches a document with legal implications.

Your organization must have the benefit of counsel. Should he/she be on staff or retainer? Which better leverages resources? If legal and compliance is a dual role, compensation scales for an attorney and compliance officer differ. Should the compliance officer be full time with a separate part-time general counsel? Or perhaps one person can be in both positions, allocating half time to each.

Perhaps the hybrid role merits compensation at a combined higher rate because of counsel's expertise. In addition, attempting to compartmentalize the positions for purposes of compensation becomes difficult, especially for a salaried employee.

As noted—don't take a cookie cutter approach. Good strategic planning requires thinking not beyond the proverbial box, but acting as if one never existed.

Some lawyers still believe in the art of "counseling." At one time a lawyer put out a sign that read "Attorney and Counselor at Law." Counseling is focusing on the big picture, short- and long-term consequences, and being mindful of the dangers of "legalism." Hence, a good lawyer is an advisor, not just an attorney, who identifies issues otherwise overlooked that do not have anything to do with the law. Although it's an ancient part of the legal profession too often forgotten in the modern era, the art of "counselling" can be invaluable in an overlapping legal-compliance role.

Conclusion

Organizations, regardless of size, must have periodic discussions about the prudent stewardship of resources. Compliance officers, if not able to serve in a dual capacity because of concerns about conflicts or the absence of legal training, must have access to staff or outside counsel on retainer.

If resources dictate a hybrid role, be sure there are clear boundaries with assessments done to show that law and compliance have not become interchangeable. Always be mindful why the Dodd-Frank and Sarbanes-Oxley reforms came into existence. In general, Dodd-Frank focuses on financial risk; Sarbanes-Oxley addresses fraud, using greater transparency and tighter auditing controls. Both laws have had a rippling, profound impact in other areas and influenced governance and best practices in many industries.[11,12]

Finally, the legal and compliance role is ripe for robust, ongoing discussion at national and statewide ethics and compliance conferences.

1. US Senator Chuck Grassley: "Grassley Investigates Tenet Healthcare's Use of Federal Tax Dollars," September 7, 2003. Available at http://1.usa.gov/1LBKi9i
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11. *See* Melissa Makeske: "8 ways SOX changed Corporate governance" *Inside Counsel*, January 1, 2012. Available at http://bit.ly/1SlqkRI
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by Erika M. Bol, CHC, CHPC, CIPP/US, CISM

Top Ten for the New Year

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There is no doubt—the Office for Civil Rights (OCR) is using enforcement actions to teach those of us subject to its regulations what we should and should *not* be doing regarding HIPAA compliance. In 2015, six covered entities entered into resolution agreements with OCR for various alleged violations of the Privacy and Security rules. A quick glance at the titles of these agreements on the OCR website makes this clear: "Settlement Underscores Need for Organization Wide Risk Analysis," "Settlement Reinforces Lessons for Users of Medical Devices," or "Settlement Highlights Importance of Safeguards When Using Internet Applications." Whatever safeguards, controls, or practices you've established to get your organization into tip top HIPAA shape, make sure you don't leave out the valuable learning lessons from these very large and public examples. Following are my *Top Ten Learning Lessons from 2015 OCR Enforcement Actions*:

Bol

- Ensure your IT security team addresses basic risks, such as firewalls and ensuring that software updates and patches are administered promptly.
- Protected health information (PHI) on paper counts—protect it as you would any other PHI.
- If you allow employees to remove hardware and/or electronic media containing PHI from your facility (think laptops), ensure your employees know what they can and cannot do when taking PHI offsite.
- If you have workstations that are used by multiple users, ensure you are able to track user identity by having a unique user name for those logging on.
- Physician practices—even small ones—are *not* immune from OCR enforcement actions.
- If you're going to backup information from encrypted devices, such as laptops, on to other devices, make sure the backup media is *also* encrypted.
- Don't use sample policies and procedures as if they were your own. Ensure your policies are specific to your organization, your processes, your systems, etc.
- Don't throw PHI in unsecured, public dumpsters.
- If you discover that something is wrong with your privacy or security program, develop and implement a plan to fix it.

> Words of wisdom… which we would all be wise to keep in mind for the future.

- And lastly, recognize that risk assessments aren't a one-and-done safeguard. You must ensure they are "…comprehensive in scope and conducted *across the organization* to sufficiently address the risks and vulnerabilities to patient data."[1]

Words of wisdom from Jocelyn Samuels, OCR Director, which we would all be wise to keep in mind for the future.

1. Health and Human Services, press release: $750,000 HIPAA settlement underscores the need for organization–wide risk analysis" December 14, 2015. Available at http://1.usa.gov/1njCsFE

by Steven A. Greenspan, JD, LLM and Ralph Wuebker, MD, MBA

CDI programs: Promoting quality and physician engagement for success

» Hospitals are concerned about quality and capacity issues of clinical documentation improvement (CDI) programs as we move toward a reimbursement model based on quality and outcomes, and not volume.

» Beyond reimbursement, accurate and complete CDI can provide benefits in the areas of quality of care, increased patient safety, and increased accuracy and specificity.

» Despite a strong commitment to CDI programs, many hospitals are still encountering documentation issues (often due to low physician adoption of and engagement in these programs) and poor presentation documentation.

» Using a physician advisor or physician champion to facilitate communication between physicians and attending or treating physicians helps support physician engagement and query resolution.

» Proper physician documentation is the cornerstone of medical necessity that helps validate the level of patient care provided, helps ensure appropriate reimbursement, and lends to the defense against audits.

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Audit scrutiny in the government space continues to be on the rise. Medicare Administrative Contractor (MAC) denials from the Probe & Educate period clearly proved that reviewers will still focus on medical necessity, regardless of the actual or expected length of stay. Meanwhile, other program integrity efforts are in somewhat of a holding pattern, but will shortly be back at full force. New Recovery Auditor (RA) contracts, originally expected to be awarded and finalized in 2015, will now take place in 2016. In addition, the end of the enforcement delay is here, meaning that RA activity will be ramping up under the current contracts. Many hospitals are ill equipped to manage the return of the audit levels previously seen and will require research, data, technology, and physician expertise to combat the issue.

Greenspan

Wuebker

The Centers for Medicare & Medicaid Services (CMS) has made it clear that the expectation of a stay of a certain length, or even an actual stay of a certain length, is not enough. An inpatient order, a strong rationale, and well-documented medical necessity for the expected stay (or actual stay) are critical to support the claim.

Tighter budgets and declining reimbursement levels continue to plague hospitals, but one of the biggest

concerns that goes well beyond financial is the quality and capacity issues of Clinical Documentation Improvement (CDI) programs. Physician engagement, which we will be addressed later in this article, is essential to the success of the program, but has been slow in acceptance.

To assist hospitals in their CDI programs, the American Health Information Management Association (AHIMA) has created guidance by defining purposes, goals, and roles, as well as policies and procedures to further outline the benefits of thorough documentation. Although the content contained within these guidelines is offered more as professional advice, the message is clear:

> The focus of most CDI programs is on improving the quality of clinical documentation regardless of its impact on revenue. Arguably, the most vital role of a CDI program is facilitating an accurate representation of healthcare services through complete and accurate reporting of diagnoses and procedures. …Improving the accuracy of clinical documentation can reduce compliance risks, minimize a healthcare facility's vulnerability during external audits, and provide insight into legal quality of care issues.[1]

Barriers and benefits to physician documentation

One of the greatest barriers to CDI lies with the physicians themselves. In a recent survey of more than 1,000 CDI, coding, health information management (HIM), and other hospital professionals in CDI programs throughout the United States, 98.5% of the survey respondents noted that their physicians could improve their documentation practices, and that 66.5% of these physicians had a lack of understanding of the importance of strong documentation.[2]

Although few would argue that accurate and complete physician documentation is essential, there are definitely a number of prominent benefits beyond reimbursement:

- **Quality of care** – A 2008 *Archives of Internal Medicine* article indicated that "medical records for patients with NSTEMI (a type of myocardial infarction) often lack key elements of the history and physical examination." As noted in the article, "Patients treated at hospitals with better medical records quality have significantly lower mortality… (and) the relationship between better medical charting and better medical care could lead to new ways to monitor and improve the quality of medical care."[3]
- **Increased patient safety** – Some research points towards a correlation between documentation and hospital mortality rates. According to a study published in the September 2013 issue of the *Journal of Patient Safety*, between 210,000 and 440,000 patients each year, who go to the hospital for care, suffer some type of preventable harm that contributes to their death.[4]
- **Increased accuracy and specificity** – With increased proficiency in accuracy and specificity from better documentation, in addition to timeliness of the information recorded, comes a better description of services provided to the patient. This outcome can also lead to an increase in quality scores a physician or hospital receives—the higher the quality scores, the greater the reflection of patient acuity.

Unfortunately though, as strong as the benefits of proper documentation can be, there are no shortages of documentation challenges in this arena, and each one can contribute to the next:

- Gaps created with patient hand-offs between departments and/or medical staff

- "Siloed" perspective of clinicians
- Physicians don't "think in ink"
- Diagnosis and plan of care not properly documented
- Key information omitted in physician summary
- Unresolved or lack of physician queries
- Inaccurate DRG or lack of detail in coding
- Weakened defensibility
- Case mix index (CMI) and quality impacts

Although improvements to the physician documentation process have evolved over the years, the road traveled has been a rocky one, to say the least—with some even claiming that documentation has deteriorated the more it progresses.

The advent of the electronic medical record (EMR) has raised the question: Have we truly progressed, or has the technology only served to take shortcuts in the documentation efforts? The push for hospitals to fully adopt EMRs is well on its way, but the problems can start, essentially from the planning stage, because EMRs are typically designed by non-clinicians (i.e., programmers who are not as familiar with how hospitals and clinicians actually function). In addition, the EMR was initially designed to help with billing and it is a well-known fact that the EMR has not contributed to improved quality of care. Lastly, the end-user (the physician) was generally not consulted and/or trained in the use of the EMR.

As reported in a *New York Times* article, "cutting and pasting" (C&P), commonly referred to as "copy forward," may allow for "information to be quickly copied from one portion of a document to another, as well as reduce the time that a doctor spends inputting recurring patient data," but it also leaves the window open to potential fraud. In an effort to cut down on C&P abuse by physicians who are performing less work than they actually bill, the Department of Health and Human Services, Office of the Inspector General (OIG) named the issue of cloning in the medical record as a priority in 2015.[5]

To further muddy the concerns on documentation, the EMR is limited in providing the opportunity for physicians to include their own thoughts and comments. So much within the record is a template or a checkbox, for example, that physicians do not have the luxury of documenting their impressions, assessments, and courses of action for the patient.

On top of all of this, most (if not all) EMR systems require the physician to spend more time documenting. So, in an age of physicians being even more pressed for time, and patient signs and symptoms more complex than ever before, we are asking physicians to spend more time on a perceived non-clinical activity. This does not promote buy-in from the physicians.

It starts with the physician

Complete and specific clinical documentation ensures an accurate representation of patient severity and care, supporting revenue integrity and correct capture of a hospital's case mix index (CMI). However, despite a strong commitment to CDI programs, many hospitals are still encountering documentation issues, often due to low physician adoption of and engagement in these programs.

As noted earlier, a recent CDI program survey reported that a lack of understanding among physicians on the importance of strong documentation ranked highest (66.5%) as the greatest barrier prohibiting physicians from being effectively engaged in Clinical Documentation Improvement, with lack of time (47.5%) and lack of interest (38%) taking the second and third spots, respectively.[6]

In many hospitals, executive support to engage physicians in these activities is lacking. Many hospitals do not require physician CDI participation, with only 17% of them having policies in place to mandate physician

compliance.[7] This lack of participation contributes to high rates of unanswered queries, as well as untimely and delayed physician responses. The transition to ICD-10 will only exacerbate these issues, because physicians will be required to document with greater detail and specificity. So what resources can be further provided to improve physician engagement and documentation practices?

Communication between a physician (in the form of a physician advisor or physician champion) and the attending or treating physicians is proving to be one of the most effective tools to help support physician engagement and query resolution. A successful CDI program must target complex cases and associated queries that may otherwise be challenging and time-consuming for a CDI specialist to address with the appropriate treating physician. Physicians (Utilization Management physician and attending) must interact concurrently to expedite responses in a timely fashion—while the patient is still in the hospital.

AHIMA noted that, "In general, the Physician Advisor acts as a liaison between the CDI professional, HIM and hospitals' medical staff to facilitate accurate coding, DRG assignment and representation of severity, acuity and risk of mortality."[8]

In order to achieve the optimal outcome through CDI, the following four-step approach should be followed:

- **Review** – Determine if greater specificity is needed in the documentation.
- **Substantiate** – Clarify if a query is valid or needed.
- **Engage** – Interact directly with the treating physician to gain clarification in the documentation and provide case-specific education and feedback.
- **Document** – Provide a written summary of the physician conversation to the CDI specialist who can then validate that the physician has updated the medical record.

An interactive approach to CDI can help reinforce accurate and detailed documentation methods that are difficult to achieve retrospectively, or without the medical expertise and perspective of another physician. The ultimate goal of these interactions is to engage treating physicians in improving the specificity and clarity of their documentation.

Following best practices

Proper physician documentation provides the cornerstone of medical necessity that not only can help validate the level of patient care provided, but also helps to ensure appropriate reimbursement to the hospital for services provided, and lends to the defense against audits.

In summary, a healthy CDI program produces significant benefits, including:

- **Accurate coding and quality measures** – A robust CDI program can produce a dynamic regulatory and coding environment that requires physician-to-physician documentation education. This, in turn, can help reduce physician queries that remain unanswered or improve the quality of responses, as well as support the capture of correct documentation, accurate CMI, and quality measures (i.e., severity of illness and/or risk of mortality).
- **Improved physician engagement** – Increased physician support will help drive engagement and adoption. Real-time reinforcement supports accurate and thorough documentation practices, and conversations occurring concurrently serve as another layer of physician education to improve documentation skills.
- **Increased query responsiveness** – Concerns should be addressed while the patient is still receiving care. Reviewing the patient file concurrently with a peer physician can assist in identifying vague and/or conflicting documentation, as well as potential gaps in documentation.

Providing a summary to the CDI team of the physician-to-physician documentation conversation helps the hospital coding specialist ensure the medical record documentation is complete prior to coding.

- **Increased audit defensibility** – The physicians working within the CDI program must leverage an extensive knowledge of the Medicare regulations from CMS to drive specific and accurate CMI capture–even in complex cases–and documentation improvement, thereby helping withstand the scrutiny of audit programs.

Conclusion

Although hospitals' focus has long been set on providing the highest quality of patient care, many physicians feel that regulatory and reimbursement constraints interfere with their ability to properly practice medicine. Now this singular focus is challenged by the need to maintain fiscal discipline and remain compliant in shifting regulatory environments.

Many hospitals are evaluating additional physician resources to serve in operational capacities: driving case/utilization management, helping treating physicians stay focused on patient care, and, of course, supporting CDI efforts. But the most complex piece of this puzzle will be in how providers can introduce these resources, while maintaining optimum operations, physician engagement, and alignment with the quality and financial goals at hand.

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5. Reed Abelson and Julie Creswell: "Report Finds More Flaws in Digitizing Patient Files" *The New York Times;* January 8, 2014. Available at http://nyti.ms/21KfDKI
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8. Ibid., Ref #1

by Frank Ruelas

Finding files easily

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"Now what was the name of that file?" Does this question sound familiar? It wasn't long ago that my ability to find files was related to my recollection of their filenames. In turn, I started using filenames that were getting longer and longer, until I realized there was a better approach that was much easier and gave me much more flexibility in finding files.

Ruelas

Although there is nothing wrong with using long filenames, I think you may find the usefulness of this month's computer tip a welcome option. Keep in mind that this tip applies to files created in Microsoft Word, Excel, and PowerPoint.

Comment field and search terms

A file created in Word, PowerPoint, or Excel includes fields where a user can enter text, which can then be used as search terms to help find the file. One of these fields is the "Comments" field, which can be accessed by going to the file properties option in Word, Excel, or PowerPoint. The Comments field is a free text field that can hold more than 65,000 characters. There are other fields that can be used, such as the Tag field, but I prefer the Comments field because of its capacity to hold more text.

Searching

Let's say you have a file of important contacts, but you don't want to include the words "important contacts" in the filename. Simply enter the text "important contacts" in the Comments field for that file, and then name the file whatever you like. When you want to find this file later, click on the Start button in the lower left hand corner of your desktop and enter "important contacts" in the search box. You should see your file appear in the search box results on your computer.

Practice and ingenuity

Using the Comments field may take a little practice at first. However, using the Comments field with search terms adds a great deal of flexibility that will help you organize and, more importantly, find files long after you saved them. It is a welcomed alternative to resorting to the use of long and cumbersome filenames. Give it a try, and don't be surprised if you start using interesting search term phrases like "Top secret" or "For my eyes only."

by Linda A. Baumann, Esq., Samuel C. Cohen, Esq., and Hillary M. Stemple, Esq.

Providers take note: What the new Stark regulations mean to you

» All providers need to be aware of new changes to the Stark regulations, which largely went into effect January 1, 2016.

» A number of the changes in the regulations and guidance in the preamble should help facilitate compliance with the strict liability law, and some may impact prior arrangements.

» The requirements for a "signed, written agreement" in numerous Stark Law exceptions should be easier to satisfy because a single formal contract is not required and signatures can be obtained within 90 days.

» Leases and personal service arrangements can be held over indefinitely under certain circumstances but, among other requirements, the arrangements must be fair market value when they expire and throughout the holdover period.

» Other key changes include new exceptions to the Stark Law for certain timeshare arrangements and for the recruitment of non-physician practitioners, as well as changes related to physician-owned hospitals.

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In an important development, the Centers for Medicare & Medicaid Services (CMS) issued additional final regulations implementing the Stark Law as part of the Physician Fee Schedule for calendar year 2016.[1] The final rule adopts the majority of the changes proposed in July 2015 by CMS.[2] Note, however, that some of the key provisions appear in revised regulatory text, but others are only contained in the regulatory preamble to the final rule. Many of the changes, including the creation of a new timeshare arrangement exception, are intended to make it easier for providers to comply with the Stark Law's complex requirements. Various "clarifications" described in the preamble also should generally make it easier to comply, particularly with those Stark exceptions that require a signed, written arrangement with a minimum term of one year. The final rule also includes a new exception for the employment of non-physician practitioners and finalizes certain changes related to physician-owned hospitals.

The vast majority of provisions in the final rule were effective January 1, 2016. However, in light of the fact that certain arrangements involving physician-owned hospitals may need to be unwound due to the change to the definition of "bona fide investment level," the applicable provision in the final rule will not be effective until January 1, 2017. Moreover, some of the "clarifications" in the preamble reportedly reflect how CMS has always interpreted certain regulatory provisions. As a result, some of these clarifications may have retroactive impact.

Because the Stark Law is a strict liability statute, and because there have been a substantial number of multi-million dollar settlements in False Claims Act cases related to the Stark Law recently, providers should carefully determine whether the revised regulations impact their

Baumann

Cohen

Stemple

current arrangements and take any action necessary to ensure compliance now and in the future. Some of the most significant provisions in the final rule are briefly summarized below.

Overview of key regulatory revisions and clarifications

According to CMS, many of the regulatory revisions were designed to make it easier for providers to comply with certain exceptions to the Stark Law (and reduce the number of unnecessary self-disclosures being submitted to the CMS Self-Referral Disclosure Protocol). The vast majority of the following revisions were adopted without modification from the proposed rule.

No single formal contract

Clarification that the "writing" or "written agreement" required by numerous Stark Law exceptions does not have to be a single formal contract; it can be a collection of documents as long as "the available, contemporaneous documents… would permit a reasonable person to verify compliance with the applicable exception." Moreover, the documents "must clearly relate to one another and evidence one and the same arrangement between the parties." Because this guidance is being characterized as a "clarification" of the existing requirements, CMS notes that parties may rely on this guidance in determining whether there is any need to use the Self-Referral Disclosure Protocol for conduct that pre-dates the final rule's effective date.

Term of lease

Clarification that a lease of space or equipment or a personal services arrangement does not need to include a specific written "term" provision as long as the arrangement lasts for at least one year.

Signature requirement

Allowing 90 consecutive calendar days from the date an arrangement became non-compliant from failure to satisfy the signature requirement (regardless of whether compensation is paid or referrals occur during this period) to obtain the missing signatures, regardless of whether the failure to obtain the signature was deliberate or inadvertent. However, the limitation remains that this signature exception can be used only once every three years per physician, and CMS points out that the impact of this limitation can vary, depending on whether the contracting party is a physician or a physician organization.

Renewable arrangements

Permitting arrangements of any length covered by the fair market value exception, not just those lasting less than one year, to be renewed any number of times under certain circumstances.

Holdovers

Another provision that was modified from the proposed regulations in the final rule is designed to facilitate compliance with the Stark Law, related to holdovers. Specifically, space and equipment leases and personal services arrangements can now be held over indefinitely (not just for six months), as long as the terms and conditions do not vary, the holdover arrangement is in compliance with the applicable exception at the time it expires, and the arrangement remains in compliance during the holdover period. Although CMS cautions that ongoing compliance with the fair market value (FMV) requirement is necessary during the holdover period (and that long-term arrangements may be at risk of falling out of compliance with the fair market value requirement even before the original agreement expires), it did not offer guidance on how often compensation should be checked to ensure that it is still fair market value.

Interestingly, CMS also warned providers that failure to pay any holdover premium

required under the original lease could prevent use of the holdover exception and could create a separate financial relationship between the parties that would have to meet an applicable exception. Further, CMS stated that parties that are in a valid six-month holdover on January 1, 2016 (the final rule's generally applicable effective date), may continue the holdover indefinitely, but if the holdover has lasted for more than six months as of January 1, 2016, then the indefinite holdover provision cannot be used for the arrangement.

Timeshare arrangements exception

The final rule also contains a new exception for timeshare arrangements, with certain modifications from the proposed rule. This is a narrow exception that would permit certain timeshare arrangements for the use of space, equipment, personnel, items, supplies, or services between a physician or physician organization in which the physician is an owner, on the one hand, and a hospital or physician organization in which the physician is not an owner, employee, or contractor, on the other.

Among numerous other requirements, the compensation over the term of the arrangement must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. Compensation also cannot be determined using a formula related to a percentage of the revenue raised or otherwise attributable to the services provided while using any of the items and/or services, etc. covered by the arrangement. Using a compensation formula based on per-unit of service fees that are not time-based also is not permissible under specified circumstances.

The exception further requires that the premises, equipment, personnel, items, supplies, and services covered by the arrangement be used predominantly to furnish evaluation and management (E&M) services to patients and on the same schedule. It also requires that the equipment covered by the arrangement is located in the same building where the E&M services are provided. CMS noted that this exception was not intended to affect existing arrangements, but rather establishes an additional exception that may be used by parties to a timeshare arrangement under certain circumstances.

Recruitment and retention

New exception for arrangements with NPPs

CMS also finalized, with some modification, a detailed new exception permitting hospitals, federally qualified health centers (FQHCs), and rural health clinics (RHCs) to provide financial assistance to physicians in order for the physicians to directly employ or otherwise contract with non-physician practitioners (NPPs). Notably, although the proposed rule limited the exception's availability to the employment of NPPs for the purpose of providing primary care (i.e., general family practice, internal medicine, pediatrics, geriatrics, and OB-GYN services), CMS responded to comments on the proposed rule by expanding the scope of permissible employment to include the provision of mental health services. As a result, under the final rule, an NPP is defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified

The final rule also contains a new exception for timeshare arrangements, with certain modifications from the proposed rule.

nurse midwives, clinical social workers, and clinical psychologists. Among numerous other requirements, the compensation paid by the hospital may not exceed 50% of the actual compensation, benefits, and signing bonus ("total compensation") paid by the physician to the NPP, and the total compensation must not exceed fair market value for patient care services furnished to patients in the physician's practice.

The exception can be used only for the first two consecutive years of the arrangement between the NPP and the physician/physician organization and can be used only once every three years with respect to the same referring physicians (with certain exceptions). Numerous other requirements also must be satisfied, including certain criteria designed to prevent "cycling" NPPs through a physician practice.

The exception can be used only for the first two consecutive years of the arrangement between the NPP and the physician/physician organization…

Modification to existing exception related to FQHCs and RHCs

The regulations also finalized a new definition of the geographic area that FQHCs and RHCs may serve for the purposes of the existing recruitment and retention exceptions. This geographic area is defined as the lowest number of contiguous or non-contiguous zip codes from which the FQHC or RHC draws at least 90% of its patients, as determined on an encounter basis. The geographic area also can include zip codes from which the FQHC or RHC draws no patients, as long as these zip codes are entirely surrounded by the zip codes from which the 90% of patients are drawn. CMS also finalized its proposed technical revisions to the retention exception.

Physician-owned hospital requirements

Public website and public advertising

In addition, CMS finalized, without modification, revisions to the physician-owned hospital standards regarding public website and public advertising disclosure requirements. Under the new rules, public advertising for a hospital includes only communications paid for by the hospital that are "primarily intended to persuade individuals to seek care at the hospital," thus excluding communications such as those primarily intended for recruitment, public services announcements, or community outreach. In addition, the advertising disclosure requirement now can be met by "any language that would put a reasonable person on notice that the hospital may be physician-owned."

Bona fide investment level calculation

The proposal to change the methodology for calculating the baseline bona fide investment level and the (subsequent) bona fide investment level for physician owners/investors in physician-owned hospitals was finalized to include direct and indirect ownership interests held by a physician, even if the physician does not refer patients to the hospital (e.g., physicians who may have retired or moved away). The effective date for the new methodology has been postponed until January 1, 2017, to give hospitals that meet the current bona fide investment level requirements (which do not require counting ownership interests held by non-referring physicians), but will not meet the new requirements, an opportunity to come into compliance.

Per-click compensation

Providers also will be interested to note that CMS used the preamble to briefly address the D.C. Circuit's recent decision in *Council for Urological Interests v. Burwell*.[3] The D.C. Circuit has instructed the Department of Health and Human Services to reconsider whether a ban on per-click compensation arrangements is consistent with the relevant legislative history. According to CMS, the court did not hold that the Stark Law's legislative history "requires [CMS] to allow per-click arrangements," but rather "upheld [CMS's] authority to prohibit per-click arrangements where [CMS] determines that such a prohibition is necessary to protect against program or patient abuse." CMS further noted that the decision to prohibit per-unit of service compensation in the new timeshare arrangement exception is not affected by the court's decision. Finally, CMS indicated it is considering options as to how to comply with the court's ruling, so further guidance and potential changes may be forthcoming.

Additional significant provisions

The final rule also confirmed the following provisions and guidance from the proposed rule on various topics.

Stand in the shoes

The unique Stark Law definition of "stand in the shoes" has been revised to clarify that only a physician standing in the shoes of a physician organization, usually an owner, is considered a party to the arrangement for purposes of the signature requirement of an applicable exception. Such a physician satisfies the signature requirement of the applicable Stark Law exception when the authorized signatory of his/her physician organization has signed the required writing. However, for other purposes, all physicians in a physician organization are considered parties to the arrangement. Accordingly, compensation to a physician organization from an entity furnishing designated health services cannot take into account referrals or other business generated by any of the physicians, whether they are owners, employees, or independent contractors of a physician organization.

Split billing arrangements

In order to clarify confusion related to the discussion in *U.S. ex rel. Kosenske v. Carlisle HMA*,[4] on so-called split bill arrangements, CMS specifically states that a physician's use of certain hospital resources (e.g., an exam room, supplies, and personnel) when treating hospital patients does not constitute remuneration from the hospital to the physician as long as the physician only bills for his/her professional fees. However, CMS pointedly notes that it is not addressing the exclusive use of space.

Compensation that does not reflect referrals

CMS confirms in the final rule that there is only one standard in the various compensation exceptions related to the requirement that compensation paid to a physician should not be determined in a manner that takes into account the volume or value of a physician's referrals. (The standard is the same regardless of whether the phrase "takes into account," "based on," or "without regard to" are used.)

Revised definitions

The final rule revises the definitions of "remuneration" and "locum tenens physician" to remove potential confusion arising from the current wording.

Ownership exception for publicly traded securities/mutual funds

The language in the Stark exception for ownership in certain publicly traded securities and mutual funds is updated to remove the reference to National Association of Securities

Dealers (NASD) and to cover securities listed for trading on an electronic stock market or over-the-counter quotation system that meets specified standards.

Conclusion

Providers likely can benefit from many of the changes in the final rule, particularly when assessing whether they potentially have a "technical violation" of the Stark Law. However, even with the new exceptions, CMS's additional guidance, and the "clarification" of some requirements in certain exceptions, the regulations remain complex and the stakes for violating the strict liability Stark Law remain high. The final rule also raises several potential issues that providers may not have focused on in the past (e.g., what to do if the compensation paid is no longer fair market value at some point after the arrangement begins). Providers entering into new arrangements with physicians should confirm with counsel that the arrangement complies with the Stark Law, as revised, and evaluate whether any of the new exceptions, revised regulations, or guidance may be helpful in structuring the arrangement. It also is important to consider whether and how the new guidance affects existing arrangements. Providers who believe they may have identified potential violations should consult with counsel to determine whether any of the additional guidance provided by CMS could mitigate the reporting obligation.

1. *See* 80 Fed. Reg. 70,886 (November 16, 2015).
2. Linda A. Baumann, Samuel C. Cohen and Hillary M. Stemple: "CMS to Providers: 'We Hear You!' CMS Proposes Significant Changes to Stark Law Regulations that Could Benefit Providers" *Health Care Counsel*, July 27, 2015. Available at http://bit.ly/1WXeAUC
3. *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015). Available at http://bit.ly/1SlrTin
4. *U.S. Court of Appeals ex rel. Ted D. Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009). Available at http://1.usa.gov/1SlrZXq

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by Lynn Handy, LPN, CPC, COC, CCS-P, CPC-I, CHC and Jodi Good Nayoski, CPC, CPC-I, CCS-P, CHC

ICD-10 lessons learned from the trenches

» The electronic medical record (EMR) can be challenging when searching for an ICD-10 code.
» There is one ICD-10 code for all immunizations.
» The orthopedic initial encounter code represents active treatment.
» General exams are coded with or without abnormal findings.
» Work flows may need revision to accommodate ICD-10 requirements.

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Can you believe we are well into our seventh month after ICD-10 went live? How was your first 30 days? We spent the first 30 days in the trenches with the providers, and we want to share our lessons learned. Some were good and some were not so good! We worked directly with the providers in their clinics while they were seeing patients. We offered ICD-10 support, assisted them with finding the correct ICD-10 codes, and answered any questions they had.

What we found was a profound sense of confidence among most of the providers. They had very few questions and thought they were doing well. They saw a corresponding ICD-10 code to each of their active problems and, in their minds, that was enough. After a few days, we started to get that gut feeling (you know the one), and we started looking over their shoulders. We watched as they searched and entered the diagnosis codes into their assessments and encounters. We started to ask probing questions and eventually started pulling notes they had completed the day before. I think you can imagine where this is going!

It turns out we were dealing with a chronic case of "They don't know what they don't know." We settled into a daily routine of pulling a few completed notes for each provider and giving them specific feedback in a short amount of time. There were a few providers who actually enjoyed discussing their experience with ICD-10, but most gave us about 30 seconds between patients.


Handy


Nayoski

Challenges

The most common challenge we heard from the providers was the difficulty finding the more specific ICD-10 codes in their electronic medical record (EMR). As a result, many were just picking the first ICD-10 code they found, which most of time was "unspecified." Why does this sound so familiar? We heard comments like, "If they want us to pick a code with laterality, why does 'unspecified' come up first?" Or "Why does the EMR allow us to pick the unspecified code when there are codes for laterality?" And our favorite, "Why don't they just remove all of the unspecified codes so we have to pick the codes with laterality?" We needed a feasible solution. After much debate, an alert was added to the

unspecified laterality codes, which reminds the providers to indicate a separate side.

Another major challenge was the conversion process itself. We encountered hundreds of issues where codes did not map correctly from ICD-9 to ICD-10. The verbiage a provider is selecting seems to be accurate based on the documentation, but the associated code is incorrect. For example, "autoimmune diabetes" converted to category E13, when in fact, the guidelines direct us to E10.[1] We also found many examples of the verbiage covering a combination of disorders, but the associated code represented only one. The selected wording described Hepatitis B with cirrhosis, while only the Hepatitis B code was linked. This proved to be a huge obstacle (one that is not yet fixed), because it expects providers to know more about coding than we ever anticipated.

Another major challenge was the conversion process itself. We encountered hundreds of issues where codes did not map correctly from ICD-9 to ICD-10. The verbiage a provider is selecting seems to be accurate based on the documentation, but the associated code is incorrect.

Working with the Orthopaedic providers was a challenge, to say the least. We first had to educate them on the difference between an initial and a subsequent encounter. The term "initial" is very misleading and is quite confusing to the providers. As we know, there can be multiple "initial" encounters, depending on whether or not there was active treatment.[2] As soon as we felt like we had that covered, a patient with an open fracture came in, and we had to try and explain the difference between 7th characters B, C, E, F, H, J, M, N, Q, and R. The providers were not enjoying their serving of alphabet soup. We couldn't blame them. All providers have very little time between patients, and trying to wade through the myriad of options for a radial fracture was proving to be too much. Certainly, they needed more education on the codes, but we found them needing a great deal of assistance with searching the EMR for the *right* code.

While working with the Primary Care providers (i.e., Family Med, Internal Med, Pediatrics, and OB/Gyn), we found a great deal of confusion regarding the proper use of the general exams with and without abnormal findings.[3] What is considered an abnormal finding? Is it a complaint or an incidental finding? Is it a chronic condition or an exacerbation of a chronic condition? Is it something minor (e.g., newborn acne) or does it require a treatment plan (e.g., otitis media)? We found that the "what if" scenarios could go on and on. For our group of 200+ providers, we settled on a firm interpretation of new findings at today's visit. However, we will continue to monitor this and hope for more specific guidelines from an authoritative source.

Workflow logistics presented another challenge related to general exams. In the past, orders for lab work, referrals for preventive services, hearing and vision exams, or routine immunizations were entered into the system by the back office staff at the initiation of the visit. Historically these services were linked to the general medical exam diagnosis code. However, ICD-10 requires the code to state "with or without abnormal findings," which isn't known until the end of the visit and is not

always communicated to the back office staff. Many offices had to reconsider and alter their work flow. Providers were excited to find only one ICD-10 code for immunizations administered, but then they saw all the options for immunization refusals! We did our best to create a 1–2 page guide for the general exams and screening codes they use most often. We also encouraged all providers to use their "favorites" lists and customize the verbiage for the common terms they use.

Conclusion

Overall, it was a very positive experience for us and most of the providers. It was exciting to finally go live with ICD-10, as opposed to seeing it as a future concept. Some of what we feared became a reality, and some of our reality became fears. We knew from the beginning of this process, providers would not be successful without the assistance of a strong, intuitive search engine and a good foundation of education. October 1, 2015 was not the end of this journey, only the beginning. It is important to continue support and education for the providers, but make it tangible. Include the functionality of the EMR in your training, and if there are limitations, provide guidance to work through or around them. Provide feedback specific to the provider's own documentation and code selection. Remember, "They don't know what they don't know." Most importantly, have patience with the providers. Spend a day shadowing them, and we guarantee you will have a greater understanding of how truly difficult and important their job is.

1. CMS: ICD-10-CM Official Guidelines for Coding and Reporting FY 2016, Chapter 4. Available at http://go.cms.gov/1HRidJy
2. Idem., Chapter 19
3. Idem., Chapter 21

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by Peggy Binzer, JD and Terri Karsten, JD

The Patient Safety Evaluation System: Building an even safer healthcare system

» Discover the benefits of an effective Patient Safety Evaluation System (PSES).
» Learn how to meet the requirements of section 1311(h) of the Affordable Care Act.
» Create a learning system to prevent the same mistakes from being repeated by other healthcare professionals.
» Learn to use a PSES with integrated care models and new quality performance data tools.
» Use a PSES to create high-reliability in healthcare.

Peggy Binzer *(pbinzer@allianceforqualityimprovement.org) is Executive Director for Alliance for Quality Improvement and Patient Safety and* ***Terri Karsten*** *(tkarsten@qualityhealthlaw.com) is Principle, Quality Health Law, LLC in Washington, DC.*

The Patient Protection and Affordable Care Act (ACA), signed into law in March 2010, has increased attention on quality, efficiency, and value in healthcare delivery. The Centers for Medicare & Medicaid Services' (CMS's) recent final rule implementing section 1311(h) of the ACA requires, among other proposed options, that hospitals with more than 50 beds contracting with a qualified health plan must have a Patient Safety Evaluation System (PSES) by 2017 in order to qualify as a provider for health plans participating in a health insurance exchange.[1] The PSES was established by The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act),[2] in response to the Institute of Medicine report, *To Err is Human*,[3] which ignited widespread discussion about how to prevent medical errors from occurring.

By providing privilege and confidentiality protections for providers who work with federally listed Patient Safety Organizations (PSOs), the Patient Safety Act has become the cornerstone of the federal effort to reduce preventable injuries and deaths in the United States' healthcare system. In passing the legislation, Congress intended to improve the quality of patient care by creating a "culture of safety" through a non-punitive, confidential, voluntary reporting system, and to ensure accountability by raising standards for continuous improvements in healthcare.[4] Creating a PSES provides a great opportunity for hospitals, because it is the only program that permits healthcare providers to evaluate patient care throughout the healthcare continuum without fear of litigation or harm to professional reputation.


Binzer


Karsten

Many healthcare providers and organizations practice in silos, without meaningful connections and information exchange with other healthcare entities to develop peer benchmarking and best practices. The Patient Safety Act breaks the silos and provides necessary confidentiality and privilege protections that permit the sharing of quality data and lessons

learned, which may not otherwise be developed to positively influence the behavior and decisions of the providers for the benefit of patients. The PSES can be used as a tool to help maximize integration and patient care. This article is designed to provide insight into how a provider and PSO use a PSES to improve the quality of care in every healthcare organization across the nation, including new models of care delivery and new performance tools.

Maximizing the quality of patient care

A PSES under the Patient Safety Act is the process a hospital uses to collect, analyze, manage, and maintain information for reporting to or by a PSO.[5] The PSES allows providers to methodically evaluate systems and processes to determine what actually caused the systems to fail and prevent the reoccurrence of the failure without fear of discovery of the information and liability in criminal, civil, administrative, or disciplinary proceedings or harm to professional reputation. The confidentiality protections are intended to encourage greater participation of providers to investigate how they are providing patient care and how they can do a better job without fear of litigation or harm to professional reputation. Many quality programs look only at the what, whereas a PSO can help healthcare professionals figure out the how, in a safety culture that reinforces professionalism and learning, to the benefit of patients. Greater participation of providers throughout the healthcare continuum will allow providers to identify, address, and prevent adverse events from recurrence, thereby improving patient safety overall. The PSES also permits the further sharing of quality information among all the facilities within a health system or with unaffiliated providers who are also members of the PSO. The protections encourage candid dialog among all providers, which permits the exposure of underlying causes that may not be evident in an incident report or are sometimes missed in a root-cause analysis that focuses on one facility rather than the entire system.

The Patient Safety Act was intended to overcome the fear of analyzing incidents and sharing learnings caused by the erosion of state peer review laws, and instead create a national system of sharing and learning with the goal of improving the quality and safety of patient care among all licensed providers and across the continuum of care through a safety culture. The protections also encourage the creation of a learning system for medical providers to report errors and "near-misses" to a PSO, allowing such reports and learnings to be shared among healthcare entities under the protections of the PSES. The goal is to prevent the same medical error from occurring over and over again in organizations across the nation.

The Patient Safety Act was intended to overcome the fear of analyzing incidents and sharing learnings caused by the erosion of state peer review laws…

The provider community that works with PSOs focuses on providing consistency in quality and implementing innovative patient safety programs, including care coordination and evaluating systems gaps throughout the continuum of care (e.g., EMS, primary care, ambulatory care, pharmacy, inpatient care, rehabilitation, post-acute care, long-term care, and home healthcare). It follows that the creation of a learning environment is critical to fostering the development and continual

quality improvement of evidenced-based clinical guidelines and high reliability in the quality of patient care.[6]

Through a uniform and national privilege and statutory confidentiality protections, innovative programs (e.g., safe tables and peer review in primary care), developed by healthcare providers and PSOs, can promote transformational change in the quality of healthcare provided to patients.

Integrated care models and new quality/performance data tools

Most state peer review statutes did not contemplate new healthcare models, such as clinically integrated networks, that evaluate a physician's performance by assessing clinical quality and value. Such models necessarily require the sharing of clinical quality documents, such as physician scorecards, outside of the four walls of the provider's facility. State legislatures also did not foresee big data drawn from many providers or health systems to develop dashboards, benchmarking, and predictive statistical analysis. This data is used to drive performance improvement across the healthcare continuum.

In contrast, the Patient Safety Act was designed "to accelerate the development of new, voluntary provider-driven opportunities for improvement" and to "set the stage for breakthroughs in our understanding of how best to improve patient safety."[7] With few limitations, the Patient Safety Act provides protections for new types of clinical quality reports that contain information that could not be produced under the state peer privilege, such as sharing peer data across medical groups for use as benchmarks or in physician scorecards. Thus, the Patient Safety Act contemplates the collection, discussion, and sharing of information that has never been collected or shared because of the concern that it may not be kept confidential. The Patient Safety Act ultimately eliminates this key barrier to clinical integration.

…the Patient Safety Act provides protections for new types of clinical quality reports that contain information that could not be produced under the state peer privilege…

Privileged patient safety work product

The term "patient safety work product" (PSWP) is broadly defined in the Patient Safety Act and means any data, reports, records, memoranda, analyses (e.g., root-cause analyses), or written or oral statements which could result in improved patient safety, healthcare quality, or healthcare outcomes.[8] The privilege for PSWP applies to information, such as primary healthcare information, to the extent that it was collected for the purpose of reporting to a PSO and reported to a PSO.[9] Information developed by the PSO or analysis or deliberations that occur in the PSES is also PSWP. However, original records (e.g., an x-ray, lab results, or a medical record) are not PSWP. Therefore, the facts of medical errors cannot be hidden in a PSES, because the error must be documented in the medical record. Additionally, information required to be reported under federal, state and local laws also cannot be PSWP.

Congress developed a carefully constructed balance between confidential provider self-driven quality improvement and accountability through regulatory agencies, and the tort system. Congress excluded from the privilege original patient provider records, such as medical and discharge records necessary for regulatory oversight and for plaintiffs to seek

redress for injuries. Thus, the Patient Safety Act does not prevent medical error information from being collected from original records by CMS, state agency surveyors, or plaintiff counsel for use in malpractice lawsuits. However, the Patient Safety Act prevents a plaintiff from being enriched by collecting information from the provider's PSES or the PSO that would not otherwise have been created by healthcare providers but for the promise of the Patient Safety Act's privilege and confidentiality protections.

Conclusion

The Patient Safety Act includes privilege and confidentiality provisions to facilitate building a culture of safety and high reliability in which all licensed healthcare providers are able to openly discuss in a protected manner patient safety hazards, risks, and quality gaps. Providers can learn from the analysis, and share the information with other providers to prevent recurrence. The Affordable Care Act further promotes new care models for clinical integration and patient safety evaluation systems to be developed to improve the quality of patient care. As healthcare shifts to a more performance-based system focused on delivering value, entities across the continuum of care (including EMS, primary care, ambulatory care, pharmacy, inpatient, rehabilitation, post-acute care, long-term care, and home healthcare) will need to embrace the opportunities provided by the legislation and build an effective PSES.

1. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017, 81 Fed. Reg. 12204 (March 8, 2016).
2. The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 229b-21, et seq.
3. The Institute of Medicine: Report: *To Err is Human: Building a Safer Health System*, November 1999.
4. H.R. Rep. No. 109-197, at 9.
5. 42 U.S.C. § 299b-21(6).
6. H.R. Rep. 109-197, at 9; S. Rep. No. 108-196, at 3.
7. Patient Safety and Quality Improvement, Proposed Rule, 73 Fed. Reg. 8112, 8113 (February 12, 2008).
8. 42 U.S.C. § 299b-21(7).
9. 42 U.S.C. §§ 299b-21(5)(B).

by Cassandra Andrews Jackson, MA, CHC, CHPC

Compliance and managing EHR risks, Part 3

» Your risk assessment should identify new technology as a risk that ought to be considered by your organization.

» The RTI report can help us evaluate our EHR and put solid government endorsed safeguards into our EHRs.

» The compliance officer should be copied on audit correspondence from the state Medicaid Inspector General and OIG to help focus on risks relative to the EHR.

» The compliance professional can lead the effort to correct the EHR, but the greater part of your role is to manage and maintain the process.

» The EHR is a tool that won't correct itself; it will do exactly what it's been designed to do.

Cassandra Andrews Jackson *(candrewsjackson@sbhny.org) is the Compliance & HIPAA Privacy Officer with SBH Health System in Bronx, NY.*

This is the last installment of a 3-part series on electronic health records. The first part was published in the February issue of Compliance Today.

In the earlier parts of this series, we've made a clear case that the Compliance function should be concerned about the electronic health record (EHR), its functionality, and the increased risk for fraud. Our role is to prevent fraud, waste, and abuse at our organization.

Andrews Jackson

Therefore, compliance professionals should spend some time looking at this risk area, which means doing a risk assessment. The 2013 revised Federal Sentencing Guidelines placed significant emphasis on the requirement to periodically assess risks of the occurrence of criminal conduct,[1] and the 2005 OIG Supplemental Program Guidance calls for periodic evaluation of an organization's compliance program, including the need for a periodic risk assessment.[2] You should be doing a risk assessment, and you want to pull this into your routine process for identifying and assessing risk. That process should identify that new technology is a risk that should be considered, so take a look at the EHR, both as new technology and as a mechanism that might facilitate fraud or contribute to waste and abuse in your organization.

Risk assessment

In order to complete a good compliance risk assessment, you should consider internally identified risks; senior staff can be a great resource to identify risks. For example, ask your IT people, your chief medical officer (CMO), the chief medical information officer (CMIO), and the chief financial officer (CFO) about the elements of the EHR that cause concern. Review your hotline reports in aggregate for patterns. Relative to the EHR, consider the topics that are being discussed at your quality assurance, documentation, or clinical advisory committees, because they may have already identified a particular EHR issue and may be addressing it. It can be really helpful to be familiar with the points of discussion in these groups, especially in regard to co-opting (see page 70).

The risk assessment should consider the OIG's Work Plan and your state Medicaid Inspector General's (MIG's) work plans. These tell you the regulators' foci and can serve as a

guidepost for your risk assessment and your work plan. The OIG reports can really target your focus, give you background information, and provide a great deal of guidance that can be helpful as you navigate through your organization. Your state's MIG's audit findings or the OIG's audit findings that are reported to your organization can also point you in the "right" direction for risks in your EHR. As a matter of course, the Compliance Office should be copied on audit correspondence from the MIG and OIG. The results are evident, audited, and measured, and again this helps your focus.

Before we move on from the risk assessment to compliance strategy, there was a 2013 OIG study that assessed whether hospitals implemented fraud safeguards in their EHR technology.[3] That OIG study used a standard from a 2007 RTI International report[4] commissioned and contracted by the Office of National Coordinator for Health Information Technology (ONC). "The major task undertaken for this contract was the creation of a set of functional requirements that aims to combat fraudulent activity in EHR-S."[5] The requirements are listed below:

- **Requirement 1:** Audit Functions and Features
- **Requirement 2:** Provider Identification
- **Requirement 3:** User Access Authentication
- **Requirement 4:** Documentation Process Issues
- **Requirement 5:** Evaluation and Management (E&M) Coding
- **Requirement 6:** Proxy Authorship
- **Requirement 7:** Record Modification after Signature
- **Requirement 8:** Auditor Access to Patient Record
- **Requirement 9:** EHR Traceability
- **Requirement 10:** Patient Involvement in Anti-Fraud
- **Requirement 11:** Patient Identify-Proofing
- **Requirement 12:** Structured and Coded Data
- **Requirement 13:** Integrity of EHR Transmission
- **Requirement 14:** Accurate Linkage of Claims to Clinical Records

Each of the 14 requirements has sub-elements that include rationales and recommendations for implementation. For example, Requirement 1: Audit Functions and Features has three sub elements (i.e., audit log content, audit log operation, and audit log support). The RTI report provides the rationale that can assist us as we make our case to the stakeholders. In reference to audit logs, RTI says "Audit reports provide the tools to self-monitor and apply preventive strategies before detection or prosecution. The audit log provides the who, what, when, where, why, and how in this cycle. This log is central to prevention, detection, and preservation of key evidence to support prosecution of health care fraud."[6]

About patient identity proofing, the RTI report provides the following rationale for the recommendation: "One of the fastest growing types of health care fraud is medical identity theft—patients commit fraud by masquerading as another individual in order to obtain medical services." All of the requirements identified through this project were framed as recommendations to the industry at large. The report, along with its recommendations, can be used to assess the audit functions of your organization's EHR. You could conduct a study using the OIG's protocol and document a complete assessment of your organization's EHR compliance with the OIG- and ONC-endorsed recommendations. The RTI report can help you evaluate your EHR and put solid, government-endorsed safeguards into your EHR. Once you use this tool to assess your EHR, be prepared, because you may identify issues, and it's going to be your job to work on making this an organizational priority and help persuade your C-suite to take them on.

Strategy for mitigating risks

You completed the risk assessment and identified the EHR vulnerabilities; now you have to craft your strategy to resolve the issues. Before you begin, form a clear idea about your role in the process. You can lead the effort, but the greater part of your assignment is to persuade and keep it on track. It's the compliance professional's role to make the case so that the organization's leaders prioritize this effort, cooperate, participate, and—most importantly—assume ownership of EHR compliance. The ease with which employees "get on the bandwagon" is a significant measure of your organization's support of the compliance program and of your effectiveness as the compliance officer. As the compliance professional, your role is to raise the red flag about the risk; talk about its consequences and the potential for negative impact to the organization; and talk about the potential for reputational, financial, and legal risk.

Connect the dots with some "If we don't fix this" scenarios (e.g., What happens to our reputation as an organization with integrity? Can we take a hit to our reputation in our immediate community, with our patients, in the industry, or with the regulators? Financially, what's the potential cost in terms of repayments? Legally, are we at risk for litigation or fines and sanctions? If the risk is large, what about the potential for exclusion from federal health programs?).

As you persuade the movers and shakers, your job is to make the connection for each functional area about their role in mitigating the risk, documenting the process and the progress toward the goal, assisting with coordinating the strategy with the operational folks, and keeping the group on course with project management, especially when working to avoid "scope creep." As the term suggests, scope creep is a subtle process that starts with small adjustments and ends up resulting in projects that take far longer to complete or even fail *before* they are finished. Even if the project is completed, scope creep can result in final deliverables that look nothing like what was originally envisioned. Scope creep jeopardizes your ability to reach compliance if your end result does not correct the risk that was identified. The following are some steps you could take.

Identify the functions that have hands-on interaction with the EHR

We want to ensure that we address the workforce in various roles, titles, and departments throughout the organization. Who is impacted by the EHR? Getting a sense of the scope makes your planning more effective. If we correct an issue and educate only part of the population, we've made some inroads, but we want to be as effective as we possibly can be, and that means taking the time to do a comprehensive assessment of the functions. Which functions support, use, or access the EHR, and for what reasons?

In most organizations, it's usually the clinical staff who record the services, the medical decision-making, medical necessity, and the results of diagnostic exams. It's the coding staff who code, based upon the clinician's documentation. The clerical staff facilitate appointments and patient registrations. In some healthcare organizations, the EHR trainers have access to the EHR and, of course, there's IT support staff. Alternatively, we can use as our universe a list of users with current EHR access, although some organizations will say that the list of users may be inaccurate and too expansive, so keep that in mind if you choose to go that route. Recognize that your scope may creep to include user access controls, which you may or may not have identified during your risk assessment. If we do this correctly, when we implement our corrective action, it should have the intended maximized effect.

Identify the stakeholders

Who needs to be in on the discussion and the decision-making? Who are the people who have a vested interest or concern? Compliance should be involved in the discussion. If you're a compliance person without a clinical background or IT expertise, or even if you have that background, an effective compliance program involves the stakeholders in this process. Our expertise is in compliance, assessing and responding to risks, and ensuring the effectiveness of the organization's compliance program. If Compliance is your only function, you want to maintain your focus on compliance. Therefore, we should leverage the expertise and the manpower of other staff, including IT and the coding, billing, and clinical staff as necessary.

If Compliance is your only function, you want to maintain your focus on compliance.

As you continue to identify the stakeholders, ask the following questions: Who has the authority to approve changes to the EHR? Who are the people who have an interest or investment in the EHR, and who will be affected by the outcome? Is it the IT folks, because they implement and manage? Is it the clinical folks, because they're the end users? Is it the billing and coding folks, because they use it to code? Is it revenue cycle folks, because they use it to submit bills to Medicare and/or Medicaid and private insurers?

Your IT folks can be helpful with answering those questions, particularly your EHR trainers or those in a similar function. Maintaining a firm working relationship with IT is essential to successfully addressing EHR issues. In the event there's an issue that has to be reported, your state or federal regulatory agency becomes a stakeholder. Reportable issues might include overpayments, false claims or reverse false claims, or double billing.

Consider leveraging or co-opting existing groups

Who has a piece of this process? Co-opting resources means there's a group or a committee that's already working on resolving EHR issues, and you want to commandeer their processes to accomplish your purpose. This is when your compliance personality really makes a difference; this also is another measure of the effectiveness of the compliance program. How easily will your priority become one of their priorities? This is one of those times when you find out how well Compliance is integrated into your organization.

For example, you may be able to co-opt an IT workgroup that's already working on Meaningful Use certification. That group is already deeply engaged with the EHR. If a documentation committee that looks at individual patient records to ensure they meet documentation guidelines is already actively engaged with the EHR and comparing it against the generally accepted standards of medical practice, they can tell you about documentation practices, shortcomings, and the ways that the EHR may be contributing to the issue. Plus, they may have a mechanism in place to correct issues. Consider a clinical advisory group that's working on EHR changes and that may have an established workflow to ensure that the proposed changes are vetted, approved by the authorized persons, tested and implemented by IT, and that staff are appropriately trained. We should work closely with groups, including the stakeholders or our co-opted group. Have IT review the workflows and examine the output. When you draft a plan of correction, have IT check the correction in a test environment. Educate the users, move to production, and, at an agreed upon interval, audit the outcome until the outcome

is appropriate. If necessary, continue to audit and monitor through to mitigation.

Write policies and procedures

In the 2013 study,[7] the OIG found that just one quarter of the sampled hospitals had policies regarding the use of the copy-paste feature in EHR technology. A co-opted workgroup or *your* workgroup may have to create or edit policies that speak to appropriate uses of the EHR's time-saving functionalities. For example, a "copy paste/copy forward" policy could specify that providers should minimize insertion of patient data available elsewhere in the record and discourage copying as a way of improving clinician productivity. The policy should stipulate the circumstances under which information may be copied, outline the provider's responsibility for copied information and notification of errors, specify corresponding sanctions or disciplinary actions, require source attribution for copied text, and adopt a "zero tolerance" policy on unethical copying practices.

Working through a hypothetical vulnerability

Let's work through a hypothetical risk assessment to correct an identified vulnerability. We'll use the RTI tool that will identify that our EHR allows retroactive alteration of a note and does not designate "amended note." The work group will draft a plan of correction that will require that we change the EHR to ensure that documentation cannot be altered without an audit trail of the original entry. We decide that after the provider e-signs a note or when a practice automatically closes an encounter, amendments will be marked as a change, the amendment will be auto-dated with the user's name, and it will include the modification and the original text. This plan is documented by the compliance officer or his/her designee. At our hypothetical organization, the CMIO will authorize the change, IT will work with the EHR vendor to make the change, IT will check it in a test environment, the work group will coordinate training for the EHR users, and IT will move the change into production. At an agreed upon interval, the group will audit a truly random sample of records and will find that the EHR is title driven and still allows certain staff to turn off the audit trail. For example, a senior attending physician can turn off the function, but the residents cannot. This finding should be documented by the compliance officer or designee. In order to mitigate the issue, the group considers the results and repeats the entire process to ensure that no staff can turn off the function. (Just as an aside, as a compliance professional, you should consider conducting an investigation of the person who turned off the function.)

Conclusion

The EHR is a tool that won't correct itself. The EHR will do exactly what it's been designed to do. It's our responsibility as dedicated compliance professionals to: (1) ensure that our organization does an assessment of the EHR's capabilities to detect and prevent fraud; (2) ensure that we work to mitigate the risks of fraud, waste, and abuse in our EHRs; and (3) ensure that within the context of the prevention of fraud, waste, and abuse that our EHR complies with the medical record guidelines and ultimately improves the quality of care that is provided to our patients.

1. United States Sentencing Commission: 2013 USSC Guidelines Manual, §8C2.5(f)(1). Available at http://bit.ly/1N9XeAk
2. DHHS, Office of the Inspector General: OIG Supplemental Program Guidance for Hospitals. January 31, 2005. Available at http://bit.ly/1273dKE
3. DHHS, Office of the Inspector General: Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology. December 2013, OEI-01-11-00570. Available at http://1.usa.gov/1vrnkWx
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7. DHHS, Office of the Inspector General: CMS and Its Contractors Have Adopted Few Program Integrity Practices to Address Vulnerabilities in EHRs. January 2014, OEI-01-11-00571. Available at http://1.usa.gov/1fVwo24

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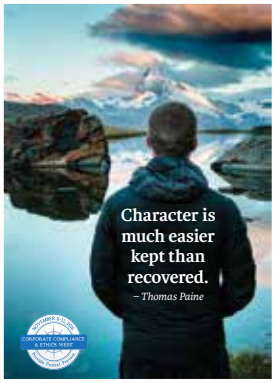

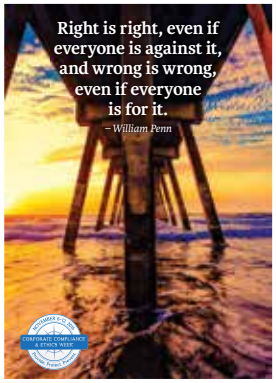

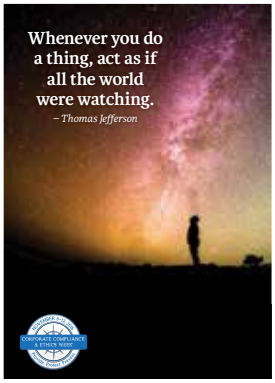

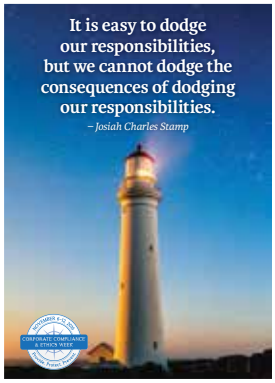

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by Thomas R. Fox, Esq.

The Clean Company Act and healthcare in Brazil

» Although the Brazilian Clean Companies Act follows other anti-bribery legislation, it has significant differences.
» The financial penalties can be severe, up to 20% of a company's annual revenue.
» Hotlines and anonymous reporting take on increased importance under the Brazilian law.
» Documentation must be available for the regulators to review.
» The Brazilian healthcare industry is actively pursuing transparency in medical device and pharmaceutical suppliers relationships to physicians.

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Rather amazingly, in the midst of one of the largest corruption scandals currently ongoing (i.e., the "Lava Jato" or Petrobras corruption scandal), Brazil issued some excellent guidance around its signature anti-corruption legislation, the Clean Company Act.[1] Rafeal Gomes, in an article entitled "Compliance Programs Under the Brazilian Clean Companies Act" wrote that this new anti-corruption law applied:

Fox

> …to any Brazilian business organization, company, foundation, association of persons or entities, formally organized or not, regardless of how they are organized or the corporate model they adopt, as well as foreign companies having office, branch, or representation in the Brazilian territory, even if informally and/or temporarily. The Act subjects companies to severe civil and administrative penalties and sanctions for bribing domestic or foreign government officials, and the fines can be of up to 20 percent of the company's annual gross revenues.[2]

However, one of the difficulties was the Clean Company Act "did not provide Guidance on what said mechanisms and procedures consisted of, or how much discount or credit would be granted to companies that have effective compliance programs in place."[3] This problem was rectified in March 2015 when the Brazilian government issued Guidance around its anti-corruption law. This Guidance centered on five areas of the law:

- Procedural rules for the administrative enforcement of the Clean Company Act against organizations;
- Calculation of the penalties under the law;
- Leniency agreements for corporate cooperation;
- Compliance programs; and
- Sanctioned, banned, or restricted companies lists.

In an article entitled "Document, Document and Document Under the Brazilian Clean Company Act"[4] Gomes pointed out that the Clean Company Act provides for strict liability for a company that benefits from violations of the Act, as well as those actions of third-party intermediaries acting on their behalf. Gomes clear guidance is that any company doing business in Brazil needs to have a

well-documented and "robust compliance program in place to prevent, detect and remediate instances of wrongdoing."

Comparing the laws

Although the Clean Companies Act generally follows the strictures of such anti-corruption laws as the FCPA and UK Bribery Act, there are some significant differences. Carlos Ayers, writing the FCPAméricas,[5] has identified five significant differences.

1. Scope of the Clean Companies Act

First and foremost, companies that have compliance programs in place "specifically to comply with foreign anti-bribery laws, should acknowledge the necessity of adapting them to Brazil's new legislation, in particular to cover fraud in public procurement and in the execution of contracts with the Public Administration." Moreover:

> …the Clean Companies Act covers more than just corruption. Significant parts of its prohibited acts address illegal conduct related to public tenders and public contracting (not necessarily linked to corruption). Given this, the Guidance highlights that compliance programs designed to prevent and detect only corrupt conduct might not address all the conduct prohibited by the Clean Companies Act. Therefore, companies operating in Brazil should revise their compliance programs to make sure they cover all conduct prohibited by the Clean Companies Act.

2. The importance of monitoring your compliance program going forward

Ayers stated the:

> Guidance notes that the pressure on companies to meet unrealistic commercial goals may lead employees to commit wrongdoing, in violation of the company's compliance program. Given this, the Guidance considers it important for companies to monitor the stated goals of their enterprises so they are not conveying the impression that business should be obtained at any cost, at the expense of compliance.

Here the Guidance takes the hotline requirement a few paces past those required in the U.S.

3. Maintenance of complete and accurate books and records

This is more required under the Brazilian Clean Company Act than under the FCPA accounting provisions for such accurate books and records. Obviously with a nod to the corruption engaged in by Petrobras employees, the Guidance also includes a requirement that records should "justify the need to hire third parties and include information about the price agreement and the market price, with justification for payments above market value." Yet it even goes further to require ongoing monitoring "related to transactions that represent higher compliance risks."

4. Additional requirements for hotline and other internal reporting

Here the Guidance takes the hotline requirement a few paces past those required in the U.S. A company must be transparent in its response and allow an employee who reports to reasonably track the progress of any such legitimate report. The "Guidance suggests that companies implement channels to give reports and answer questions about the compliance programs. The channels should be free and easily accessible to everyone in the company

and open to third parties and the public, where appropriate."

5. The importance of internal investigations
Although Ayers had labeled this section as "the *increased* importance of internal investigations" after the Yates Memo, I do not think that the Brazilian importance around internal investigations exceeds the pressure on US companies going forward. Yet, the Guidance highlights that "the detection of evidence of the occurrence of illegal acts against the local or foreign Public Administration should lead the company to initiate an internal investigation which will serve as basis for appropriate actions to be taken." The Guidance further provides that "internal rules should address core aspects of internal investigations, such as deadlines, responsibilities for investigating allegations, and identification of who should receive the results of the investigation."

The Brazilian "Sunshine" Act

The Brazilian Clean Company Act was a welcomed addition to the international fight against bribery and corruption. As a country, Brazil has now moved into the forefront of this battle. But this battle against corruption is not limited to legislation and attendant Guidance, solely from the national level. The healthcare industry is particularly suited to meet this new challenge, because it is one of the fastest growing sectors in Brazil. As a country, there are more than 400,000 practicing physicians, mostly concentrated in large urban centers.

Until recently, there were few rules that sought to regulate the relationship between Brazilian physicians and the pharmaceutical industry. Yet the Regional Council of Medicine of the State of São Paulo, where 30% of the country's registered physicians practice, released a standard[6] that seeks to make more transparent the relationship between physicians enrolled in this council and pharmaceutical industries. Sergio Sztajnbok, MD has stated, "such a standard is a breakthrough and the first step towards complete transparency in the close relationship between doctors and pharmaceutical industry in Brazil."[7]

Moreover, at a November anti-corruption conference[8] held in São Paulo, aimed at the healthcare industry, Don Sinko, the Chief Integrity Officer at the Cleveland Clinic was a keynote speaker.[9] The topics ranged from developments in legislation to classifying fraud involving the supply and prescription of prostheses and orthopedics as a criminal offense. There was even a pledge taken by attendees to place anti-bribery language in commercial contracts between manufacturers, distributors, and other third-party representatives.

Conclusion

The business environment is rapidly changing in Brazil and healthcare is, in many avenues, leading the way. CEOs, leaders, executives, directors, managers, physicians from the major Brazilian healthcare institutions, and people who seek change—all want to make their organizations and the healthcare trade in Brazil more ethical. Healthcare is leading the way in developing business solutions to the legal problems addressed by legislation such as the Clean Company Act, through the search for self-regulation, sustainability, and implementation of strong and effective compliance programs.

1. Brazilian Law No. 12.846/2013
2. Rafael Gomes: "Compliance Programs under the Brazilian Clean Companies Act" *FCPA Compliance & Ethics* blog; March 27, 2015. Available at http://bit.ly/219TK5s
3. Idem.
4. Rafael Gomes: "Document, Document, and Document under the Brazilian Clean Companies Act" *Compliance & Ethics* blog; June 26, 2015. Available at http://bit.ly/1QnP2hM
5. Carlos Ayres: "Brazilian Government Issues Compliance Program Guidelines" *FCPAmericas Blog*; November 10, 2011. Available at http://bit.ly/21GYe9g
6. Sergio Sztajnbok: "CREMESP Resolution No. 273/2015: First step to Brazilian Sunshine Act?" *Compliance Today*; January 2016, pp.75-77
7. Idem.
8. Hospitais Compliance 2015. Available at http://bit.ly/1RKJPkj
9. FCPA Compliance and Ethics Report podcast, interview with Don Sinko. Available at http://bit.ly/1VT4p3b

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Takeaways

April 2016

Compliance TODAY

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Communicating protected health information via text messaging

Joan Feldman and William Roberts (page 25)

- Many individuals depend on text messaging to communicate with clinicians.
- Text messaging can improve communication and patient outcomes.
- Providers must assess risk before sending PHI via text message.
- Risks exist with using text messaging in the clinical setting.
- Providers can mitigate risk when text messaging with patients.

Embracing 340B reform: What's in store for 2016?

Kyle A. Vasquez (page 31)

- Congress and federal agencies continue to implement policies that directly impact the 340B Program.
- 2016 promises to be a busy year for covered entities managing 340B Program compliance.
- Stakeholders need to dedicate resources to stay informed of and quickly adapt to regulatory updates to ensure ongoing 340B Program compliance.
- Prior audit results, the Mega-Guidance, and reports by the OIG and GAO can guide an evaluation of your 340B program and identify risk areas.
- Stakeholders should consider reaching out to members of Congress and HRSA to present ideas on how to drive compliance and efficiency in the 340B Program.

Is the compliance officer practicing law without a license?

Paul P. Jesep (page 41)

- Make clear distinctions between Legal and Compliance functions in policies and procedures.
- Know when being a compliance officer ends and becoming an attorney begins.
- If the organization is too small to have an attorney on staff, consider putting one on retainer.
- Within the department budget, permit the compliance officer to selectively use outside counsel.
- Engage the board to decide whether Legal and Compliance could be combined in limited cases, using an attorney on staff to serve in both roles, with safeguards to maintain the distinction.

CDI programs: Promoting quality and physician engagement for success

Steven A. Greenspan and Ralph Wuebker (page 46)

- Hospitals are concerned about quality and capacity issues of clinical documentation improvement (CDI) programs as we move toward a reimbursement model based on quality and outcomes, and not volume.
- Beyond reimbursement, accurate and complete CDI can provide benefits in the areas of quality of care, increased patient safety, and increased accuracy and specificity.
- Despite a strong commitment to CDI programs, many hospitals are still encountering documentation issues (often due to low physician adoption of and engagement in these programs), and poor presentation documentation.
- Using a physician advisor or physician champion to facilitate communication between physicians and attending or treating physicians helps support physician engagement and query resolution.
- Proper physician documentation is the cornerstone of medical necessity that helps validate the level of patient care provided, helps ensure appropriate reimbursement, and lends to the defense against audits.

Providers take note: What the new Stark regulations mean to you

Linda A. Baumann, Samuel C. Cohen, and Hillary M. Stemple (page 52)

- All providers need to be aware of new changes to the Stark regulations, which largely went into effect January 1, 2016.
- A number of the changes in the regulations and guidance in the preamble should help facilitate compliance with the strict liability law, and some may impact prior arrangements.
- The requirements for a "signed, written agreement" in numerous Stark Law exceptions should be easier to satisfy because a single formal contract is not required and signatures can be obtained within 90 days.
- Leases and personal service arrangements can be held over indefinitely under certain circumstances but, among other requirements, the arrangements must be fair market value when they expire and throughout the holdover period.
- Other key changes include new exceptions to the Stark Law for certain timeshare arrangements and for the recruitment of non-physician practitioners, as well as changes related to physician-owned hospitals.

ICD-10 lessons learned from the trenches

Lynn Handy and Jodi Good Nayoski (page 59)

- The electronic medical record (EMR) can be challenging when searching for an ICD-10 code.
- There is one ICD-10 code for all immunizations.
- The orthopedic initial encounter code represents active treatment.
- General exams are coded with or without abnormal findings.
- Work flows may need revision to accommodate ICD-10 requirements.

The Patient Safety Evaluation System: Building an even safer healthcare system

Peggy Binzer and Terri Karsten (page 63)

- Discover the benefits of an effective Patient Safety Evaluation System (PSES).
- Learn how to meet the requirements of section 1311(h) of the Affordable Care Act.
- Create a learning system to prevent the same mistakes from being repeated by other healthcare professionals.
- Learn to use a PSES with integrated care models and new quality performance data tools.
- Use a PSES to create high-reliability in healthcare.

Compliance and managing EHR risks, Part 3

Cassandra Andrews Jackson (page 67)

- Your risk assessment should identify new technology as a risk that ought to be considered by your organization.
- The RTI report can help us evaluate our EHR and put solid government endorsed safeguards into our EHRs.
- The compliance officer should be copied on audit correspondence from the state Medicaid Inspector General and OIG to help focus on risks relative to the EHR.
- The compliance professional can lead the effort to correct the EHR, but the greater part of your role is to manage and maintain the process.
- The EHR is a tool that won't correct itself; it will do exactly what it's been designed to do.

The Clean Company Act and healthcare in Brazil

Thomas R. Fox (page 73)

- Although the Brazilian Clean Companies Act follows other anti-bribery legislation, it has significant differences.
- The financial penalties can be severe, up to 20% of a company's annual revenue.
- Hotlines and anonymous reporting take on increased importance under the Brazilian law.
- Documentation must be available for the regulators to review.
- The Brazilian healthcare industry is actively pursuing transparency in medical device and pharmaceutical suppliers relationships to physicians.

HCCA's Upcoming Events

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

April 2016

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
27	28	29	30	31	1 *April Fool's Day*	2
3	4	5 WEB CONFERENCE *How to Increase Efficiency and Compliance by Centralizing your Clinical Trials Administration*	6	7 WEB CONFERENCE *Information Governance: Challenges and Opportunities for the Compliance and Privacy Professional*	8	9
10	11	12 WEB CONFERENCE *NEO and the Compliance Officer: A Winning Combination*	13	14	15	16
17 **20th Annual Compliance Institute** **Las Vegas, NV**	18	19	20 **CHC, CHPC, and CHRC Exams**	21	22 *Passover Begins at Sundown* *Earth Day*	23
24	25 **Basic Compliance Academy** **Boston, MA**	26	27 WEB CONFERENCE *Hijacking Your Life Support: The Impact of Medical Device Security Weaknesses*	28 **Regional Conference** **San Juan, PR** **CHC Exam**	29 *Arbor Day*	30

May 2016

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4	5 WEB CONFERENCE *ZPIC Auditor Raid: Defense and Compliance Tactics* *Isra and Mi'raj* *Cinco de Mayo*	6 **Regional Conference** **Columbus, OH**	7
8 *Mother's Day*	9 WEB CONFERENCE *Are Your Business Associates Increasing Your Risk?*	10	11	12 WEB CONFERENCE *501(r) Compliance for Your Revenue Cycle*	13 **Regional Conference** **New York, NY**	14
15 *Pentecost*	16 WEB CONFERENCE *Home Health Audit Defense: ZPICs, SMRC, and OIG — Oh My!*	17 WEB CONFERENCE *Medical Record Ethics in a Pediatric Privacy Setting*	18	19	20	21 *Armed Forces Day*
22	23	24	25 WEB CONFERENCE *Compliance Officers: So Many Roads to Choose — Peer Review Disclosure or Patient Privacy*	26	27	28
29	30 **HCCA OFFICE CLOSED** *Memorial Day*	31	1	2	3	4

Dates and locations are subject to change.

20th Annual Compliance Institute
April 17–20 • Las Vegas, NV

Research Compliance Conference
June 5–8 • Baltimore, MD

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

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

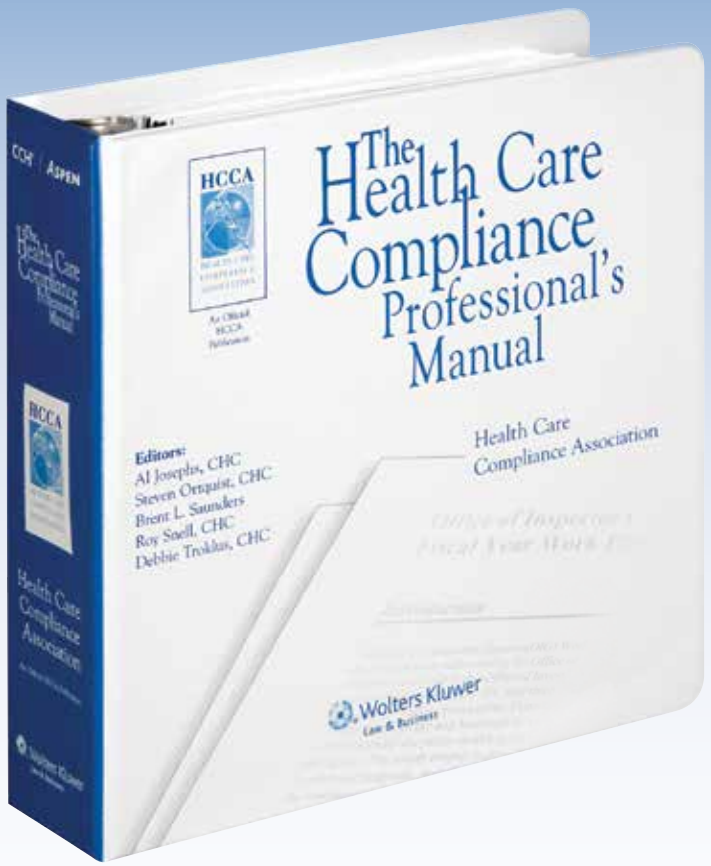
Regional Conferences
April 28–29 • San Juan, PR
May 6 • Columbus, OH
May 13 • New York, NY
June 3 • Philadelphia, PA
June 10 • Seattle, WA
June 17 • Orange County, CA
September 9 • Boston, MA
September 16 • Minneapolis, MN
September 23 • Kansas City, MO
September 30 • Indianapolis, IN
October 7 • Pittsburgh, PA
October 13–14 • Honolulu, HI
October 21 • Denver, CO
November 4 • Louisville, KY
November 11 • Phoenix, AZ
November 18 • Nashville, TN
December 2 • San Francisco, CA
December 9 • Houston, TX

Basic Compliance Academies
April 25–28 • Boston, MA — **SOLD OUT**
June 13–16 • San Francisco, CA — **LIMITED SEATS**
June 20–23 • Scottsdale, AZ
July 25–28 • Honolulu, HI
August 8–11 • New York, NY
September 12–15 • Chicago, IL
October 3–6 • Las Vegas, NV
October 24–27 • Nashville, TN
November 14–17 • Orlando, FL
December 5–8 • San Diego, CA

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

Healthcare Privacy Basic Compliance Academies
June 20–23 • Scottsdale, AZ
October 24–27 • Nashville, TN
November 7–10 • San Diego, CA

The Health Care Compliance Professional's Manual



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

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

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

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