




Compliance TODAY

June 2013

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

A portrait of Tessa Lucey, a woman with curly brown hair, wearing a dark blazer over a red top. She is looking upwards and to the right with a thoughtful expression. The background consists of vertical grey slats.

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by Roy Snell, CHC, CCEP-F

Compliance professionals struggle for independence

*Please don't hesitate to call me about anything any time.
612 709-6012 Cell • 952 933-8009 Direct
roy.snell@corporatecompliance.org*

SCCE and HCCA conducted a survey of its members regarding their relationship to other departments. The survey showed the Compliance Officer's most important partner is the Legal department and the General Counsel. SCCE and HCCA also surveyed its



Snell

11,000 compliance professionals for their perspective on whether the CO should report to the GC. Of over 800 respondents, 80% felt they should not report to the Legal department. The same survey showed that 88.5% rejected the idea that the GC should also be the Compliance Officer. Although Legal is its greatest partner, the compliance profession is struggling for independence.

Some advocates for having the CO report to the GC indicate that the CO should report to the GC because compliance is all about the law. Others believe compliance is not about the law but rather putting systems and procedures in place to ensure the law is followed. Some believe compliance should report to the GC for attorney-client privilege protection. It's highly unlikely they could protect most of the work the Compliance Officer does—policy development, education, general audits, etc. When a CO conducts investigations, that investigation can be protected without forcing the CO to report to the GC. The mere idea of wanting to block the release of information to leadership is one of the reasons compliance programs were established in the first place. If you

are implementing a compliance program to receive a break in the fines and penalty phase, as the Federal Sentencing Guidelines suggest, you can render it ineffective if you continue to do things as you have in the past.

The people surveyed were asked why the CO should be independent from the GC's office. Many cited the inherent conflict of interest. Compliance professionals are often asked to follow-up on legal issues. Most legal decisions were made under the purview of the GC. You cannot report to the person you are investigating and remain independent. The other conflict most often cited was the Legal department's role in defending the company. Defending the company is an important role. But if the Compliance Officer reports to the person responsible for defending the company, his independence is rendered ineffective.

The very nature of a compliance program requires independence.

The very nature of a compliance program requires independence. Many have suggested that you can overcome the independence problem by having COs who report to GCs have access to the audit committee of the Board. If the decision to hire/fire and the performance review of the CO is controlled by the GC, there is no independence and no dotted line will fix that. The Compliance Officer should not report to the GC or be the GC. By doing so, you are putting your company at risk. ☹



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Compliance Today is printed with 100% soy-based, water-soluble inks on recycled paper. Interior pages are double-coated sheets made from 80% recycled content, which includes 60% post-consumer waste.

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“ Like many people, I have a ‘To Do’ list. I think the last time I checked everything off of that list was in the early 90s. ”

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Intermountain, Deloitte forge alliance around big data and analytics

On February 28, 2013, Deloitte Consulting LLP and Intermountain Healthcare announced “a landmark alliance around big data and analytics.

“Drawing on Deloitte’s leading-class professional services and informatics capabilities and Intermountain’s pioneering experiences in capturing and using data to provide high-quality care at lower costs, the organizations have signed a five-year deal to develop and provide health analytics insights to the medical community.

“Leaders at both companies say the alliance will help the health-care industry unlock the power of big data to reduce costs and improve patient outcomes. They note that health care has arrived to a point in which vast reservoirs of clinical data are collected, but the riddle is how to translate the information into meaningful insights.” For more:

www.deloitte.com/view/en_US/us/press/Press-Releases/9ca2c0d48ab1d310VgnVCM2000003356f70aRCRD.htm

ERC issues report: “Building a Corporate Reputation of Integrity”

The Fellows of the Ethics Resource Center (ERC) have assembled insights from brand management and public relations gurus to produce a guide on how to establish, develop, and protect a corporation’s reputation of being an honest broker in the marketplace.

The guide will help executives maneuver through the increasingly complicated landscape on the path to “Building a Corporate Reputation of Integrity.”

Use this link to download the report:

www.ethics.org/files/u5/integrity.pdf

KPMG: Business leaders call for changes to corporate reporting

According to a February 14, 2013 press release, “With the effectiveness of corporate reporting under the spotlight in the wake of the financial crisis, KPMG published a new report which brings together a range of leaders in their field discussing the direction that reporting needs to take.

“The report—The future of corporate reporting: towards a common vision—contains the views of influential figures from key different vantage points in the financial

chain: preparers, users, standard-setters, regulators, auditors.

“KPMG’s global chairman Michael Andrew, writing in the foreword of the report, says: ‘If there is one point of consensus, it is that corporate reporting definitely needs to move on. It has to evolve if it is to be fit for purpose in a rapidly changing world.’”

Use this link to view the report:

www.kpmg.com/Global/en/IssuesAndInsights/ArticlesPublications/Pages/future-of-corporate-reporting.aspx

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

Regulatory News

New Joint Commission alert issued

On April 8, 2013, The Joint Commission issued a Sentinel Event Alert addressing medical device alarm safety in hospitals. The constant beeping of alarms and an overabundance of information transmitted by medical devices, such as ventilators, blood pressure monitors, and ECG (electrocardiogram) machines, is creating “alarm fatigue” that puts hospital patients at serious risk, according to the alert. More at: www.jointcommission.org/new_joint_commission_alert_addresses_medical_device_alarm_safety_in_hospitals.

Medicare DMEPOS Competitive Bidding Program contracts awarded

In April, the Centers for Medicare & Medicaid Services (CMS) announced that 13,126 contracts were awarded to suppliers of medical equipment and supplies selected through competitive bidding in 91 areas. The press release noted “that 799 suppliers* have been awarded contracts as part of Round 2 of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program

to provide certain medical equipment and supplies (such as scooters, wheelchairs, and oxygen) to beneficiaries in 91 communities across the country.” Additionally, CMS announced 18 suppliers that accepted contracts to provide mail-order diabetic testing supplies at competitively bid prices nationwide.

The competitive bidding program, which has already resulted in \$202 million in savings in its first year of implementation in nine areas, is expected to save the Medicare Part B Trust Fund an estimated \$25.7 billion between 2013 and 2022. Beneficiaries are expected to save an estimated \$17.1 billion as a result of lower co-insurance and premium payments.

Consumers, physicians and other providers can find a list of Medicare contract suppliers in their areas by visiting www.medicare.gov/supplier/home.asp or by calling 1-800-MEDICARE. People can also visit the local offices of the various partner groups for help in finding a Medicare contract supplier, such as their State Health Insurance and Assistance Program, Administration for Community Living, and a number of community

organizations that can provide information on the program.

For additional information about the Medicare DMEPOS Competitive Bidding Program, please visit: www.cms.hhs.gov/DMEPOSCompetitiveBid.

**This release provides the number of contract suppliers as of April 9, 2013. For a current comprehensive list of contract supplier locations in each competitive bidding area (CBA), please visit www.medicare.gov/supplier.*

Medicare dashboard advances ACA goals for chronic conditions

In late March, Marilyn Tavenner, Acting Administrator of the Centers for Medicare & Medicaid Services (CMS) announced in a press release that “A new Medicare Chronic Conditions Dashboard furthers the Affordable Care Act’s goals for health promotion and the prevention and management of multiple chronic conditions. The dashboard offers researchers, physicians, public health professionals, and policymakers an easy-to-use tool to get current data on where multiple chronic conditions occur, which services they require, and how much Medicare spends helping beneficiaries with multiple chronic conditions.” More at: <http://go.cms.gov/10h93JN>.

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HCCA *conference news*

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June 2–5 | Austin, TX

General Session Speakers:

- ▶ **Research Compliance: A Year in Review**—
F. Lisa Murtha, Partner, SNR Denton US LLP
- ▶ **View from the Trenches in Clinical Trial Litigation**—Dr. Ernest D. Prentice, Associate Vice Chancellor of Academic Affairs, University of Nebraska Medical Center
- ▶ **Reviewing the Hard Cases in Research Compliance Billing**—Ryan Meade, Partner, Meade, Roach & Annulis, LLP

Fraud & Compliance Forum

September 29–October 1 | Baltimore, MD

The Fraud & Compliance Forum is jointly sponsored by HCCA and the American Health Lawyers Association (AHLA). All sessions are designated as either “compliance focused” or “legal focused.” An individual could attend all “compliance” sessions or all “legal” sessions for the entire program, or choose to select diverse sessions and network with an expanded group of individuals. The Fraud and Compliance Forum consolidates the quality of HCCA and AHLA sessions with the added benefits of the expanded networking power of a combined program.

Clinical Practice Compliance Conference

October 13–15 | Philadelphia, PA

Physicians, compliance officers, managers, and coders will learn to manage an effective compliance program. Designed with networking in mind, the conference provides many opportunities for choosing breakout sessions that cover topics of interest for all.

Basic Compliance Academies

In 2012 all our Academies sold out, and the first ones of 2013 are also sold out. Academies are limited to 75 attendees and fill quickly, so register today to ensure you are able to attend the one that works best with your schedule. The CHC exam is offered on the final day.

Research Basic Compliance Academies

Focus on compliance issues related solely to research. With a wide range of research-related issues becoming hot topics with enforcement agencies, Research Academies provide attendees with the opportunity to get information on many areas that affect research compliance officers and their staff on a day-to-day basis. A small audience encourages hands-on educational techniques, small group interaction, and networking. The CHRC exam is offered on the final day.

Privacy Basic Compliance Academies

The Privacy Academy is comprehensive, covering a broad spectrum of law and regulations that affect health care organizations. The faculty is made up of experts in the field. Courses are designed for participants who have a basic knowledge of compliance concepts and some professional experience in a compliance function. The CHPC exam is offered on the final day.

Regional Conferences

Network locally and get the latest on the key challenges facing your compliance community. HCCA Regional Conferences provide a forum to interact with local compliance professionals, share information about your compliance successes and challenges, and create educational opportunities for compliance professionals to strengthen the industry.

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@hcca-info.org with any questions about HCCA's website.

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Other related products

Are you new to compliance and want to do some reading, but you're not sure where to start? Or maybe you really enjoyed a certain HCCA book and want to know if there are other helpful books out there. HCCA has added a *Related Products* tab to each product on the website. You will be able to see what other books or products are suggested with the product you are currently viewing. For example, if you are starting a new compliance program, you might look at *501 Ideas for your Compliance and Ethics Program*. Under the related products tab, you will see *Compliance 101* is also recommended. Check out all HCCA products at www.hcca-info.org/products.

HCCAnet® news

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 - CHRC exam www.hcca-info.org/chrcgroup
 - CHPC exam www.hcca-info.org/chpcgroup

Are you HIPAA compliant?

Subscribe to the *HIPAA* group—the most popular group on HCCAnet—at www.hcca-info.org/hipaagroup and reply to these popular discussions:

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- ▶ **Breach vs Non-Breach**
Do we need to maintain a log for “non-breach” incidents?
<http://bit.ly/nonbreach>
- ▶ **Discharge paperwork, making sure patient gets their information**
<http://bit.ly/dischargepaperwork>
- ▶ **Mobile Device Policy**
<http://bit.ly/mobilepolicy1> and <http://bit.ly/mobilepolicy2>
- ▶ **Performing a HIPAA audit**
<http://bit.ly/performingaudit>
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<http://bit.ly/balanguage>
- ▶ **Personal representative for a minor**
<http://bit.ly/hipaaminor>
- ▶ **Discarding PHI**
Does all PHI being discarded need to be shredded?
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- ▶ **Calling patient names in lab waiting room**
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- ▶ **Release of Information**
<http://bit.ly/patientnames>

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

► Lawrence Memorial Hospital recently named **Brian W. Kozik**, CHC, CCEP, as its Chief Compliance Officer.

► Recently, Prime Therapeutics (Prime), a leading pharmacy benefit manager (PBM), announced that it hired **Ann Tobin** as Chief Compliance Officer.

► Saint Peter's Healthcare System recently appointed **B. J. Welsh** as the organization's Chief Compliance Officer.

► Cooper University Health System in Camden, NJ recently appointed **Angela M. Melillo**, MBA, CHC, CHRC, CPC, as Administrative Director – Integrity & Compliance in the organization's Corporate Compliance department.



► **Pamela Rundell** was recently appointed Manager, Compliance Reporting for Parkland Health and Hospital System in Dallas, Texas.

► The Ethisphere Institute recently named **Cleveland Clinic** as one of the World's Most Ethical Companies.

The award, presented in March, "highlights companies

that outperform industry peers when it comes to ethical behavior," according to the Ethisphere Institute. The 2013 award winners "are those that truly embrace ethical business practice and demonstrate industry leadership, forcing peers to follow suit or fall behind."

**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.

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Tessa Lucey, MHA, CHC
**Corporate Compliance Officer/
 Chief Privacy Officer**
Hallmark Health System
Medford, MA

an interview by Margaret Hambleton

Meet Tessa Lucey

This interview with **Tessa Lucey** (TLucey@hallmarkhealth.org) was conducted in April by **Margaret Hambleton** (Margaret.hambleton@stjoe.org), Senior Vice President, Ministry Integrity, Chief Compliance Officer with St. Joseph Health System in Orange, California and a member of the HCCA board of directors.

MH: Ms. Lucey, thank you for agreeing to do this interview for *Compliance Today*. Please tell our readers a little about your background and how you became the Corporate Compliance Officer and Chief Privacy Officer for Hallmark Health System.

TL: Looking back at how I got into Compliance, it's not that surprising. I was always the kid who followed the rules. I was a very cautious child who got nervous when others were doing things they weren't supposed to be doing. Breaking the rules is

something that always gave me anxiety, even from a very young age. It still does to this day. I think being a compliance officer is in my genetic makeup.

I was involved in sports and, even though I was cautious and a rule follower, I was the class clown in my senior class. Teenagers are often worried about what others think about them, and I was no different. Through sports, I was able to learn teamwork and I gained confidence. Through my humor, I was able to deflect a lot of the "dorkiness" that comes with being cautious and being afraid to go against the rules. And, if I wasn't really able to deflect it, at least I thought I did! It's like the old saying, "If a tree falls in the woods and no one is there to hear it, did it make a noise?" In my case, if my classmates really

thought I was a big nerd but I didn't pick up on it, did I just think I was really cool? After high school, I played intercollegiate basketball and was part of an improv troupe in Boston for several years. This may seem somewhat contradictory—for a compliance officer to do comedy—but for me, it worked.

I got into Compliance quite by accident. I was working as the Operations Manager at an outpatient rehabilitation company in 1998 when the COO approached me and said the government had just come out with compliance guidance. This guidance talked about a “compliance officer.” He thought I'd be good at it and suggested I look into it further. I already had experience in medical billing, human resources, payroll, finance, and operations. I wrote a lot of policies and procedures, set up systems, and handled most of the organization's training programs. I was the stereotypical “jack of all trades, master of none.” I knew a little about a lot and really had no idea where I wanted to “specialize.” That COO thought this “compliance thing” would be good for me. And that was the beginning of me as a compliance officer.

I became the Compliance Officer for Community Rehab Centers in 1998, which was later bought by Kessler Rehabilitation Corporation, where I became the Compliance Officer and Vice President of Administrative Operations. After Kessler was purchased by Select Medical, I tried my hand at my own consulting business. After a few years of consulting, the business was at the point where I needed to either (1) kick it up to the next level

and hire some additional staff; or (2) shut it down and work for someone else. My wife and I were also thinking about starting a family and stability was important, so we decided to go with #2.

In 2007, I became the Director of Compliance and the Chief Privacy Officer at South Shore Hospital in Weymouth, MA. Although not that far mileage-wise, anyone who has had to deal with Boston traffic knows that going from north of the city to south of the

city can take over an hour; sometimes more. I was not actively looking to change jobs, but while looking for sample job descriptions, I stumbled across an ad on the HCCA Job Board for a compliance officer at Hallmark Health System. It just so happened that our first son, Oscar, was born earlier that year, so

I was not actively looking to change jobs, but while looking for sample job descriptions, I stumbled across an ad on the HCCA Job Board for a compliance officer at Hallmark Health System.

being in the car for up to three hours a day was not exactly pleasurable for me. I also had recently graduated with my Masters in Health Administration. Going from a director-level position at a community hospital to a compliance officer at a health system was a great next step for me professionally. Cutting my commute time from 3 hours a day to less than 30 minutes was what I needed personally. Being able to get onsite quickly if I'm needed off-hours is ideal. Our second son, Marcus, was born six months ago. Being able to get home for dinner with my family and not being stuck in traffic is priceless.

MH: I understand the Hallmark Health System is a complex, charitable provider serving Boston's northern communities. Can you

tell us a little about the health system and how your compliance program is structured within it?

TL: Hallmark Health System is an integrated health care delivery system that includes Lawrence Memorial Hospital of Medford, Melrose-Wakefield Hospital, Hallmark Health Medical Center, Hallmark Health Hematology and Oncology Center, a visiting nurse association, hospice, and employed physician practices. The compliance program covers all of these. I serve as the Corporate Compliance Officer and the Chief Privacy Officer.

Operationally, I report to general counsel (GC), but I also simultaneously report to the chair of the Audit and Compliance Committee of the Board of Trustees. I know there are mixed feelings in the compliance community about compliance reporting to legal but, in my case, it works.

I'm lucky in the sense that my GC himself has experience as a compliance officer. He knows what it takes run to an effective compliance program, and he gives me the autonomy that I need to succeed.

In my department, I have a staff of 2½. I have two full-time compliance specialists—one focuses primarily on privacy and security, and the other primarily on billing and coding. There is an overlap between the two positions for all the other compliance issues that arise, and those are assigned on a case-by-case basis. I also have a part-time administrative assistant/data analyst. Although that position was

originally supposed to do more of the data analyst function, out of need, this position has really turned into a RAC process coordinator.

MH: What are some of the most pressing challenges you face today in maintaining an effective compliance program?

TL: Just by its nature, compliance is challenging. Most compliance officers that I know struggle with the same thing—trying to do more with less. The number of pre-pay probe reviews, RAC requests, private insurance audits, breach reporting requirements, changes to regulations—they all continue to increase. Yet, staffing stays the same and revenues decrease.

In my career, I've been lucky. I hear stories from other compliance officers who don't get the support that they need from the board and senior management. I've never had that. I've always had the sup-

port that I need, but I've also recognized that it's all about balance. Let's face it—ask *anyone* in health care and they will say that they don't have the resources, the time, or the staff that they need. Compliance is not unique in that way. *Everyone* could use more resources, more staff, more time. I've tried really hard to take those things out of the equation as much as I can. How can I do the best job I can with what I have? I would say that is my biggest challenge. How can I keep up and do a good job with what I've already got? And, when I can't, how can I get what I need? For me, I've made a conscious effort to give as much as I take.

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MH: You have been a member of HCCA for a very long time. Can you tell us when and why you originally joined? Why do you continue to be a member?

TL: I first joined HCCA in either 1999 or 2000 (I can't remember exactly). To be honest, I originally joined because I had no idea what I was doing. There was not a lot of information out there for health care compliance professionals. I remember when I tried to find out what a compliance officer was, someone told me, "It's kind of like TQM [Total Quality Management] but different." Yeah, thanks. That helps a lot.

But, I somehow found out about HCCA. HCCA was the only organization that I could find that actually had information that could help me be a compliance officer. After I became a member, I had access to additional resources that helped me set up my first compliance program. I originally joined so I could learn as much as I could about this emerging profession. That was way back when.

I continue to be a member because of the valuable information and resources that are available. I continue to be a member because of the ability it gives me to connect with peers. I continue to be a member to help me keep up with what is going on, so I don't miss something. I continue to be a member to have access to all the educational sessions that are offered.

MH: You are also Certified in Healthcare Compliance. When did you become certified and how has that helped your compliance program and your career?

TL: I originally became certified in 2004. For those people who know what health care compliance is, the certification is definitely recognizable. Those folks know what it is and know that it is not something that everyone has. Having that additional certification definitely helped me when I got the job at Hallmark Health System. Even for people who

don't know what CHC means, to be able to say that I have been a compliance officer for over 10 years—and that I'm certified by the largest health care compliance association in the world—makes folks listen.

MH: Do you attend the HCCA Compliance Institute or other national, regional, or local conferences? What benefit do you get from attending?

TL: I attend whenever I can and, when I can't, I always try and send other staff from my department. I find that these conferences, more than anything else that I do throughout the year, give me the tools and insight to succeed. I also find that these conferences are very affirming to me. While sitting through a session, I often have moments of, "Yes! I do that!" But, to be fair and honest, I also have moments of, "Oh, crap!" But, that's what I get out of the HCCA conferences. I get assurances that I'm doing a good job and I get insight into where I may need to focus more time and energy.

The ability to have that many compliance professionals in one place is also very helpful to me. As I said earlier, I report directly to the Board of Trustees. There is a tremendous benefit from peer relationships. Given the nature of what we do, there are not a lot of people that compliance officers can talk openly with. Often, we are working on confidential issues—things that we can't openly discuss with others at work. Being able to build relationships with other compliance officers who are in the same boat has been extremely helpful to me. Having the ability to bounce "hypothetical" situations off other compliance professionals who don't know the players is invaluable. I've connected with and met some great people at these conferences.

MH: How does HCCA best support the work you do? What more could HCCA do to support your work?



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TL: HCCA best supports my work with the materials, information, education, and connections. Providing the national and regional conferences has really supported me in my career. I would like to see more local conferences, but I understand that this is difficult to do, especially in an area like Boston where conference costs tend to be higher.

MH: We all know how stressful the role of the compliance officer is. What causes you the most stress and how do you deal with it?

TL: Stress is definitely an individual thing. For me personally, there is a huge difference between work stress and non-work stress. I know there are some folks out there who are going to want to kick me in the face for saying this, but work stress for me feels more like a challenge. If a crisis comes at me at work, I tend to kick it into high gear and try and figure out what I have to do to fix it. If I think about how much health care has changed, especially in compliance, and how much it is going to change, that gets me motivated. It's the non-work stress that I don't deal with as well. In my family, I am the only working parent. When I think about the future for my family and my kids, when I think about what would happen to them if anything happened to me, that's where I stress out.

I also tend to worry more about others when I see *them* stressed out. Let's face it—most people come to work every day and want to do a good job. They want to do the right thing. Most people do not come to work and say, "Today is the day I'm going to defraud

the federal government." Obviously, there are people out there who just want to commit fraud but, in my experience, I haven't had to work with them. And I hope I never do. It's when I get the audit letter and I have to call a meeting where I see the pharmacy director, the coding manager, the billing supervisor turn white and look like they're going to throw up—those are the instances that I have a hard time with. I hate to see people struggle, people who come in every day and do a really good job, but may have missed something—not on purpose—but missed something just the same. That's the part of my job that does not bring me joy.

MH: What do you enjoy most about working in the Compliance profession?

TL: I love what I do. Trying to narrow it down to the one thing I enjoy the most is difficult. I would say one of the things that I love is that no two days are the same. I love coming to work not knowing where I'm going to be or what I'm going to be doing. Like many people, I have a "To Do" list. I think the last time I checked everything off of that list was in the early 90s.

Everyone is different and what works for one person may not work for someone else. If I had a "task oriented" job that was the same every day, I think my head would explode. If I had to work with numbers day in and day out, I'm pretty confident that I'd have blood shooting out of my eyes. But, in the Compliance profession, I can work with numbers on Monday, deal with privacy

Let's face it—most people come to work every day and want to do a good job. They want to do the right thing. Most people do not come to work and say, "Today is the day I'm going to defraud the federal government."

issues on Tuesday, attend staff meetings to do education on Wednesday, start an audit on Thursday, and give guidance on a billing and coding issue on Friday. In between all of this, I can answer staff questions or read CMS guidance or the Federal Register. For me, I love the balance between the high-stakes, fast paced time and the relaxed and quiet “reading and research” time.

I love the fact that I’m involved in so many areas of the health system. I would not be happy if I was in a job where I sat at my desk all day long and didn’t interact with people. Being in Compliance, I sit on a lot of committees and I get out to the various sites as often as I can. I love that about my job.

MH: What has been your most memorable experience as a compliance professional?

TL: I had the honor of being the first in the country to go through an OIG Medicare Compliance Review. I had never been audited by the OIG before on any level, but one thing I knew was that the OIG audits consisted of a single “issue.” Imagine how I felt when I got the letter and there were *ten different audit areas* on it. “What the WHAT?!?!?!?” I got the fax on a Friday afternoon, a week before my vacation, so you can just imagine how relaxing *that* vacation was! Of course, now we know it’s what they do, but being the first in the country was, shall we say, a bit disconcerting. But, in all reality (cue more kicks in the face), once it was all said and done, it wasn’t that bad. The folks from the OIG were pleasant. Don’t get me wrong, I don’t wish an OIG audit on anyone and I wouldn’t be upset if I never had another one for the rest of my career. Did I like that there was a report posted to a public site that showed my hospital had to pay back thousands of dollars and that my name was on it? Heck, no! I took it personally and hated that my hospital, the place I was proud to be a part of, had to have their name out there like this.

But, while the OIG was on-site, was it weeks of living hell? No, not at all. It was me doing my job and them doing their job. It was one of the best learning experiences I have ever had. Again, I don’t wish it on anyone, but what I got out of it could never be taught “hypothetically.” I took that experience as an opportunity to try and improve how I do my job.

MH: What advice would you give to compliance colleagues who are new to the profession or considering entering the profession?

TL: A physician I worked with in the early 1990s had this philosophy about hiring: He always would try and talk the person out of the job. It sounded crazy to me at the time, but he felt that if the prospective employee was right for the position, he/she would not be scared away. I’ve used this to hire staff ever since. So, I would say to someone looking to enter the Compliance profession:

- ▶ If you are the type of person who needs a task-oriented job, this is not the job for you.
- ▶ If you are the type of person who likes to sit in your office and away from the “hustle and bustle,” this is not the job for you.
- ▶ If you enjoy knowing exactly what the day is going to look like, this is not the job for you.
- ▶ If stressful and high-stakes situations make you shrivel up in a corner, suck your thumb, and call for your Mommy, this is not the job for you.
- ▶ If you don’t like talking in front of large groups of people, this is not the job for you.
- ▶ If the thought of confronting physicians and executives with strong personalities makes you want to throw up, this is not the job for you.
- ▶ If you have a hard time speaking up and being objective, this is not the job for you.

On the other hand, if you can bring people from other departments together and work

together as a team to achieve a common goal, this is ideal for you. If you enjoy doing different things every day, if you like a fast-paced environment but don't need it every day, this is a perfect profession for you. If you are able to listen to what others are saying, but to ultimately come to your own conclusions based on facts and not subjective comments, you will do well as a compliance professional. If you have a good sense of humor and don't take yourself too seriously all the time, you could do really well in Compliance. In this last one, the emphasis is on "all the time." We all have to take ourselves seriously, but don't be afraid to laugh at yourself either.

MH: What is your hope for the future of the compliance profession?

TL: I hope the Compliance profession continues to grow, but not just in numbers. I would like to see it go in a different direction. We've heard for a while statements like, "Compliance is everyone's job." We know that compliance should be integrated into job descriptions and annual evaluations. That's true. But, what I would like to see is to have compliance integrated more at the ground level. Many compliance officers I know attend general hospital orientation and do a little dog-and-pony show about the compliance program. Most of us also have annual mandatory education programs that include compliance. But, what I would love to see is to have *all* health-related professions have a class on compliance. Not just a workshop or a one credit elective, but a full class. Physicians, nurses, coders, allied health professionals—all positions at all levels of the health care system that require either a license, certification, or special education should have to take a course on compliance as part of the educational program.

MH: Thank you for sharing your insights with us. ☺

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A man in a dark suit and white shirt is standing in a brightly lit hallway, looking upwards and to the right. The hallway has a polished floor and fluorescent lights on the ceiling. In the background, a person is walking away from the camera.

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by Shawn DeGroot, CHC-F, CCEP, CHRC

Don't judge a book by its cover

Shawn DeGroot (shawn.degroot@navigant.com) is an Associate Director at Navigant Consulting in Denver. Shawn also serves as President of the HCCA Board of Directors.

Is anyone suffering from the Compliance Institute Blues? Well you may not be alone! There are two perspectives of people returning from a conference of more than 2,000 like-minded professionals. First and foremost, reconnecting with old friends, sharing “war” stories, and creating new relationships in a safe environment filled with laughter can regenerate your passion for the field. Conversely, returning from the CI with an abundance of information, ideas gained from brainstorming, and examples of effective or ineffective compliance can sometimes create an overwhelming feeling of “where to start and what to focus on?”



DeGroot

Hopefully, you returned home with fresh new ideas and I really hope you selected a book to read from the CI. If you have found an excellent book on compliance, auditing, ethics, or fraud, consider purchasing a book for each of your Compliance and Audit Committee members of the board. Or, if your budget will not allow purchasing a book for everyone, buy one for the chair. View the expense as an investment toward their education and understanding of compliance. Board members are typically highly intellectual and/or successful business leaders in the community. Select a book that could drive home a point you have been trying to explain or help the board develop an understanding.

If it is management that you need to reach, purchase one book. Use it as reference material when you speak about regulations, culture, or transparency, and house it in your office for managers to check out.

Finally, the last thought on using books from the CI would be to start a book club. Yes, I understand. Who would start a book club on auditing? Read the prologue before you judge a book by its cover or title. In fact, I would avoid purchasing a book for a board member with any reference to compliance on the cover. Rather, select a book like *The Immortal Life of Henrietta Lacks* by Rebecca Skloot, which is based on a true story of human subject research without compliance and Institutional Review Board processes in

If it is management that you need to reach, purchase one book. Use it as reference material when you speak about regulations, culture, or transparency, and house it in your office for managers to check out.

place. Even if you are not in research compliance, the book can provide insight when compliance infrastructure or transparency is non-existent. For a topic on compliance, quality, and retaliation try *Waking Up Blind* by Dr. T. Harbin. I tabbed the book with every instance where quality intersected with compliance, and I tabbed (with another color) the issues that may have had different outcomes if an effective compliance program was instituted. The process of tabbing the various compliance issues made me realize that we don't always comprehend the significant degree of impact of compliance and ethics programs. ©



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by Alice G. Gosfield, Esq.

Quality fraud: Two pathways to trouble

- » Exclusions, civil money penalties, and false claims charges have been imposed for provider quality failures in the past.
- » The OIG and Department of Justice now have a more refined and developing focus on quality process failures by hospitals and physicians.
- » Provider quality reporting is a separate basis for false claims liability.
- » It is only a matter of time until whistleblowers hone in on these two new targets.
- » Providers can take proactive steps to avoid trouble.

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

The fact that quality is increasingly being touted as a basis for liability under the fraud and abuse laws is fairly well recognized in the compliance community.

What is less well recognized are the developing bases, activities, and theories of liability,

which are being deployed both by the Department of Justice and by the Office of the Inspector General (OIG). Whistleblowers will not be far behind. This article looks first at traditional bases for enforcement for quality and then at the developing context for failures associated with (1) clinical processes themselves, and (2) quality reporting.



Gosfield

Traditional quality fraud

In terms of quality failures, it has long been the case that providers can be excluded from Medicare for providing items or services (whether or not they are eligible for benefits under Medicare and Medicaid) which are substantially in excess of the patient's needs.¹ This was the basis for the threatened exclusion of the Redding Medical Center² and for the facilities that have been involved in recent

high-profile cases involving overuse of stents. In addition, providers may be excluded for providing services which fail to meet professionally recognized standards of care.

In addition to exclusion, a range of civil money penalties can be imposed for quality deficiencies. These include claims for a pattern of medical items or services that a person knows or should know are not medically necessary.³ A person who provides false or misleading information that could be expected to lead to premature discharge also faces civil money penalties.⁴ Where hospitals make payments to physicians to reduce services, even off a baseline of overuse, both the payment and the acceptance of the payment are subject to civil money penalties.⁵ And physician incentive plans that put physicians at substantial financial risk—which entails a swing of 25% from the lowest to the highest amount the physicians could be paid—can also be subject to civil money penalties.⁶

Quality has been the basis for large false claims settlements involving criminal pleas, including United Memorial Hospital in Michigan, where the hospital paid more than \$1 million in settlement of claims for medically unnecessary anesthesia pain management services.⁷ During Jim Sheehan's tenure as an Assistant U.S. Attorney in

Philadelphia (1980-2007), he identified implicit quality issues as subject to false claims, such as whether services were medically necessary or met all quality requirements, including that the personnel were appropriately supervised, the supervising personnel were appropriately trained, and the personnel had appropriate clinical privileges.

More recent focus by enforcers

The OIG's Work Plans began mentioning quality and patient safety in 2003, although every single model compliance guidance mentions quality. In 2007, the OIG and the American Health Lawyers Association (AHLA) jointly published a document regarding "Corporate Responsibility in Health Care Quality" which was hospital focused, but the principles in it can be applied in many other health care settings.⁸ There, the OIG distinguished between general fiduciary responsibilities and a duty to act, as in the board's responsibility for medical staff credentialing. Taking the position that oversight of the health care business enterprise entails quality as part of the core mission and that quality is linked to cost and payment, the document offers ten questions boards should ask, focused around a range of concerns that are increasingly of interest to the OIG. These include goals, benchmarks, and metrics for quality; policy standards and integration of quality assurance in corporate operations; reports to the board on performance and quality concerns; integration of quality improvement with compliance; resource

allocation and support for quality improvement; and response to adverse events.

As compliance professionals know, the presence of a topic in the OIG's Work Plan does not mean that enforcement will be immediate. Rather, this is more in the nature of telling the class what to study for on the exam. Usually, issues are included in the Work Plan when Medicare Administrative Contractors or other audit agencies have identified problems or the OIG in its auditing activities has found anomalies. Often, issues in the Work Plan carry forward from year to year. These issues are especially meaningful and should be taken seriously as matters for preventive action.

In the 2009 Work Plan, OIG announced that it would conduct a study of "never events" in hospitals (including the types of events and payments by any party for them) and hospital

...the presence of a topic in the OIG's Work Plan does not mean that enforcement will be immediate. Rather, this is more in the nature of telling the class what to study for on the exam.

compliance with CMS requirements associated with present on admission (POA) coding. This theme continued in 2010 with a focus on POA coding, and a review of adverse events (defined to be broader than "never events"). Here, the OIG considered national incidence among beneficiaries, methods to identify events, and

review of CMS methods to implement policies on hospital-acquired conditions (HACs) in the field. They also reviewed responses of state survey and certification agencies, state licensure boards, and Medicare accreditors to adverse events, while reviewing policies and practices of CMS and selected patient safety organizations for disclosing information about adverse events.

The Work Plan in 2011 included continuing study of adverse events, review to determine which types of facilities are more frequently transferring patients with certain POA diagnoses, and a continuing review of hospital-acquired conditions (HACs). The 2012 Work Plan included continuing review of the types of facilities transferring patients with POA conditions, but moved also to a study of whether specific hospitals transfer patients with POA conditions to other hospitals. The most recent 2013 Work Plan explicitly calls out ambulatory surgery centers and hospital outpatient departments for a review of the safety and quality of care, including in preparation for and during procedures, as well as identification of adverse events.

OIG has also recently created a quality-of-care Corporate Integrity Agreement webpage⁹ which parallels the regular Corporate Integrity Agreement (CIA) webpage.¹⁰ These quality-of-care CIAs have all of the features of the basic CIA plus retention of peer review consultants. To date, two hospitals and five nursing homes are operating under quality-of-care CIAs. In the nursing home context, the general problems are underservice or failure to staff adequately. By contrast, in the hospital setting, the issues are excess procedures as in the over-stenting cases.

Quality reporting as false claims

Even before the Patient Protection and Affordable Care Act (health care reform), physicians, hospitals, and others found themselves in an environment of increased

reporting regarding their quality performance. For physicians, this is predominantly in the Physician Quality Reporting System (PQRS), and for hospitals this includes reporting of adverse events as well as inpatient and outpatient core measures.

At the same time, states have increased requirements to report adverse events as well as implementing state report cards and commercial pay-for-performance programs.

At the same time, states have increased requirements to report adverse events as well as implementing state report cards and commercial pay-for-performance programs. Even during the era of Jim Sheehan's role as an Assistant United States Attorney, the Department of Justice

was focused on false data reported, false statements in support of a claim, false statements to avoid repayment to the government, and any false statement made in the mail or via a wire.

Interest in reported quality was identified in the OIG/AHHA paper, specifically citing quality reporting and measurement, and noting concerns about inconsistency in data and identification of quality problems not acted upon. Those issues are, of course, subject to the "intent" standards that include claims submitted by a provider who should have known of their falsity or acted in "reckless disregard" or "deliberate ignorance" of the truth or falsity of the claims.

The 2009 Work Plan identified the reliability of hospital-reported quality measurement data. The 2010 Work Plan continued to review that reliability; and in 2011 and 2012, expanded to a study of the extent to which hospital systems captured adverse events in 2010 and reported them to external agencies. Study of the reliability of hospital-reported quality measure data also continued.

Whistleblower risks

As whistleblower claims have continued to thrive and expand, these new avenues of potential false claims open the door to additional whistleblower cases. Medicare hospital claims data is publically available. The pneumonia upcoding cases of a number of years ago came from a Freedom of Information Act request where a consultant analyzed the claims data. A Washington DC district court has ordered Medicare physicians' claims data to be released.¹¹

Given the government's emphasis on implicit falsity in claims, the types of issues that insider whistleblowers might allege could include:


- ▶ an insufficient number of nurses assigned to a unit to render appropriate care;
- ▶ unavailability of resources required by clinical practice guidelines;
- ▶ inadequate equipment;
- ▶ untrained, unqualified personnel performing skilled services;
- ▶ inadequate supervision; or
- ▶ failure to provide the six planks of the Institute for Health Care Improvement's "100,000 Lives Campaign" of several years ago.¹²

For physicians, it is only a matter of time until whistleblowers target the same under-service issues by them. By the same token, given the "Choosing Wisely" campaign¹³ regarding unnecessary medical services, whistleblower claims on the overuse side of the continuum can also be expected.

Action steps

These developments make it clear that compliance professionals need to integrate quality-relevant liabilities into their work. The first step is to become familiar with the quality metrics, report card, and transparency initiatives relative to your enterprise. Making

sure you know what data populates them will be critical. Find out who in your business is reporting what and to whom about quality. It will be increasingly important to monitor reportable data for accuracy, consistency among reports, timeliness, completeness, and clues to other problems. It would be wise to develop a plan in this regard. Carefully review any marketing or advertising for quality claims. Jim Sheehan has traditionally referred to these as "promises made but not kept." Include quality-relevant and enforcement challenges in your compliance program. Team up with Risk Management and Quality Assurance to collaborate on these issues.

Finally, in today's world, where alignment between physicians and hospitals is an increasingly major strategic emphasis, true clinical integration that incorporates explicit standardization of care to deliver high quality and value can help prevent liability and will be important to succeed in an ever-more-dangerous landscape.¹⁴ 

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by Adam H. Greene, JD, MPH and Rebecca L. Williams, JD, RN

Complying with the new HIPAA Omnibus Rule: Part 2

- » The definition of business associate has been broadened.
- » Business associate agreements are required for all qualifying, downstream subcontractors.
- » Direct and vicarious liability for non-compliance has been increased in scope.
- » Patient rights to access and restrict PHI disclosures are expanded.
- » Enhanced enforcement of noncompliance due to willful neglect is likely.

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This is the second part in a two-part series designed to assist you in understanding the new rule. Part 1 (in our May 2013 issue) focused on changes to the breach notification standard and new limits and flexibility on uses and disclosures of PHI. Part 2 explains new requirements for business associates and subcontractors, enhancements for patient rights, and enforcement clarifications.

On January 17, 2013, the Department of Health and Human Services (HHS) released the long-awaited “Omnibus Rule,”¹ which amends a wide range of privacy, security, and breach notification requirements under the Health Insurance Portability and Accountability Act (HIPAA)² and the Health Information Technology for Economic and Clinical Health (HITECH) Act.³ The Omnibus Rule represents the most comprehensive set of changes to the HIPAA regulations since their inception, and it is important to understand how the changes apply to your organization.

Expansion of the definition of “business associate”

Covered entities, business associates, and subcontractors are facing a new world. The Omnibus Rule modifies the definition of a “business associate” to include an entity that “creates, receives, maintains, or transmits” protected health information (PHI) on behalf of a covered entity. This expanded definition seems likely to bring certain organizations into the business associate fold that previously may not have been affected, such as certain document storage organizations.

The Omnibus Rule also adds certain entities to the list of entities defined as business associates, including:

- ▶ Subcontractors
- ▶ Patient safety organizations
- ▶ Health information organizations (and similar organizations)
- ▶ E-prescribing gateways
- ▶ Vendors of personal health records that provide services on behalf of a covered entity



Greene



Williams

Business associate contracts

HHS emphasizes the continued need for business associate contracts, even though business associates now are held directly accountable for many provisions of HIPAA. HHS notes that business associate contracts are necessary to clarify and limit permissible uses and disclosures of PHI, ensure business associates are contractually responsible for activities for which they are not directly liable under HIPAA, and clarify respective responsibilities related to patient rights, such as access to PHI. Of note, each agreement in the business associate contract chain must be as-or-more stringent than the one above it regarding the uses and disclosures of PHI.

Covered entities likely will need to revise their business associate contracts to address some or all of the following:

- ▶ Require compliance with all applicable provisions of the Security Rule (not just the provisions set forth in the HITECH Act or the administrative, physical, and technical safeguards);
- ▶ Require reporting of breaches of unsecured PHI in accordance with the Breach Notification Rule (which encompasses both the timing and content of a business associate's breach notification to the covered entity);
- ▶ Revise provisions related to subcontractors (e.g., ensuring that the business associate passes on the same or more stringent restrictions to any subcontractor that creates, receives, maintains, or transmits PHI on the business associate's behalf); and
- ▶ Ensure that, if the covered entity delegates to the business associate any compliance obligations under the Privacy Rule (e.g., distributing the covered entity's Notice of Privacy Practices), the business associate will perform such obligations in



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compliance with the Privacy Rule as if the business associate were the covered entity.

Subcontractors

As noted above, subcontractors are among the entities the Omnibus Rule pulls into the definition of business associate. The Omnibus Rule defines a subcontractor as “a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.” This means that a subcontractor of a business associate that creates, receives, maintains, or transmits PHI on behalf of the business associate is now itself a business associate and subject to the same HIPAA provisions applicable to business associates. This does not mean, however, that a covered entity is required to enter into a contract or other arrangement with business associate subcontractors. Rather, a covered entity only needs to contract directly with the business associate with which it has a direct relationship.

Direct liability

The Omnibus Rule makes business associates (and business associate subcontractors) directly liable for non-compliance with the Security Rule and with some of the Privacy Rule requirements of the business associate contract. HHS explains that directly liability will flow from the following violations:

- ▶ Impermissible uses and disclosures;
- ▶ Failure to provide breach notification to the covered entity;
- ▶ Failure to provide access to a copy of electronic PHI to either the covered entity, the individual, or the individual’s designee (whichever is specified in the business associate contract);
- ▶ Failure to disclose PHI where required by HHS to investigate or determine the business associate’s compliance with HIPAA;
- ▶ Failure to provide an accounting of disclosures; and
- ▶ Failure to comply with the applicable requirements of the Security Rule.

Business associates also remain contractually liable for other requirements of the business associate contract.

Agency liability

Prior to the Omnibus Rule, covered entities generally could not be held liable for the actions of agents who were business associates if a valid business associate agreement was in place (there was an exception if the covered entity learned the business associate was violating its business associate contract and the covered entity failed to take appropriate action). The Omnibus Rule, however, eliminated the covered entity exception for business associate agents. As a result, HHS will be able to hold a covered entity liable for the actions of a business associate that qualifies as an agent.

In the Preamble to the Omnibus Rule, HHS clarifies that the essential factor in determining the existence of an agency relationship is whether the principal has the authority to control the questioned conduct of the agent in the performance of the agent’s duties. If the principal lacks that authority (e.g., the principal’s only recourse would be to modify the underlying agreement or sue for its breach), then the business associate will not be considered an agent and the covered entity cannot be held directly liable for the business associate’s conduct. HHS further noted that the existence of federal agency will depend on the facts and circumstances of each relationship. Federal common law has identified several analytical factors that must be considered:

- ▶ When, where, and why the agent acted the way it did;
- ▶ Whether an agent’s conduct was subject to the principal’s control;

- ▶ Whether the agent was doing something that typically is done by such agents; and
- ▶ Whether the principal reasonably expected the agent to engage in the questioned conduct.

A covered entity will need to be sensitive to whether a business associate may qualify as an agent. In particular, a covered entity should be cognizant of contractual provisions that authorize the covered entity to provide interim instructions that control how the business associate performs the service (e.g., the business associate will perform certain services “in the time and manner” as instructed by the covered entity). When a business associate is an agent, the covered entity should consider whether it is reasonably monitoring the business associate’s compliance obligations and whether any indemnification provision adequately protects the covered entity from potential liability based on the business associate’s conduct.

Implementation deadline

Business associates, like covered entities, must comply with the Omnibus Rule’s provisions by no later than September 23, 2013. The Omnibus Rule provides up to a one-year extension (until September 22, 2014) for updating business associate contracts that are not otherwise modified after March 26, 2013. Accordingly, for all business associate contracts that are modified after March 26, 2013, covered entities should ensure that such contracts reflect the Omnibus Rule (otherwise the parties will need to amend the contract by September 23, 2013). For contracts that are not modified after March 26, 2013 (e.g., evergreen contracts that are automatically

renewed each year), covered entities have until September 22, 2014 to update the contracts.

Expanded individual rights under the Omnibus Rule

Finalizing provisions of the HITECH Act, the Omnibus Rule provides individuals with greater rights to access electronic copies of their PHI and greater ability to restrict when their information is shared with health plans. Additionally, covered entities will need to revise their Notices of Privacy

Practices to reflect the Omnibus Rule’s new rights and restrictions with respect to PHI.

Expanded rights to access PHI

The Omnibus Rule has expanded an individual’s right to obtain an electronic copy of PHI stored electronically in a designated record set (e.g., medical records, billing records, and other records relied upon to make decisions about the individual). This is a relatively minor change. HIPAA already provided that an individual has the right to receive access in the form and format requested by the individual, if readily producible. If not readily producible, HIPAA previously required the covered entity to provide a hard copy. Under the Omnibus Rule, if an individual requests an electronic copy and the covered entity maintains the designated record set electronically, then the covered entity must continue to provide a copy in the form and format requested by the individual, if readily producible, but now must provide an electronic copy as a default if it cannot readily produce the requested form and format. For example, if a covered entity maintains an electronic medical record and the patient requests to receive

A covered entity
will need to be sensitive
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as an agent.

a copy of the medical record through a secure patient portal, but the covered entity does not offer such a patient portal, then the covered entity must provide the patient an electronic copy as a default (e.g., an electronic copy in PDF format provided on a CD or USB drive) rather than a hard copy.

The individual also has the right to direct that the copy of the PHI be transmitted directly to another person designated by the individual. A covered entity must comply with such a directive, as long as it is in writing, signed by the individual, and clearly identifies both the designated person and where to send the PHI. An authorization would not be required in such a situation.

As clarified in the Preamble to the Omnibus Rule, if an individual requests that a copy of his/her PHI be sent via unencrypted email, then a covered entity is permitted to do so, as long as the covered entity has advised the individual of the risks and the individual still prefers the unencrypted email. Covered entities may wish to document the individual's request and that the covered entity warned the individual of the risk in such circumstances.

Also, covered entities will have 30 days fewer to respond to requests for access when the information is maintained offsite. Previously, a covered entity had 60 days to respond to a request for access when the information was not accessible onsite. Under the Omnibus Rule, electronic and hard copy PHI, no matter where located, will need to be provided within 30 days (with a single 30-day extension permitted if the covered entity

provides notice of the delay to the requesting individual within the initial 30 days).

The Omnibus Rule also clarifies the fees that may be charged (e.g., the covered entity may only charge its costs for copies to individuals, even if state law permits a greater charge).

Right of individuals to request restrictions on PHI

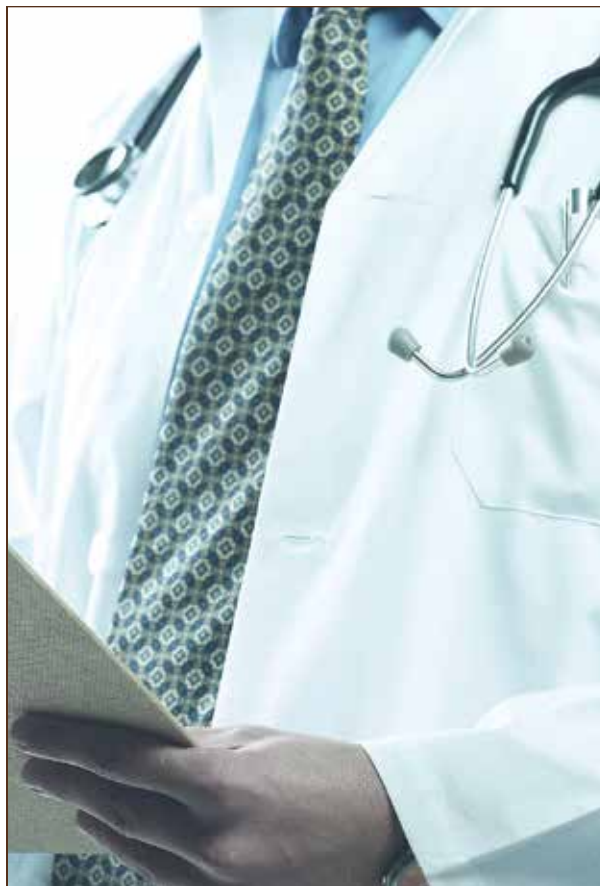
The Omnibus Rule incorporates the HITECH Act requirement that a covered entity comply with an individual's request to restrict uses and/or disclosures of PHI, such as disclosure to a health plan (or the plan's business associate) of his/her PHI that pertains solely to a health care item or service for which the health care provider has been paid out-of-pocket and in full. There is an exception to this right for disclosures required by law, such as mandatory claim submission provisions under Medicare and similar requirements under Medicaid or state law.

This right extends to situations where a family member or other person, including another health plan, pays for the service on behalf of the individual.

It may be advisable for providers to collect payment up front in connection with these requests, to the extent permitted by law. According to the Preamble, if payment by an individual making

a restriction request is dishonored, HHS expects providers to make a reasonable effort to contact the individual and obtain payment prior to billing the health plan. What efforts a health care provider must make is left to the

...the Omnibus Rule provides individuals with greater rights to access electronic copies of their PHI and greater ability to restrict when their information is shared with health plans.



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provider's policies and individual circumstances, consistent with its usual payment and collections processes.

With regard to referrals to and treatment by other providers in the future, it is the responsibility of the individual—not the provider—to notify subsequent providers of a restriction request. HHS, however, encourages providers to engage in dialogue with patients so that patients understand they may need to make the restriction request with a subsequent health care provider (e.g., a pharmacy) if they wish to avoid the information being disclosed to the health plan.

Updates to Notices of Privacy Practices

Providers and health plans likely will need to update their Notices of Privacy Practices (NPPs). These revisions include:

- ▶ The duty of a covered entity to notify affected individuals of a breach of unsecured PHI;
- ▶ The individual's right to opt out of receiving fundraising communications from the covered entity (only applicable if the covered entity uses PHI for fundraising and wishes to do so without authorization);
- ▶ The right of the individual to restrict disclosures of PHI to a health plan with respect to health care for which the individual has paid out-of-pocket and in full;
- ▶ The requirement for an authorization for uses and disclosures for marketing, sale of PHI; and for most uses and disclosures of psychotherapy notes; and
- ▶ In addition, most health plans will need to inform individuals of the prohibition against using or disclosing genetic information for underwriting purposes.

Covered entities also will want to review their NPPs to ensure that they accurately describe their privacy practices, especially in light of the Omnibus Rule's new requirements.

The requirements for distributing updated NPPs have been modified for health plans but not health care providers. Health plans may include their revised NPP in their next annual mailing (rather than within 60 days of the change) as long as they prominently post the revised NPP on their websites by the effective date of the material change to the NPP. Health plans that do not have customer service websites are required to provide the revised NPP, or information about the material change and how to obtain the revised notice, to individuals covered by the plan within 60 days of the material revision to the NPP.

Enforcement efforts continue to increase

HHS's HIPAA enforcement powers were significantly strengthened by the HITECH Act and the interim final enforcement rule.

The Omnibus Rule left intact much of the HIPAA enforcement approach with some additional expansion and clarification.

For instance, business associates (including their subcontractors) are now subject to civil money penalties and other enforcement actions for non-compliance with applicable provisions of HIPAA.

Another change under the Omnibus Rule provides HHS with discretion to resolve violations of HIPAA by informal means. Previously, HHS was required to seek informal resolution prior to imposing a civil money penalty. Under the Omnibus Rule, HHS may move directly to a civil money penalty, which may be especially likely when HHS determines that non-compliance is due to willful neglect.

The Omnibus Rule retains the definition of willful neglect as "conscious, intentional failure or reckless indifference to the obligation to comply" with HIPAA. The HITECH Act requires HHS to

formally investigate a complaint, which anybody can file, if a preliminary investigation indicates a possible (as opposed to probable) violation due to willful neglect. To implement that change, HHS amended the enforcement rule to eliminate its investigatory discretion in such cases, require a compliance review of the offending party, and mandate civil money penalties if willful neglect is found. HHS retains the discretion to investigate and to resolve complaints by informal means when there are not indications of willful neglect.

The Omnibus Rule also modifies the definition of reasonable cause, which relates to violations due to reasonable cause and not to willful neglect. Essentially, "reasonable cause" becomes anything where the entity knew of a violation (or through reasonable diligence would have known of the violation) but that

does not arise to the level of "willful neglect." HHS revised the definition of reasonable cause to ensure that conduct always fits under one of the categories upon which the level of civil money penalty is based.

Finally, HHS revised the factors that may be

considered in determining civil money penalty amounts. The factors are:

- ▶ The nature and extent of any violation, including the number of individuals affected and the duration of the violation;
- ▶ The nature and extent of any individual's resulting physical, financial, or reputational harm, including any hindrance to the individual's ability to obtain health care;
- ▶ The history of prior non-compliance, including similar prior indications of non-compliance and the offending party's responses to them;
- ▶ The financial condition of the offending party, including difficulties that could have

The Omnibus Rule left intact much of the HIPAA enforcement approach with some additional expansion and clarification.

affected compliance or that could cause a money penalty to jeopardize the future provision of health care; and

- ▶ Such other matters as justice may require.

Steps for responding to Omnibus Rule changes

Given the Omnibus Rule's expansion of HIPAA obligations to business associates and subcontractors, organizations subject to HIPAA should consider taking the following steps:

- ▶ Revising business associate contract templates;
- ▶ Revisiting which third parties are and are not business associates, based on the revised template (i.e., covered entities may have more business associates);
- ▶ Beginning the painful process of examining, amending, and re-negotiating business associate agreements, including considering what due diligence and monitoring may be warranted in light of potential liability for business associates that are agents; and
- ▶ Evaluating existing liability coverage in light of these changes.

To address changes to enhanced patient rights, organizations should consider taking the following steps:


- ▶ Updating NPPs to ensure that they accurately describe the organization's privacy practices, and advising individuals of their rights to request and to restrict disclosures of PHI under certain circumstances;
- ▶ Targeting relevant training (e.g., training persons involved in processing patient

requests for disclosures of PHI about patients' expended rights); and

- ▶ Implement systems to ensure that restricted PHI does not inappropriately go to health plans.

With respect to increased enforcement, covered entities may wish to:

- ▶ Perform a gap review of privacy, security, and breach notification policies, procedures, and training to comply with HIPAA (both new requirements of the Omnibus Rule and remaining requirements of prior HIPAA provisions) in order to avoid potential findings of "willful neglect";
- ▶ Review whether PHI is created, received, maintained, and transmitted throughout your organization and ensure that safeguards are working; and
- ▶ Focus on areas such as your Security Rule risk analysis, the protection of PHI on mobile devices, and the use of social media as areas that have been the subject of recent HHS guidance or areas that have become particularly high risk.

Organizations should remain mindful that they generally have until September 23, 2013 to comply with these new requirements. 

1. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5,566-5,702 (Jan. 25, 2013) (to be codified at 45 C.F.R. Parts 160 and 164).
2. Health Insurance Portability and Accountability Act of 1996, as amended, 42 U.S.C. §§ 1320d to 1320d-9.
3. Health Information Technology for Economic and Clinical Health, 42 U.S.C. §§ 17901 to 17954.

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by Kelly C. Loya, CPC-I, CPHT, CHC, CRMA and Cara Friederich, CPC-I, CPC-H

Billing compliance under the Incident To provision: What's the risk?

- » Medicare designed the Incident To concept to reimburse physicians for all care received in the office in addition to the physician's direct services.
- » Services billed Incident To require the physician to be present in the office during the entire service.
- » Government audits suggest concerns about the misuse of the Incident To provision.
- » Using non-physician practitioners for more than Incident To services makes good business sense.
- » Educating staff regarding the Incident To requirements is essential to compliance.

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Have you recently hired a non-physician practitioner (NPP) to assist the physician in the office? Working independently under their state scope of practice, NPPs can bring increased care opportunities, access, and revenue to a practice. However, with increased revenue potential comes increased risk. Pay particular attention to how those services are provided, documented, and reported for appropriate reimbursement.

Reimbursement for NPP services may either be captured at a reduced physician fee schedule (PFS) rate or at full PFS rates when billing NPP's services "Incident To" the physician's care. If you are considering Incident To billing, are you prepared to restructure patient care workflows appropriately? Is the supervising physician comfortable with the approach? If so, you must determine what changes are necessary for full compliance.

History

Let's first explore the Incident To concept. When Medicare was enacted in 1965, the program was designed to reimburse physicians caring for Medicare eligible beneficiaries. Since its inception, Medicare understood the physician alone was not responsible for all patient care. Auxiliary personnel, working in tandem with the physician, provide supportive services considered to be part of the physician's reimbursement and represent expenses to the practice. There was little finite direction regarding who could provide the supportive services. However, as long as the individual was qualified to do so under accepted clinical practice guidelines and state law, the concept would apply. Auxiliary services may include tasks such as administering injections, starting and monitoring infusions, performing blood pressure checks, providing patient education, etc. Services provided Incident To are also limited by location. Locations include outpatient freestanding



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offices (coded as Place of Service 11), a patient's home, or institutions other than a hospital or skilled nursing facility (SNF) according to the Medicare Benefit Policy Manual.¹

In the Balanced Budget Act of 1997, Medicare expanded the Incident To provision payment in a slightly different way. As a result, NPPs could bill for services traditionally restricted to physicians and be paid at the full PFS rate when certain criteria were met. The expansion increased beneficiary access to a physician's care. In addition, NPPs could render services, bill independently, and be paid at a reduced rate when Incident To criteria are not met when working under a collaborative agreement with a physician.

Medicare recognizes billing practitioners, such as physician assistants, clinical nurse specialists, nurse practitioners, certified nurse midwives, clinical social workers, clinical psychologists, registered dietitians, certified nurse anesthetists, and physical and occupational therapists within a physician office setting. Reimbursement rates vary for each practitioner when billed independently (see table 1).

Specific rules apply to each discipline. This article focuses on services provided by physician assistants, clinical nurse specialists, nurse practitioners, and certified nurse midwives. Billing Incident To for these practitioners requires the practitioner to be an employee, leased employee, or independent contractor whom the provider directly supervises and whose services represent a direct financial expense to the practice. When services are reported as Incident To, they are submitted on the claim by using the physician's National Provider Identifier (NPI), rendering the NPP's services essentially invisible on the claim. Today, no modifier is required on the claim to identify the NPP's services. However, if audited, the documentation must support the service followed all Incident To guidelines and limitations.

It is important to note that the Incident To provision applies only to Medicare reimbursement. State Medicaid programs may follow this guidance, but Medicaid and commercial payers may reimburse NPP services differently. Therefore, take the time to review each participation agreement, provider manuals, and contractual arrangements with your payers. Check state laws to determine what is expected and allowed with the various reimbursement models.

What are the requirements?

Medicare Benefit Policy Manual, Chapter 15, Section 60 provides a detailed explanation of requirements that must be met. The following is an abbreviated list of the requirements. Services provided Incident To a physician's service must be:

- ▶ commonly furnished in physician's offices;
- ▶ an integral part of the physician or non-physician practitioner's professional services;
- ▶ part of the patient's normal course of treatment; and
- ▶ an expense to the billing provider.

Practitioner Services	Percentage of PFS Payment
Certified Registered Nurse Anesthetist	50% when medically directed
Certified Registered Nurse Anesthetist	100% when non-medically directed
Clinical Nurse Specialist	85%
Clinical Psychologist	100%
Clinical Social Worker	75%
Nurse-Midwife	100%
Nurse Practitioner	85%
Nutrition Professional/Registered Dietitian	85%
Occupational Therapist	100%
Physical Therapist	100%
Physician Assistant	85%

Table 1: The specific non-physician practitioners included and the appropriate payment percentage of the physician fee schedule amounts

In addition:

- ▶ The billing provider (physician) must personally perform the initial service;
- ▶ The billing provider (physician) must be “actively involved” in the treatment course; and
- ▶ The provider must “directly supervise” the service during the *entire time* the service is performed. (This does not mean in each instance the physician needs to be in the same room when the NPP is rendering services, but rather present within the office suite and immediately available to render assistance, if necessary.)

Caveats

Each requirement is necessary, but several concepts are often a point of discussion.

Billing provider personally performs the initial service

This means the billing provider (physician) must have rendered the initial service in the course of the patient’s care. Whether or not the initial service was billed, it must have occurred and be documented. Therefore, the NPP billing Incident To the physician’s service may not bill for new patients or established patient’s new problems under the provision. The “new problem” area has been the subject of conversations. In general, if the physician within the established plan of care hasn’t addressed the problem, it is defined as a new problem.

Billing provider (physician) is “actively involved” in the treatment course

Historically, a good rule of thumb is to schedule the patient for a visit with the physician directly and often enough to assess the patient’s care and be involved with the treatment plan as needed. For your practice, this could be annually or every fourth visit, but likely more often, depending on the patient’s needs, nature of their condition, and/or

aggressive nature of treatment. The billing physician should agree and be comfortable with scheduled intervals and alter the normal minimum timeframe as the patient’s condition or treatment would require.

The provider must “directly supervise” the service

Yes, this does mean that if a procedure or service lasts for hours, the physician must be present in the office suite and immediately available if assistance becomes necessary during the *entire* procedure or service. Moreover, in the event of an audit, the practice should consider what evidence exists to support that the requirement was satisfied. Office schedules, provider in/out logs, signed attestation statements for each service, or some other method to substantiate their presence must be evident. The question to yourself should not be “How are they going to prove the provider was not there?” but rather “How will we prove the provider *was* there?” This can be a costly defense if you are questioned.

What is not allowed under Incident To?

- ▶ Incident To does not apply to a hospital facility location (i.e., hospital inpatient, hospital outpatient, SNF, or Emergency Department) for professional service billing:
 - NPPs may coordinate care or provide it as part of a team (split/shared approach) with the physician, but this concept has very different billing and documentation requirements; and
 - Supplies and auxiliary staff services are not reimbursable if the supply or staff was not an expense to the physician.
- ▶ A service where the billing provider has *not* personally performed the initial service is not considered meeting the Incident To provision.

- ▶ Services rendered when the physician is only available by telephone do not meet the provision.
- ▶ Services rendered when the physician is on campus at the hospital, not in the office, do not meet the provision.
- ▶ Residents or fellows providing services in the physician's office within a residency program are not Incident To services. They are billed using teaching physician's guidelines and have very different rules regarding billing and documentation.
- ▶ Residents or fellows may not supervise Incident To services in order to satisfy the supervision requirement.

What happens if the OIG comes knocking at your door?

Each year the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) develops their Work Plan for the upcoming fiscal year. The OIG Work Plan

identifies areas of relative risk and sets forth the OIG's primary objectives for the upcoming fiscal year. Incident To services have been on the OIG Work Plan for several years and remain a focus in 2013.²

In 2009, OIG identified providers that billed Medicare for services in excess of 24 hours on a single given day. Each provider was required to submit supporting documentation justifying the service billed to Medicare. In addition, providers had to submit valid credentials for the professionals performing the services. As you can imagine, this is a labor intensive and nerve wracking process for the physician office.

Auditing conducted by the OIG is quite beneficial to the Health and Human Services

program. Historically, the Centers for Medicare & Medicaid Services (CMS) said that for every \$1 it spends in audit activities, their return on investment is approximately \$11 from successful recoveries. Although the accuracy of that figure could be challenged, for FY 2012, OIG reported "expected recoveries of about \$6.9 billion consisting of \$923.8 million in audit receivables."³

Using NPP services

In many physician practices, it has been our experience that NPPs often provide services that could be rendered and billed independently. Rather, practices restrict the NPP's

schedule to patient visits that qualify for Incident To criteria. Perhaps it is simply overlooked, but more likely it is because expected reimbursement is less than if their time is used only for Incident To services. However, offering a schedule with a combination of

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visit types improves patient access to appropriate care within the NPP's scope of practice. New and established patient preventive visits and minor-to-moderate acute illness visits when the physician's schedule may not accommodate an immediate opening to address the need are good examples. Allowing the NPP to provide these services independently increases practice productivity and improves access to care and overall patient satisfaction when properly integrated into the practice schedule. In our experience, not only do physician's fail to take advantage of this strategy, but choose not to obtain individual provider numbers for their NPPs. This could be the biggest mistake when using NPPs' services.

Consider what could occur during a government audit for claims involving NPP services. If the findings indicate those services did not meet Incident To requirements, the entire claim constitutes an overpayment. Alternatively, if the NPP is credentialed with a NPI, the supervising physician or group could challenge the extent of financial responsibility. If the NPP has an NPI, claims that do not meet Incident To criteria could be considered “direct” services where at least a portion of the payment is appropriate reimbursement. In more simplistic terms, if services are initially billed Incident To but did not meet the Incident To requirements, payments could be considered overpaid by 15% versus 100% had the NPP not been credentialed.

Preparing the office for Incident To

Establishing a strong plan of action means deciding which suspected problems might pose the highest risk. Once identified, you must decide which of those can be resolved with little effort and resources, and then plan for those that require additional resources. A good implementation process involves everyone who could affect change while maintaining compliance. Suggestions for a plan of action include:

- ▶ Understanding the rules of Incident To is essential to billing compliance.
 - ▶ Having practice management review/ understand the guidelines and educate providers and staff on the Incident To provision.
 - ▶ Working with providers to create schedules for the physicians and NPPs that conform to the physical presence requirement during clinic hours.
 - ▶ Designating an individual to monitor physical presence daily during clinic hours.
 - ▶ Promoting post education feedback from the office providers and staff.
- What did they learn about the requirements for Incident To provision?
 - Did they have any concerns whether the practice is meeting those requirements today?
 - If so, do they have any solutions to improve compliance?

Because Incident To billing is transparent, a whistleblower situation may open the door to costly reconciliation to confirm that the requirements were historically met. Therefore, it is important to address concerns by providers and staff and document their responses and any course of action taken to correct weaknesses identified in a timely manner.

In summary

Realizing the benefits and resulting financial gain are possible when using NPP services can be pleasant; however, there are significant risks if the billing requirements for their services are not followed. Billing NPP services Incident To is an option, but not the only option to consider. For other clinical staff, such as medical assistants and nurses, Incident To billing is the only way their services can be billed in a physician practice. Verify that your practice understands how to bill and when appropriate reimbursement can be expected for Incident To services. Then review and integrate necessary steps to meet requirements and implement a workflow conducive to those requirements. 📌

1. Medicare Benefit Policy Manual, Pub 100-2, Ch. 15, Sec 60.1, 60.2, & 60.3
2. The 2013 OIG Work Plan is available at <https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf>
3. OIG Semiannual Report to Congress; Fall 2012. Available at <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2012/fall/sar-f12-fulltext.pdf>

Additional sources:

- Medicare National Coverage Determinations Manual, Pub 100-3, Ch.1, Part 1, Sec 70.3
- Medicare Claims Processing Manual, Pub 100.04, Ch.12, Sec 130
- Compilation of the Social Security Laws: Part E-Miscellaneous Provisions. Available at http://www.ssa.gov/OP_Home/ssact/title18/1861.htm
- Relevant parts of The False Claims Act. Available at <http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/smd032207att2.pdf>



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by Rebecca L. Frigy, JD, MPH

Navigating security concerns with clinician tablet usage

- » More and more clinicians are using tablets and handheld devices at the point of care.
- » Handheld devices are often lost or stolen.
- » Because these devices are often not password protected or encrypted, unauthorized access to PHI is a security risk.
- » Personal use of tablets and sharing them with family members also present security risks.
- » Health care organizations should take steps to address these security risks.

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The adoption and implementation of health information technology by health care providers has been a continuous effort by health care organizations and the government over the past decade; however, in more recent years the use of wireless, mobile technology has increased in popularity. In the 2012 HIMSS Mobile Technology Survey, 80% of respondents reported that physicians use mobile technology to provide patient care.¹ Mobile technology includes laptop computers, smartphones and cellular phones, tablets, pagers, and computer workstations on wheels.



Frigy

Specifically related to health care clinicians' use of tablets, a study by Manhattan Research in May 2012 found that 62% of physicians used tablets in 2012, with half of them using their device at the point of care.²

Physicians use tablets at the point of care for a variety of purposes, including to access web-based decision tools and reference materials, to learn about new treatments, to access and handle patient information (such as by connecting to an electronic medical record), and to utilize clinical mobile applications.

Physicians may also use tablets for communicating with patients via text, video, or e-mail.

The level of compliance risk related to clinician use of a tablet depends on whether or not protected health information (PHI) is accessed, transmitted, or stored using the tablet. Compliance with privacy and security laws and industry standards, particularly the implementation regulations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), present the greatest area of compliance concern. This article will identify common risks related to tablet use by clinicians, offer advice on implementing safeguards to help mitigate such risks, and set forth some suggested action items for addressing these privacy and security concerns. This article is not intended to identify all possible risks associated with tablet use by clinicians, but rather serves as a starting point to assist an organization in addressing these issues.

Although the risks set forth below are an issue for any type of mobile device that transmits or accesses PHI, handheld devices (e.g., iPads, smartphones) are set apart from more traditional mobile devices (e.g., computer workstations on wheels, laptops) because tablet and smartphone users often do not enter passwords prior to accessing information on the device, data stored on the device

is typically not encrypted, and these devices commonly connect to public Wi-Fi networks or unsecure cellular networks.

Common privacy and security risks related to tablet use fall into one of three categories:

- ▶ Loss of physical control of the device
- ▶ Unauthorized access or disclosure of data stored on the device or transmitted using the device
- ▶ Issues related to clinicians using personal devices for professional purposes

Loss of physical control

Physical control of a tablet or handheld device presents two risks: (1) loss or theft of the device, and (2) sharing the device with others. Loss and theft are common because such devices are small, light, and highly visible. Additionally, because of the high retail price and the level of consumer attractiveness, these devices are prime targets for theft. For the same reasons, it is also attractive for a tablet user to share the device with others, particularly those devices that are personally-owned, because the clinician may share the device with his/her family. (Additional risks related to personal ownership are discussed below).

To help mitigate the risks related to loss of physical control of the tablet, clinicians should take steps to prevent unauthorized use and access to data stored on the tablet, if the tablet comes into an unauthorized individual's possession. Note: Access of PHI by a health care provider's spouse or other family member, even if such information is not further

disclosed, would be considered impermissible access for purposes of complying with HIPAA (unless of course, the family member's use or access meets a permissible use or disclosure under HIPAA).

Mitigation steps and safeguards related to the loss of physical control of a tablet are as follows.

Encryption

Encryption means converting data into an unreadable or unusable format for anyone who does not have the "key" to unlock it. Encryption technology is available for tablets, which come standard with built-in encryption hardware. Users can download additional encryption applications for further improved

security. Prior to accessing or transmitting PHI using a tablet, clinicians should ensure that encryption applications that are consistent with the standards of the National Institute of Standards and Technology (NIST) have been implemented and are

enabled. Clinicians should also be aware of whether or not PHI stored on a tablet is encrypted during any backup data process, such as storing data on the "cloud."

Strong passwords

Clinicians who use tablets should employ strong passwords, both to unlock the device and to log into an application. A strong password is hard to guess and contains at least six characters in a combination of upper and lowercase letters, at least one number, and at least one symbol. In addition to using

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strong passwords, clinicians should not store passwords on the tablet, either in a separate password reminder file or in an automatic memory function.

Screen lock

Clinicians should enable the standard function on a tablet which automatically logs off the user or password locks the device after a short period of inactivity. In the event of the loss or theft of a tablet, this security feature may at least temporarily thwart unauthorized access to PHI and/or provide the clinician with enough time to remotely wipe PHI from the tablet, as described below.

Remote wipes and locks

Remote wipe features allow a user to erase data if the tablet is lost or stolen. Clinicians should enable remote wipe features on their tablets. This safeguard is particularly recommended in instances where a clinician accesses and stores PHI on the tablet.

Automatic lock following unsuccessful log-ins

Enabling the function which disables the tablet after a certain number of failed log-in attempts will also help to at least temporarily thwart unauthorized access until PHI can be remotely wiped from the tablet.

Properly deleting PHI from the device

Oftentimes a clinician may have temporary use of a tablet, either by checking out the device from his/her employer, or by deciding to “upgrade” his/her personally owned tablet for the newest version. In such instances, if the clinician stored PHI on the tablet prior to returning, discarding, or selling the tablet, all PHI stored on the tablet must be properly deleted. The Office for Civil Rights has issued guidance regarding the proper destruction of PHI,³ which includes: (1) using software or hardware to overwrite

media with non-sensitive data; (2) degaussing or exposing the media to a strong magnetic field in order to disrupt the recorded magnetic domains; (3) disintegrating, pulverizing, melting, incinerating, or shredding the media; or (4) any other method consistent with the NIST Special Publication 800-88, Guidelines for Media Sanitization, (Sept. 2012).⁴ Regardless of the type of destruction used, the clinician should retain documentation of the method of destruction, the date of the destruction, and the information destroyed.

Store the device in a secure area

When not in use, clinicians should store a tablet which contains PHI in a locked, secure location, such as in a locked desk drawer. Clinicians should avoid leaving a tablet unaccompanied in a vehicle or other off-site location. If it is necessary to leave a tablet in a vehicle, the tablet should be stored out of sight, locked in the vehicle’s trunk.

Unauthorized access or disclosure of data

Even when the device remains in the physical possession of the clinician, unauthorized access or disclosure of PHI can occur. These instances of unauthorized access may be attributable to viruses/malware, use of an unsecured Wi-Fi networks, or use of a mobile app that does not have adequate security and privacy safeguards in place.

Viruses/malware

Inadvertently downloaded viruses or malware can compromise PHI stored on a tablet, as well as the networks to which the tablet connects. Malware often infects a tablet when a user downloads a virus disguised as a game, device patch, utility, or other useful third-party application available for download. Malware and viruses may also be attached to emails or text messages that the user receives on the tablet.⁵ Malware and viruses



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compromise the security and privacy of information stored on the device by intercepting or accessing the information, collecting and sending information out of the device, or destroying the information. Clinicians should install, enable, and regularly update anti-malware security software that protects against malware and viruses.

Unsecured Wi-Fi networks

Users of tablets often connect to the Internet using unsecured Wi-Fi or cellular networks in public places. Use of such unsecured connections enables others to open, view, and even download information from a device using the unsecured network. Clinicians should be particularly aware of the security of the network to which they are connecting and should realize that using a password to enter a network does not eliminate the risk. When using an unsecured network, clinicians should use a secure browser connection (which is indicated by “https” in the website address)⁶ or a virtual private network (VPN). A VPN is built on top of existing physical networks to provide a secure communication mechanism for data and control information transmitted between networks.⁷ Installing and enabling firewalls on a tablet can also help protect against the risk of unauthorized connections by intercepting incoming and outgoing connection attempts and blocking and permitting them based on a set of rules.

Use of applications without adequate privacy/security policies

In the HIMSS survey, nearly two-thirds of respondents reported that clinicians use mobile applications developed by a third party. These mobile apps may be used for a variety of purposes, including to view patient information, to look up non-PHI health information, to receive clinical notifications, to collect data at the bedside, to use the bar code

reader on the device, to analyze patient data (e.g., EKG measures), to e-prescribe, to capture visual representations of patient data, to refer patients, or for educational/training purposes. As indicated in the HIMSS survey, the two most common uses of mobile apps were to view patient information and to look up non-PHI health information (e.g., accessing clinical guidelines).

Use of third-party mobile apps can present privacy and security concerns for a clinician, because some apps have the potential to compromise data that is stored on the tablet. Many mobile apps have the ability to gather data that is stored on the tablet and send it to the third-party app vendor for other uses. Prior to downloading and using a mobile app, a clinician should (1) verify that the app performs only the approved functions, and (2) closely review the app vendor’s privacy and security policies.

Additionally, many apps involve access to or the use of PHI to perform their approved function, and the third-party vendor of the app may have to access or maintain the PHI in order to support the approved function. If so, the third-party vendors may meet the HIPAA definition of a “business associate.” When this is the case, even though there may not be a traditional contractual relationship with the third-party vendor, a HIPAA business associate agreement must be in place with the third-party.

Instead of depending on clinicians to use their best judgment prior to using an app supported by a third party, health care organizations may want to implement a policy which prohibits the use of third-party apps unless pre-approved and thoroughly vetted by the IT department. Similarly, health care organizations may want to put together an “approved” list of third-party applications that have been thoroughly vetted by the organization for privacy and security concerns.

Personal use and ownership of devices

With the ever-increasing ownership of tablets among consumers and the lack of funding for health care organizations to provide their employees with mobile technology, clinicians are likely to use their personal tablets for professional purposes. Personal ownership of these devices presents several levels of privacy and security concerns. On one level, personally owned devices are less likely to have all of the suggested security features installed or properly enabled. On a different level, if a clinician uses his/her personal device to store or maintain PHI and then leaves the employ of the health care organization, the employer will lose control over the device and any PHI stored on the device. This leaves the PHI even more vulnerable to impermissible use or disclosure.

To help mitigate these risks, health care organizations should consider implementing policies for the use of personally owned devices in the professional setting. Such policies may require that clinicians register their personal devices before using them to access, transmit, or store PHI. The registration process may require that the device undergoes a security assessment in which the IT department ensures that all necessary security features have been installed and enabled. Further, the policy may even go as far as requiring the clinician to authorize a remote wipe of PHI stored on the device or in certain apps when the clinician's employment is terminated.

Suggested action items for health care organizations

As with any area where privacy and security risks are involved, it is not possible for a health care organization to eliminate compliance risk entirely. However, to help mitigate the privacy and security concerns related to clinicians' use of tablets, a health care organization may begin by taking the following strategic steps.

Perform a risk analysis and create a risk management strategy

To comply with HIPAA and identify the potential risks involved, a health care organization should conduct a risk assessment to weigh the risks and benefits of using tablets. The risk assessment and analysis should consider both devices that are personally owned and those that are owned by the organization. The risk analysis should also include the purpose of the devices used; how the devices are used to communicate with the organization's internal networks or systems; what information is accessed, received, stored, and transmitted by the device; and whether proper authentication, encryption, and other security safeguards are in place. Following an initial risk assessment, periodic risk assessments of tablet use should be performed.

Because of the likelihood for loss or theft of tablets, the risk assessment and risk analysis should assume that, at some point, a device will be acquired by malicious parties who will attempt to recover PHI either directly from the device or indirectly by using the device to access the organization's network.

Implement device policies and procedures

Health care organizations should implement policies and procedures that address the use of tablets by clinicians. More broadly speaking, such policies and procedures should address the use of all mobile devices by clinicians as part of the HIPAA policies and procedures that the organization already has in place. The results of the risk assessment should be used in implementing such policies and procedures. Following any privacy or security incident involving a mobile device, the policies should be reviewed and updated to address any shortcomings. As a starting point, mobile use policies and procedures may address:

- ▶ whether personal devices may be used and how the organization will track or register

- mobile devices, including procedures for when an employee leaves the organization;
- ▶ whether restrictions should be placed on remote access to the health care organization's network;
 - ▶ what security settings/safeguards will be required to be installed or enabled on mobile devices, including whether remote wiping/disabling will be required;
 - ▶ how the misuse of mobile devices will be addressed;
 - ▶ a process for reporting incidents involving mobile devices; and
 - ▶ methods of disposal or reuse of mobile devices.

Training and education

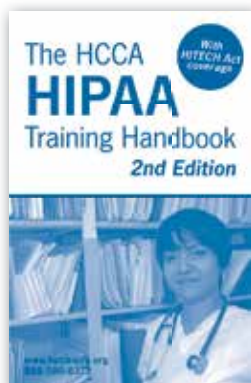
Again, as with any area where there is a privacy or security compliance concern, a health care organization should ensure that its workforce is appropriately trained and educated about its policies and procedures and the potential risks related to tablet use. Policies and procedures and required security safeguards are not effective unless the workforce is aware of them and understands them. Such training and education may be part of the health care organization's standard HIPAA training; however, upon initial implementation of mobile

device-specific policies, the use of mobile devices and compliance concerns should be separately highlighted to the workforce.

This article identifies general risks and suggests general safeguards. Health care organizations should implement policies based upon the use of tablets and other issues unique to their organization. Most health care organizations already have in place comprehensive policies and procedures to address HIPAA compliance; however, with the increased use of mobile devices, including tablets in the health care delivery setting, such policies need to address and accommodate the ever-evolving privacy and security risks that this "new" technology produces. ☐

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by Brian Santo, JD, MPH, CHC, PMP

Project management methodologies for an effective compliance program

- » Compliance programs can achieve sustained success through leveraging project management approaches.
- » The core of any project is the project management plan.
- » Consistent auditing and monitoring will promote an active approach to compliance program management.
- » A project manager must receive corporate buy-in on a project management approach.
- » Oversight, auditing and monitoring, and training are continuous elements of an effective compliance program.

Brian Santo (Bs90mph@gmail.com) is an Associate in the Washington DC office of Booz Allen Hamilton.

The use of a project management approach to accomplishing objectives has become a focus and area of growth throughout the business sector. Its application is wide-ranging, and has permeated the health care industry as well. The Project Management



Santo

Institute defines project management as “the application of knowledge, skills, tools, and techniques to project activities to meet project requirements.”¹ Project management is accomplished through the appropriate application and integration of various processes contained in the five process groups, which are, in order: initiating, planning, executing, monitoring and controlling, and closing.

Effective compliance programs are essential factors in accomplishing a culture of integrity within health care organizations. The compliance community often discusses various approaches to implementing an effective compliance program, often focusing on the seven elements (i.e., standards and procedures,

oversight, education and training, auditing and monitoring, reporting, enforcement and discipline, and response and prevention) from the Federal Sentencing Guidelines.

A project is technically a temporary endeavor to create a unique product, service, or result. Most projects are undertaken to create a lasting outcome. If a compliance program is to be effective for years to come, a planned methodology and clear set of priorities is necessary, and here is where the project management approach is used.

Concerns in compliance program operations

Significant improvements have been made in establishing compliance awareness and adherence in health care organizations. There remain, however, areas of concern. As compliance resources are often scarce, compliance activities tend to be reactive. Also, lack of a corporate culture and employee buy-in regarding compliance continues to be an issue. Compliance audits and training that address only a minimal level of effectiveness may not penetrate the essence of the organization.

It is clear that compliance programs require business investment and a need exists

to exhibit a positive cost benefit to investors and boards or directors.² To produce a high-functioning, effective, and reliable result, compliance officers can use project management techniques to accomplish the task.

Project management approach

Various project management methods, tools, and techniques can be used to create an effective compliance program. A project manager, likely the compliance officer, will head the startup of an organization's compliance program. He/she will establish that the core of any project is the project management plan. Developing the project management plan allows a project manager (or chief compliance officer, in our case) to document the actions necessary to define, prepare, integrate, and coordinate the project, as well as define how the project is executed, monitored and controlled, and closed.³ The project management plan will help ensure adherence to an implementation timetable and budget, and provide support for implementation of the corporate compliance strategy.

Other applicable project management approaches include identifying and limiting scope and prioritizing compliance initiatives. As part of this process, a risk identification and analysis should be performed, including identification of organizational process assets and environmental factors. A project budget and schedule is established to provide control. Other plans, such as the quality, human resources, communications, and risk management plans provide increased compliance plan

project structure, including assurance of quality standards, organization of internal staffing, management of stakeholders, and qualitative and quantitative analyses to identify and plan risk responses, respectively.

Audit and monitoring (and control) processes should be integrated into the project and a clear reporting format established. This strategy helps to ensure that the compliance plan syncs with the organization's existing policies and procedures and broader business goals.⁴

Getting the ball rolling

After a project manager is appointed, he/she should get buy-in from the board of directors to implement a project management approach to starting up the organization's compliance program. The project manager will serve as

the anchor point for implementing the compliance program by managing stakeholder expectations, delivering on objectives, and ensuring the program is continually adjusted to meet the needs of the organization. The project manager is able to view the situation from multiple angles. He/she is able

The project management plan will help ensure adherence to an implementation timetable and budget, and provide support for implementation of the corporate compliance strategy.

to respond to the issues that arise as tasks are carried out, draw on the correct resources to conduct the tasks, and re-focus the team as needed on the project objectives.⁵

After corporate and stakeholder buy-in, it is important to ensure clear deliverables as part of the project and state criteria against which these deliverables will be assessed, such as cost, timelines, and employee acquiescence to compliance standards. This is part of

the planning process. From here, compliance project execution, monitoring, and controlling can take place.

Finally, the project of implementing the compliance program can be closed. Of course, closing out the process of establishing the compliance program is just the beginning. Oversight, auditing and monitoring, and training activities are continuous elements of an effective compliance program.

Conclusion

Project management methodology provides a means for ensuring delivery of a valuable compliance program. Program effectiveness is also achieved by allowing resources to be

efficiently deployed and the introduction of a project manager ensures that the tasks are completed.⁶ Increasing acceptance of project management across various industries indicates that the application of its knowledge, processes, tools, and techniques can significantly impact project success.⁷ The health care compliance industry should not be an exception. ■

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by Kelly Sauders, Cheryl Golden, Nancy Toll Perilstein, and Joanna Haller

Surviving the ongoing focus on medical necessity and short stays

- » Create a multi-disciplinary “short stay work group” to address accurate level of care.
- » Review Medicare claims prior to submitting them and promptly correct those not meeting the requirements for medical necessity.
- » Verify that the patient’s status in the billing system matches the status ordered by the physician.
- » Verify accurate policies and procedures are in place and reflect current practice.
- » Assess the hospital’s denied claims, particularly current cases related to pre-pay reviews, to mitigate risk.



Sauders

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in the current environment, hospitals need to take steps that could help to mitigate the financial and compliance risks associated with medical necessity and short stays.



Golden

Driven by efforts to contain both fraud and growing costs, regulatory scrutiny of hospitals has increased significantly since the passage of the Patient Protection and Affordable Care Act (PPACA). One of the major areas under scrutiny in the hospital arena has been the issue of medical necessity and short stays, with the Centers for Medicare & Medicaid Services (CMS), the Office of the Inspector General (OIG), and even private payers rejecting claims or recouping dollars retroactively through audits for denials of short stay admissions. With an average of \$5,556 per Medicare claim¹ at risk for hospitals subjected to the CMS Recovery Audit (RAC) efforts for complex denials, this is clearly a serious financial risk. Further, the OIG and Department of Justice (DOJ) have at times pursued hospitals under the False Claims Act for overbilling related to short stay admissions. It is clear that,

The regulatory landscape

Over the past few years, the issue of medical necessity and short stays has risen to the top of many compliance officers’ list of risk areas. It is not hard to see why, with this being a focus by the RACs, OIG, DOJ, and private payers. Given the difference in payment between an inpatient case and an outpatient case, hospitals may face significant compliance risk and the potential for lost revenue if they fail to correctly assess and bill patient status. Recently, a hospital reached a settlement with the U.S. government for more than \$8 million to settle allegations of unnecessary short stay claims for Medicare and Medicaid.² This is just one of many recent settlements related to this issue.



Perilstein



Haller

However, “getting this right” can be easier said than done. Although some hospitals have taken steps to improve the accuracy of patient status assignment, others have not made noticeable progress on this front and remain “outliers” in the eyes of the government. And it’s not just current cases at risk; both the RACs and OIG continue to look at short-stay inpatient cases as far back as 2010 and sometimes earlier in the case of a false claims investigation.

A recent survey³ by the American Hospital Association (AHA) reported that approximately 1,300 hospital survey participants across the country continued to report increases in RAC activity (see Tables 1-3). According to this latest AHA quarterly report, relative to the prior quarter’s data:

- ▶ Medical record requests are up 21%
- ▶ The number of denials is up 23%
- ▶ The dollar value of denials is up 26%

According to the AHA data, the most common reason cited by hospitals for complex denials is for short stays that were deemed medically unnecessary. In fact, over 60% of short stays were denied for “medically necessary care provided in the wrong setting.”

As noted above, the OIG is also focusing on short stays. Indeed, many of the OIG’s Hospital Medicare Compliance Reviews⁴ show that the major driver behind the payment error rates is hospital short stays. These reports are a useful tool for hospital compliance officers because they highlight the risk areas and also provide insight into the government’s expectations with respect to short stays. Given the government’s apparent success with these audits, it is no surprise that this remains a focus area and this audit activity is ramping up around the country.

In addition to the OIG Hospital Medicare Compliance Reviews, the OIG and DOJ have initiated a number of investigations into

Table 1: Number of RAC Medical Record Requests

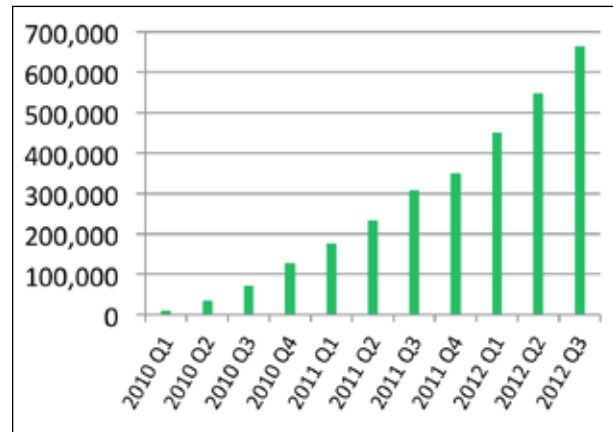


Table 2: Number of RAC Denials

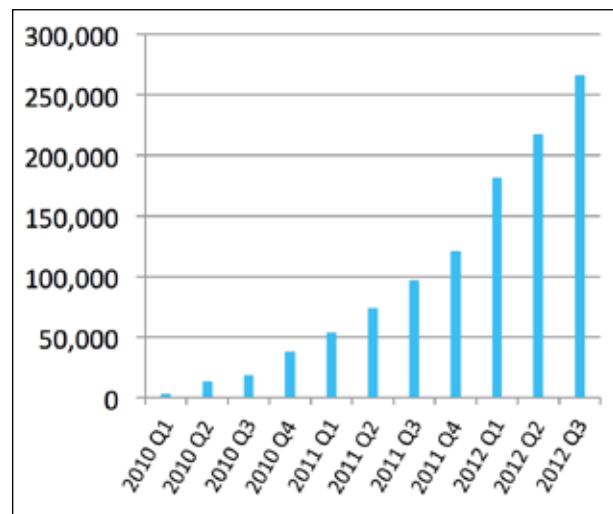
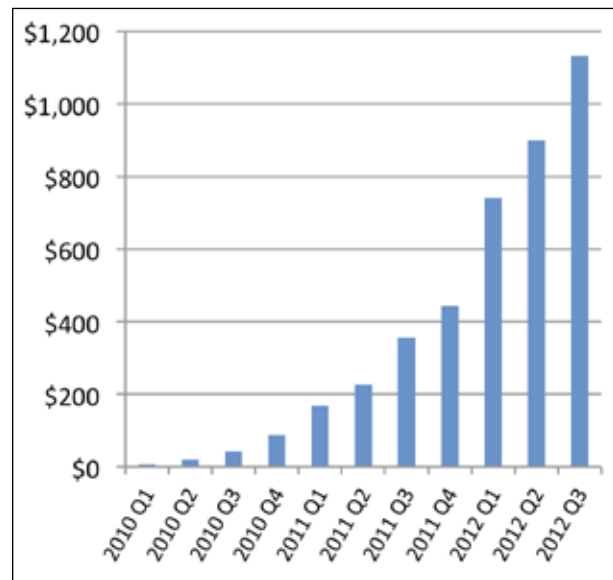


Table 3: Dollar Value of RAC Denials (in millions)



the issue of medical necessity of short stays. Several hospitals have entered into Corporate Integrity Agreements (CIAs) as a result of short stay settlements, and additional settlements may be on the way.

The area of medical necessity and short stays is complex. The Medicare appeals process may add to the complexity in this area. Administrative Law Judges (ALJ, the third level of appeal) and Medicare Appeals Counsel (the fourth level of appeal) have upheld denials of inpatient admissions but also ordered payment to the hospital as an outpatient, including observation services. In a July 13, 2012 memo,⁵ CMS recognized “There have been a number of ALJ decisions in recent months that uphold a claims administration contractor’s denial of inpatient services as not reasonable and necessary, but require the contractor to pay for the services on an outpatient basis at an observation level of care.” In this memo, CMS reminds providers that this applies to very specific ALJ decisions and noted it is not consistent with the Medicare Benefit Policy Manual and Claims Processing Manual instructions. CMS instructed that it should not be construed or interpreted as a change in the policy and to continue to follow existing policy and practices in all situations where there is not a conflicting ALJ order.

The AHA has also entered into the discussion. On November 1, 2012, the AHA issued a news release⁶ about a lawsuit filed by the AHA against the Department of Health and Human Services (HHS) for refusing to meet its financial obligations to hospitals for

services provided to some Medicare patients. Per the AHA, at issue is the HHS’s refusal to reimburse hospitals for reasonable and necessary care when the government, in hindsight, believes that such care could have been provided on an outpatient basis.

In the November 15, 2012 Federal Register, CMS issued the final Medicare Outpatient Prospective Payment System (OPPS) update for CY 2013,⁷ which included 350 public comments from hospitals related to rectifying the short stay problem. Comments included how to remedy the many well-known problems for providers and beneficiaries that result when a short stay later is found to be inappropriate. CMS summarized the comments, but did not respond and did not propose any further regulatory or policy changes.

The impact of short stay denials

Short-stay inpatient claims denials and recoupments for lack of medical necessity may have serious financial implications, because retrospective denials can result in total recoupment of the inpatient payment. Many of these inpatient claims could cost a hospital \$5,000 or more. However, if a Medicare claim is denied and the date of service was

...at issue is the HHS’s refusal to reimburse hospitals... when the government, in hindsight, believes that such care could have been provided on an outpatient basis.

more than one year prior, under the timely filing rules, CMS only allows hospitals to receive payment for limited Part B ancillaries. Inpatient ancillary services may be paid under Medicare Part B when the level of care becomes non-covered under Medicare Part A or when the Part A benefits are exhausted. Medicare Part B inpatient ancillary services include radiology, pathology,

electrocardiology, electroencephalography, physical therapy, speech pathology, renal dialysis, and medical supplies (e.g., prosthetic devices, braces, and splints.)

All of this presents significant financial, operational, and compliance challenges for hospitals, but this can also negatively impact patients. Patients who are not admitted and who remain in outpatient observation status (yet in a physical bed for one or more days) may face significantly higher out-of-pocket costs. Medicare co-insurance may be more costly than the Medicare inpatient deductible. This can also impact a patient's ability to qualify for Medicare coverage for a skilled nursing facility (SNF) or rehabilitation facility stay. Some hospitals, that may be trying to do the right thing, perform post-discharge reviews of short stays and "self deny" the inpatient hospital claims, but if a patient has already been discharged to a SNF, this can invalidate the patient's SNF Medicare coverage for post-acute care under Medicare Part A.

These billing issues cause frustration for patients and their families and can result in significant billing disputes between patients and hospitals. Patient billing disputes are increasingly familiar, and certainly underscore how this issue is causing confusion, frustration, and dissatisfaction within the industry for hospitals and their patients.

Why is it so difficult to get this right?

Hospitals face many challenges when trying to "fix" the short stay issues. One common challenge is that many hospitals don't have consistent processes and controls to ensure that the appropriate patient level of care (i.e.,

status) is determined at the time the patient is being hospitalized. Additionally, some hospitals may lack the case management staffing necessary to pre-screen patients or may not have access to tools like risk-based clinical criteria to evaluate a patient's level of care from the various points of entry. Other challenges include the fact that patients may enter the hospital and be admitted from many different points of entry, including the Emergency Department (ED), as a direct admission, as an unplanned admission following

a planned outpatient surgery, or as a transfer from another acute care hospital. To get this right, all of these entry points need to be well-controlled and managed with a consistent and compliant process.

The ED is particularly challenging, because many hospitals do not have the ability to keep patients beyond several hours in the ED, but may not have the appropriate units or beds (such as a clinical decision or observation unit) designated to manage short stay patients who need to leave the ED but are not appropriate for an inpatient admission. The ED documentation is critical to substantiate short stay admissions, but it can lack or may contradict the required elements to support the inpatient admission. Rather than documenting the risks or areas of concern supporting inpatient admission, it is common to see an ED discharge note that states "patient is stable." If this type of ED discharge note is soon followed by an inpatient admission order from an attending physician, external reviewers often point to the ED physician's discharge note as "evidence" that the patient was not sick enough to be admitted as an inpatient.

These billing issues cause frustration for patients and their families and can result in significant billing disputes between patients and hospitals.



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Further compounding the problem of short stays is the “disconnect” between hospital and physician coding and billing rules. Because of the disconnect, physicians are not impacted like the hospital when an inpatient claim is denied. Without appropriate case management support to advise physicians on the appropriate patient level of care and strong physician advisor support to intervene when there is disagreement, patients may end up being admitted to the hospital when they do not meet risk-based clinical criteria for inpatient admission.

If a patient is admitted inappropriately, hospitals still have an opportunity to identify and correct this error. If this is done while the patient is still in the hospital, the hospital may use Condition Code 44 when submitting the Medicare claim.⁸ This notifies Medicare that the patient was admitted, but did not meet criteria for admission. Hospitals must also notify the patient of any status change while they are in the hospital, since this may impact their financial obligations. In these cases, the hospital would then bill the episode as an outpatient claim. Frequent use of Condition Code 44 can be indicative of a break-down in front-end admission processes and may warrant further examination. If the hospital doesn't catch an admission error until after the patient is discharged, the hospital should avoid billing the claim as inpatient and must follow a series of complex billing rules, requiring it to submit multiple Medicare claims for the allowable outpatient services.

Improving performance and enhancing compliance

Hospitals can take some key action steps to potentially mitigate compliance risk with medical necessity and short stays. Some of these are discussed in more detail below.

- ▶ Forming a cross-functional oversight committee to lead the hospital's efforts to evaluate and enhance processes related to

short stay admissions can help get buy-in from the various stakeholders for process changes.

- ▶ Ensuring a leadership champion is in place to secure organizational support for changes to staffing, workflows, information technology, etc.
- ▶ Involving critical stakeholders, including case management, utilization review, and physicians.
- ▶ Involving the compliance officer to act as a regulatory and risk “advisor” and to play a role in monitoring and auditing of medical necessity short stay claims.

Cross-functional oversight committee

Given the complexity of the short-stay regulations and the degree of external focus, hospitals should consider addressing this issue immediately. Some hospitals have been able to successfully implement Medicare-compliant processes and controls by forming a multi-disciplinary “short-stay work group” to tackle this issue. A work group is typically comprised of at least one representative from hospital leadership (as an executive sponsor), case management and the Utilization Review committee (including a physician advisor), the ED, Admitting, Health Information Management, Patient Financial Services, Information Technology, Nursing, and potentially other highly impacted departments. The work group should meet on a routine basis and start with an understanding of current patient flow, how and when admission orders are created, what the hospital's short stay data currently reveals (e.g., Program for Evaluating Payment Patterns Electronic Report [PEPPER] and other internal data), and how case management is allocating staffing to key points of entry.

Involving critical stakeholders

Case managers play a critical role. The case manager's real-time, pre-admission review of

potential admissions for appropriate determination of the level of care (e.g., admit as an inpatient, place in observation, or keep as an outpatient) is essential. Case managers should consistently use risk-based criteria for screening potential admissions, be appropriately trained to use the criteria, and document results in real-time. Case managers should strive to review 100% of potential admissions before the physician order is written.

Managing patients who present to the ED can be the biggest challenge hospitals face with respect to medical necessity and short stays. Not all patients can be quickly treated and released, and some may not meet inpatient admissions criteria. Having an experienced and competent case manager pre-screening these types of cases in the ED is critical. Depending on the volume within a hospital's ED, more than one case manager may be required for some or all of the day. A case manager can facilitate the appropriate placement of patients within the hospital (e.g., admit, place in observation, or keep as outpatient) and should also be available to assist with the disposition of patients released to home, to a SNF, or to another safe discharge location. If a potential admission does not appear to meet the risk-based clinical criteria, the case manager should discuss the case with the attending physician on a timely basis and involve the physician advisor if needed.

Another important role is the admissions case manager who can facilitate the appropriate hospitalization of all patients who enter

from areas other than the ED. These include direct admits, transfers, and admissions from areas within the hospital, including surgery and other diagnostic or procedural areas.

When a physician calls the hospital to directly admit a patient, the call should be routed to an admissions case manager for assistance with appropriate determination of patient level of care (e.g., inpatient or observation). Another important role of the admissions case manager is to review all scheduled elective surgical admissions to assess patient status at least several days before a scheduled procedure. The surgical offices booking these procedures should be required to include the procedure code at the time of booking.

This will also allow the admissions case manager to compare the procedure code to the Medicare inpatient-only list and ensure that an inpatient order is obtained prior to these procedures. If a hospital inadvertently books these types of cases for Medicare as outpatient and does not obtain an inpatient admissions order, the hospital may not be able to bill for the case.

In addition to the case management role, a hospital's Utilization Review (UR) committee should also play an integral role in managing and monitoring short stays. Under the Medicare Conditions of Participation (COPs), hospitals are required to have an operating UR committee and UR plan. Further, Medicare guidelines require the hospital to perform an internal utilization review of any changes in patient status from inpatient to outpatient.

Managing patients who present to the ED can be the biggest challenge hospitals face... Having an experienced and competent case manager pre-screening these types of cases in the ED is critical.

As noted earlier, any admissions that do not meet risk-based criteria for admission should be promptly referred to a physician advisor designated by the UR committee.

The physician advisor reviews cases, speaks with the admitting physician, renders a final decision, or seeks additional UR committee input. The determination that an admission is not medically necessary can be made by one member of the UR committee if the treating physician concurs (or fails to present a view) or two members of the UR committee in all other cases. In all cases, as stated in the Medicare COPs, the UR committee must consult with the practitioner. In addition to getting involved in individual cases, many UR committees prepare robust agendas and also review the quarterly PEPPER, internal Medicare and RAC denial data, and other internal monitoring data related to short stay admissions and observation cases.

Key to having an effective process to manage short stays is the physician advisor role. Depending on a hospital's size and admissions volume, this may be a full-time or part-time role. Ideally, the physician advisor should have formal training in utilization review, compliance, and quality, and a solid understanding of the Medicare COPs and Medicare requirements. The physician advisor should work closely and collaboratively as a partner with case management.

Regardless of who is discussing patient status with the hospital's attending physicians, it is important to emphasize clear documentation in physician admission orders. A physician order to simply "admit" may not be sufficient to support an admission in the eyes of many external reviewers. Rather, the attending physician needs to clearly document the severity of signs and symptoms, a differential diagnosis, the clinical predictability of something adverse happening, and a plan for management of a patient who requires an inpatient setting. Unfortunately, physician

documentation for short stays can fall short of these guidelines, placing the hospital at risk for denial of the stay.

A hospital's clinical documentation improvement program can also help, but many of these programs only "follow" the patient after the first or second day of admission, rather than from the time the patient enters the hospital.

The role of compliance

As a compliance officer, you may choose to first evaluate your hospital's risk for medical necessity and short stays. A first step can be obtaining the latest PEPPER and identifying any areas where the hospital is an outlier with respect to short stays.

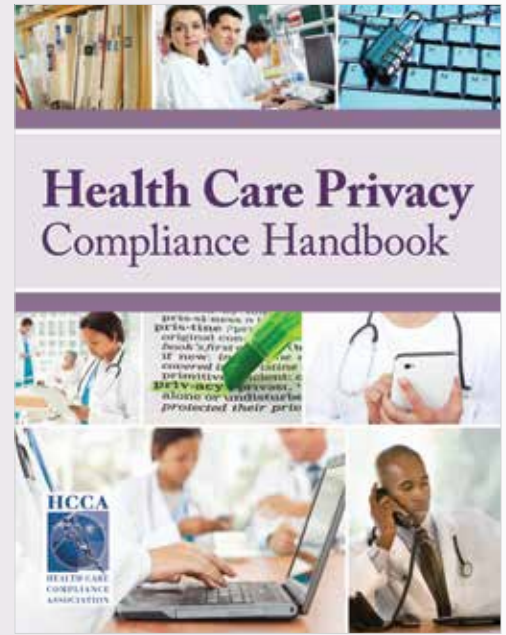
However, PEPPER data is six months old, so understanding the current process is also critical. One best practice is to inquire about case management presence in some of the key points of entry, as noted above, as well as any post-discharge reviews case management may perform on short stay discharges. It is also helpful to obtain the UR committee charter and work plan, and also read recent meeting minutes to see the extent to which short stays are being monitored by the UR committee. Another good source of information is current hospital performance on the Medicare pre-payment reviews from the Medicare Administrative Contractors (MACs). Patterns or trends in short stay denials related to certain diagnoses could indicate the need for further inquiry and controls.

Once you have an understanding of the data currently available, and have identified who is monitoring it and how key points of entry are being "controlled," you should develop a Compliance department plan for monitoring short stay hospitalizations. Some of this may be conducted via data analysis (e.g., Medicare volume of 0-1 day inpatient stays, observation stays greater than 48 hours,

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PEPPER results, Medicare pre-payment review results). Some hospitals have even used the PEPPER as a model to create an “Internal PEPPER” to assist with regular monthly monitoring. This can be done by following the instructions provided in the PEPPER relative to the calculation of the number of cases reported by type.

Conclusion

It is clear that the issue of short stay admissions may pose a high degree of financial and compliance risk. Given the intense scrutiny, it is important for hospitals to understand and take action as needed to mitigate this risk. As hospitals take steps to mitigate this risk, the compliance officer can play an invaluable role in serving as an advisor on regulatory matters, an internal consultant on new processes and controls, and a resource within the organization to support ongoing monitoring and auditing efforts. 

Note: This article was written prior to March 13, 2013, when 1455R was released.

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by Susan Haseley and Jeffrey Strauss

ICD-10: Payer and provider implementation strategies

- » ICD-10 impacts virtually the entire enterprise in both payer and payee organizations.
- » It is a massively complex undertaking that affects huge numbers of health care industry workers.
- » ICD-10 will yield significant benefits to patients, payers, and payees—including long-term savings.
- » Successful implementation depends on the collaboration of payers and payees to ensure that everyone has the same understanding of how the ICD-10 codes are used.
- » Create a structured, strategic blueprint for implementation that will deliver the best results and create the least disruption.

Susan Haseley (susan.haseley@protiviti.com) is Managing Director and Healthcare Industry Practice Leader with Protiviti in Dallas. **Jeffrey Strauss** (jeff.strauss@protiviti.com) is Associate Director and National ICD-10 Solution Leader with Protiviti in Chicago.

Implementation of the new ICD-10 codes that classify health problems and diseases has proved an enormous tactical and strategic effort for health care payers and providers alike. There is evidence that the health care sector is struggling with the task, particularly on the provider side, according to *Healthcare IT News*.¹ Many organizations are searching for a strategy that will allow them to implement the new codes with the least disruption to their business and their mission to provide appropriate care to millions of people.

Scope of the problem

The reason implementation of ICD-10 has been so difficult is that there is scarcely a department or position not affected by the change. From physician to medical technician, from chief information officer to coder, just about every employee of a health care-related organization is involved, the only exception being non-patient-care-related jobs such as cleaning staff or cafeteria workers. Everyone who touches a patient or is involved in the

payment process is affected, each somewhat differently.

ICD-10 will increase the number of codes for claims processing significantly. Diagnosis codes will grow from 14,000 under ICD-9 to 69,000 under ICD-10; procedure codes will expand from 3,000 under ICD-9 to 71,000 under ICD-10.² Somehow, around 1 million individuals and thousands of companies must succeed in shifting to ICD-10 in a consistent, coherent manner, such that everyone has the same understanding of how to use the new codes. Otherwise, both patient care and the insurance process could be disrupted, which may be costly and could impact the quality of care.

Rewards of implementing ICD-10

The rewards for successfully implementing ICD-10 are great, however. The Centers for Medicaid & Medicare Services (CMS) has outlined the following nine benefits resulting from the increased specificity and granularity of ICD-10:

- Measuring the quality, safety, and efficacy of care



Haseley



Strauss

- ▶ Designing payment systems and processing claims for reimbursement
- ▶ Conducting research, epidemiological studies, and clinical trials
- ▶ Setting health policy
- ▶ Planning for operations and designing health care delivery systems
- ▶ Monitoring resource utilization
- ▶ Improving clinical, financial, and administrative performance
- ▶ Preventing and detecting health care fraud and abuse
- ▶ Tracking public concerns and assessing risks of adverse public health events

Overall, ICD-10 can be expected to improve the quality of care and save money. In the meantime, estimates of the cost by health care providers range from \$50 million to more than \$100 million, and insurers' estimates range from \$38 million to \$1.7 billion. This is not small change, and poor implementation could drive costs even higher.

Strategy for success

Collaboration between the two sides of the industry promises successful implementation for both providers and payers. Corporations are typically not accustomed to sharing sensitive information about massive organizational change initiatives, but this may be the best possible way to tackle this huge and complex effort. If the people who record the ICD-10 codes on the provider side and those who interpret and act on the codes on the payer side have a common understanding of how to use the codes—and have gone through

training that inculcates the same processes and procedures—a successful outcome is far more likely. Conversely, if everyone hunkers down and insists on playing solo, misunderstandings and confusion will reign.

The *Journal of the American Medical Association's* blog specifically calls out payer/provider collaboration as the road to successful ICD-10 implementation. Noting that “the right hand feeds the left,” a recent blog post suggests that “this could be an opportunity for insurance providers to help their care provider partners who seem to be struggling with needs assessments, IT renovation plans, testing, and more.” The post concludes: “The good

news from a vendor standpoint, both sides are embracing they can't do this alone. Technology providers have the tools and knowledge to make all these regulations a reality—stabilizing the complexity while ensuring projects are completed on time and on budget.”³

A key area where payers and providers can collaborate is documentation training and coder management. As George Schwend, Chief Executive Officer of Health Language, Inc., notes:

...this is where collaborative partnerships between providers and payers could lead to the creation of co-strategies for limiting the risk of financial variance during conversion. With the conversion to the 5010 electronic transaction standards, the industry has already started conversations about the technical capabilities of each partner to exchange ICD-10 data, but the next step is to engage in conversations about the right codes to use. Without this

Collaboration between the two sides of the industry promises successful implementation for both providers and payers.

kind of strategic communication, contract negotiations and claims reimbursement could be adversely impacted. Because the ICD-10 conversion poses similar challenges and risks for all providers and payers, there is an incentive for both parties to work together to ensure that the transition occurs as seamlessly as possible.⁴

Payers and providers need to work together to develop formal guidelines for coding and mapping ICD-9 data to ICD-10 (and vice versa, because ICD-9 coding will still be in play until older documentation has moved out of the pipeline). Together, providers and payers need to come up with “crosswalks” that show how to get from ICD-9 codes to the new ICD-10 codes and establish general equivalencies. Payers and providers will then have a mutual understanding of how to treat the migration, and fewer errors and misunderstandings will result. CMS has established standard general equivalency maps,⁵ but they fluctuate depending on the region, type of hospital, type of provider, and type of payer. Therefore, they do not provide a road-map, but rather the foundation from which payers and providers can work together to establish guidelines.

The big picture

There are six key steps payers and providers should follow in undertaking the transition to ICD-10.

1. Create a plan to identify where and how ICD-10 affects the organization.

Most are aware of the impact on health information management staff and systems. However, ICD-10 will also affect every core process, system, interface, and associate in the organization: On the provider side, it will affect:

- Patient access
- Nurses

- Case managers
- Quality assurance
- Patient review
- Claims review
- Payer contract management
- Compliance
- Auditors
- Inpatient and outpatient coders
- Senior management
- Human resources

On the payer side it will affect:

- Senior management
- Analysts
- Nurses and physician advisers
- Actuarial staff
- Quality assurance utilization review
- Claims review and clinical coding auditors
- Medical management
- Customer call center staff
- Contract management
- Network development/provider relations
- Human resources
- Training

2. Talk with external advisers.

Even if the organization believes it can go it alone, it should consult external advisers and understand their perspective gained from working with other organizations.

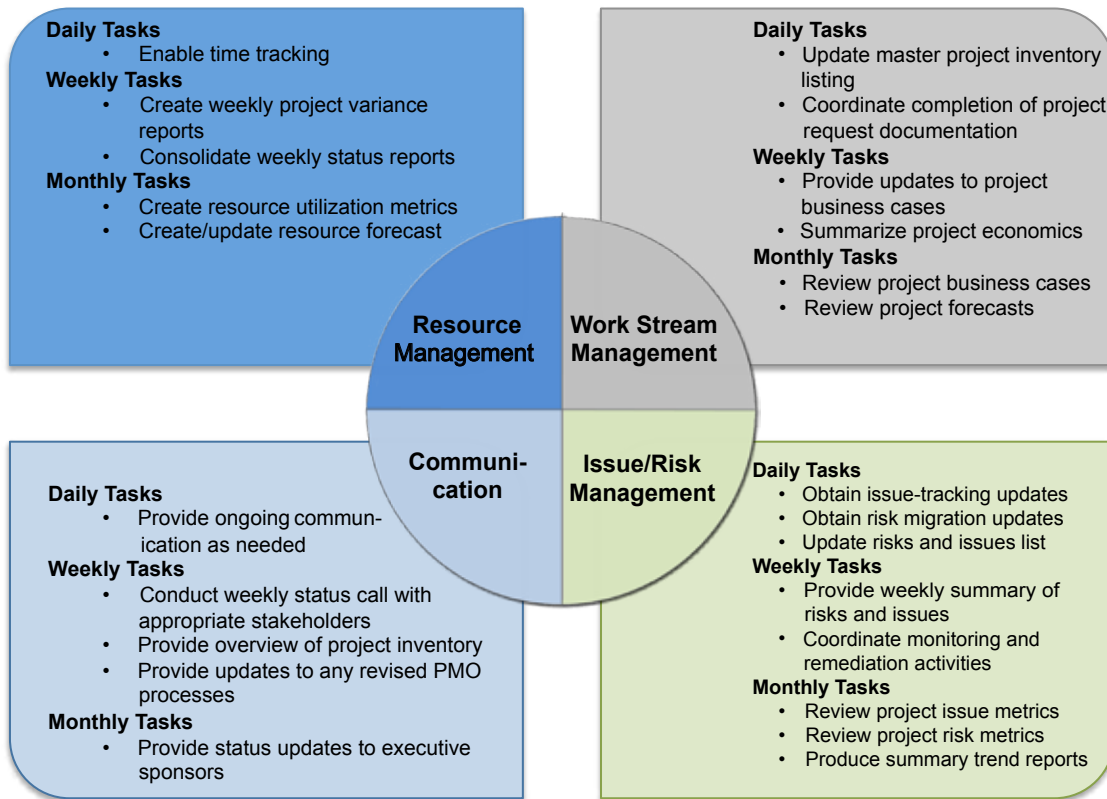
3. Consider the impact education will have on existing operations.

All staff will not require the same level of education. Technology platforms are emerging to assist with ICD-10 education efforts. Management and the existing ICD-10 implementation team should understand the education resources needed and what is available to them.

4. Remember your physician network.

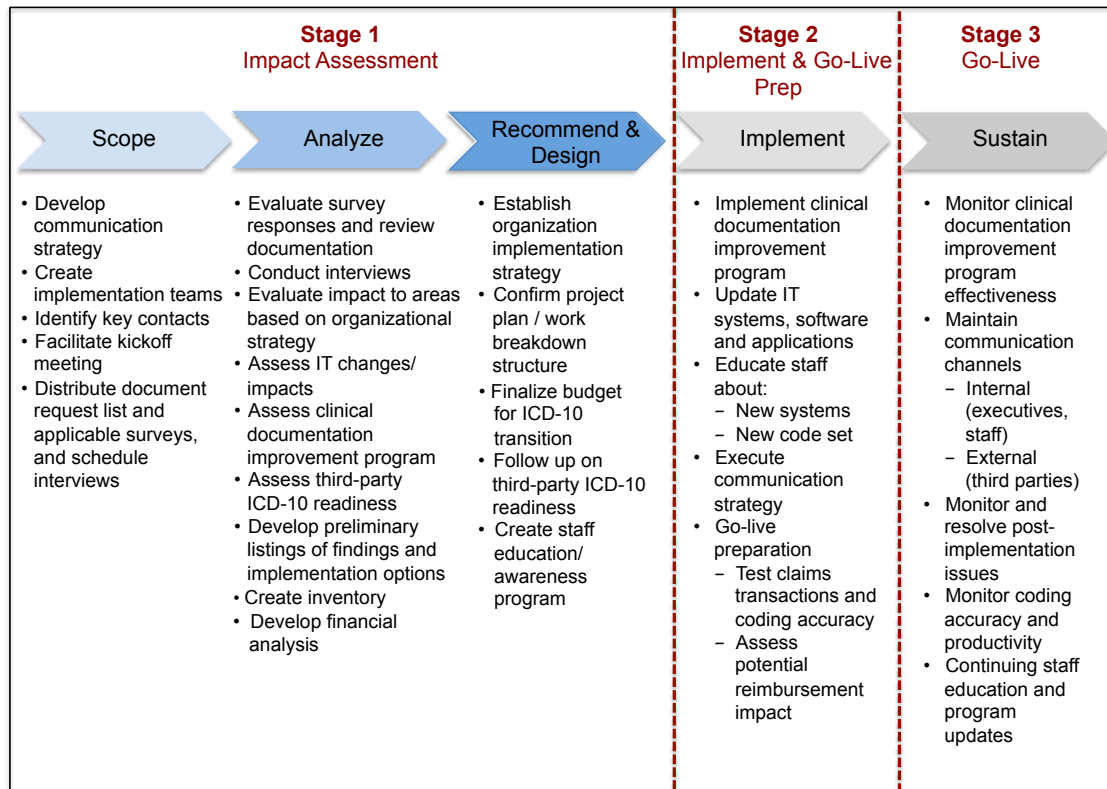
Employed physicians and their staff will be part of the plan. Given the Stark Law and other regulations, consider how independent physicians and their staff will participate in the training.

Figure 1: Responsibilities of the steering committee and subcommittees



Source: Protiviti Inc.

Figure 2: Blueprint for the steering committee



Source: Protiviti Inc.

5. **Think about contingency planning.** Many challenges will arise during the implementation process. Conduct a project risk assessment and scenario plan. Understand the potential for increases in unbilled accounts receivable, delays in reimbursement, reduced coder productivity, and increased denials.
6. **Don't overlook managed care contracts.** Expect to see "recoding" analysis efforts to gauge the impact of historical information using ICD-10, and expect managed care companies to use this information in negotiations. Payers and providers will be looking at all contracts where reimbursement is based on specific codes.

Implementation blueprint

The first step in implementing ICD-10 is to establish a steering committee tasked with overall responsibility for implementation. This should include representatives from every group affected. Subcommittees under the direction of the steering committee can work on the requirements of specific job functions and their needs for IT support, training, and processes.

There are four areas for which the steering committee has overall responsibility (see figure 1).

The steering committee will guide the implementation through three phases: impact assessment, implementation and go-live preparation, and go-live. Each of these phases are detailed in figure 2.

Every payer and provider should have an interdisciplinary steering committee, working together to plan and implement ICD-10 with as much awareness as possible of the needs and constraints of all functions affected. The old model of every department working in its own isolated silo must shift to a new collaborative model to ensure successful ICD-10 implementation with the least pain and the most gain possible. ☐

1. "Payers Outpace Providers on ICD-10," *HealthcareITNews*, March 15, 2012. Available at <http://www.healthcareitnews.com/news/payers-outpace-providers-icd-10>
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5. Centers for Medicare & Medicaid Services: *General Equivalence Mappings, ICD-9-CM to and from ICD-10-CM and ICD-10-PCS*. Available at <http://www.cms.gov/Medicare/Coding/ICD10/downloads/GEMs-CrosswalksBasicFAQ.pdf>

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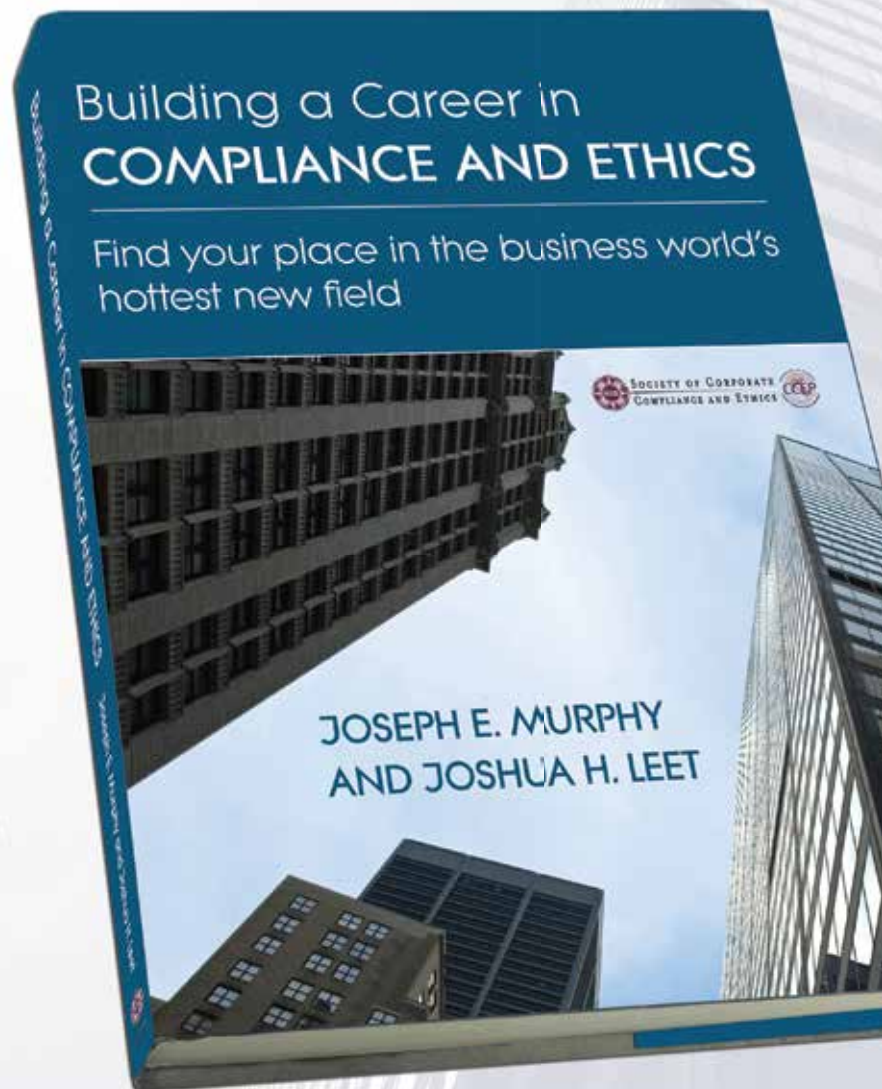
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by Leon Goldman, MD

Conflict of interest management after the Physician Payment Sunshine Act

- » The PPSA public database will not replace institutional self-disclosure.
- » Both public disclosure information and locally self-disclosed information will need to be monitored.
- » Organizations will need a process/system to collect public disclosures, compare to self-disclosed data, and resolve/explain discrepancies.
- » Presenting publicly disclosed information to the clinicians during their self-disclosure process will help improve the accuracy of their reports.
- » Having an easily downloadable, searchable, and aggregated database may change how disclosures are managed.

Leon Goldman (leon@kyru.us) is Chief Privacy Officer with Kyruus, Inc., in Boston.

The final rule of the Physician Payment Sunshine Act (PPSA) was published in the Federal Register on February 8, 2013.¹ Anxiously awaited by the health care industry and public alike, the publishing of the final rule brings to an end the uncertainty for applicable manufacturers and group purchasing organizations (GPOs) of whether or not they would be required to report. Now the challenge of trying to figure out how to collect and report the data begins in earnest. The rush is on for applicable manufacturers and GPOs to ensure their organization's processes and systems are ready and able to report the data to the Centers for Medicare & Medicaid Services (CMS) by the deadline of March 31, 2014.



Goldman

However, the publication of the final rule has not provided any more clarity for hospitals and physicians as to what exactly they need to be doing to prepare, nor does it clarify what

the impact of such reporting will be on them. Aside from providing an opportunity to review data posted about them, PPSA is silent about the objects of the disclosures, and it places no statutory obligations on them. As a result of the PPSA, a great deal of information about physicians' and teaching hospitals' financial interactions with industry (which has long been either unavailable to the majority of the public or at least difficult to come by) will now be readily available. While the impact of such availability is uncertain, it would be unwise for hospitals and physicians to completely ignore such information in the context of their conflict-of-interest assessment and management.

The standard process by which hospitals have monitored financial relationships with industry has relied almost completely on individual disclosure up to now. These disclosures have been collected on an annual or transactional basis triggered by specific events, such as seeking permission to perform research studies. However, proactive review of publicly available information has not been part of standard review for most institutions—often

because the perceived benefit of implementing such a process has not outweighed the cost of review, in both dollars and time. But that may be changing now as PPSA mandates not only the collection of a vast amount of information about “covered recipients,” but also the creation of an easily downloadable, searchable, and aggregated database, making the information readily available to anyone who wishes to see it. How and to what extent this will actually change the playing field is yet to be known; however, one can reasonably postulate that it will change the way organizations manage conflict-of-interest disclosures.

For the first time, this database (as best we can guess) will provide the public, regulators, and the media with ready access to a vast amount of information. Although some information is already available via select states’ reporting and approximately 50 companies currently disclosing, PPSA will significantly increase the amount of information available to the public.

At Kyruus, Inc., we project that PPSA will provide data covering:

- ▶ more than 3 million public industry payment disclosures amounting to over \$4 billion;
- ▶ more than 700,000 health care professionals indicated with public industry payment disclosures; and
- ▶ more than 1,500 companies disclosing payments

We have little doubt that agencies, such as the National Institutes of Health, will use the information as a way to “verify” what they are told by their grant applicants.² The media, too, will see the data as an interesting source of

information for investigative reporting. Lastly, individual patients and families will likely use the data to become more informed about their physicians and the relationships those physicians have with industry. Given all who will likely use the data, it behooves hospitals and covered recipients to be aware of the data.

As already noted, institutions and others have historically relied on physician self-disclosure to monitor relationships that might create

a conflict of interest.

However, many studies have shown that self-disclosure misses some relationships that may be relevant to administrators who are trying to assess the presence or absence of conflicts of interest.^{3,4} Our

internal work has shown that the discrepancies between self-reported data and publicly available records may be as high as 79%. The reasons for such discrepancies may not always be a conscious effort to deceive or hide a payment. In many cases, human factors that range from simply forgetting a specific payment or lack of clarity around the relevance of a given relationship may be the cause. However, it is clear that self-disclosure alone does not provide the most complete or most reliable information upon which to make decisions—and perception may be as important as reality when this discrepancy is revealed to the public or regulators.

Discrepancies will be further complicated by the report timing of the PPSA. Because the public database will be an after-the-fact event, such a public database will *not* relieve institutions of the need to gather information on their own, as they have been doing up to this point. This is because:

1. The annual posting of the data may not provide adequate information for organizations

...perception may be as important as reality when this discrepancy is revealed to the public or regulators.

- to fulfill their transactional obligations for events such as accepting payment from the Public Health Service for funded research.
2. The PPSA database will contain nothing about non-physicians receiving payments or transfers of value about which the organizational policies require disclosure.
 3. There may be payments to physicians that need to be disclosed under an organization's policies, but which are exempt from reporting under the PPSA and can only be discovered through an active disclosure process.
 4. Consolidation of reporting by manufacturers may make the information that is reported less useful to the institution for their assessment need. Again—the institution will need to continue to monitor data internally to understand what PPSA will mean for them and what they need to do.

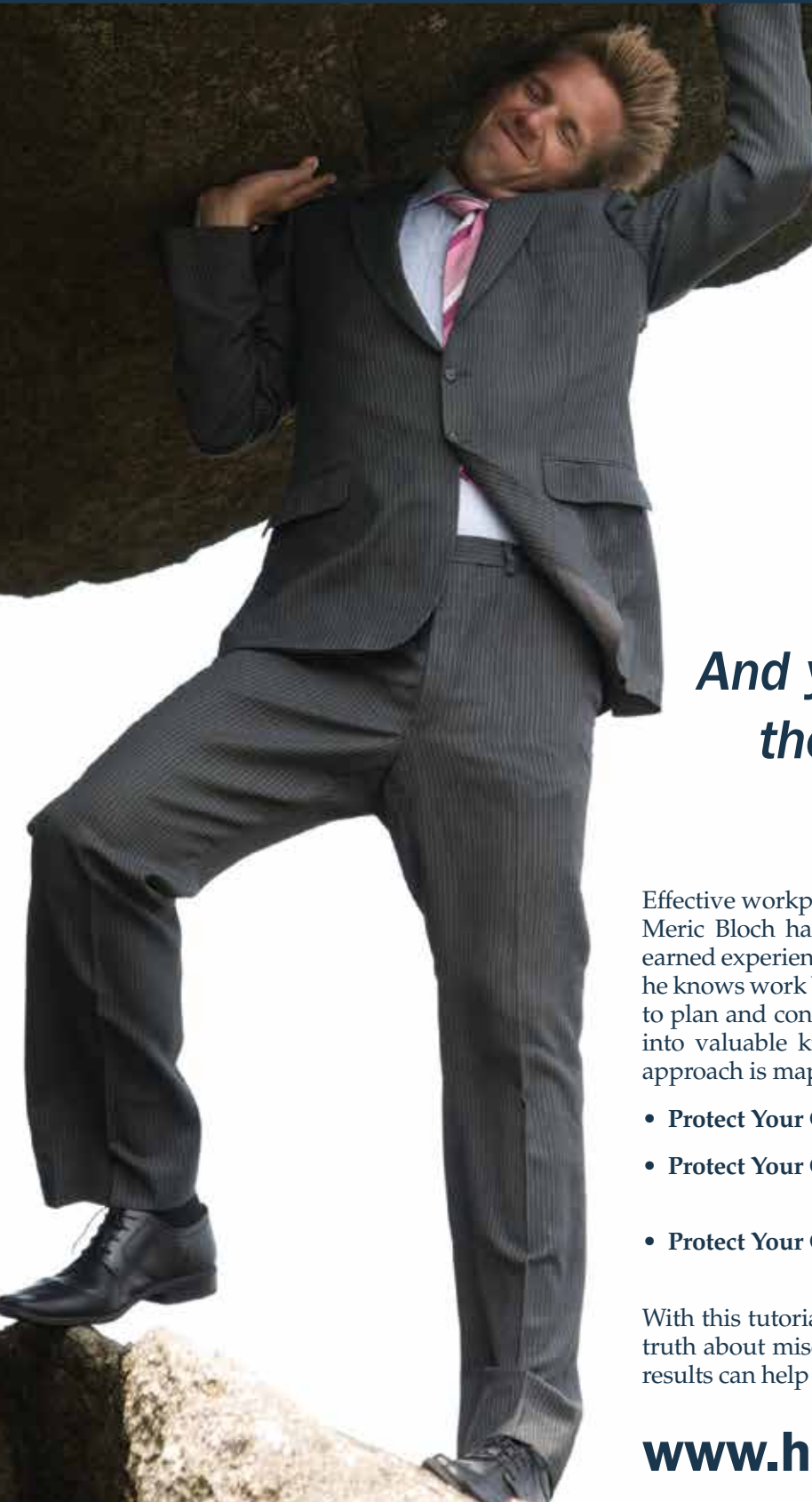
Finally, there is the dilemma of what will happen to all the current disclosure sites mandated by state law or corporate integrity agreements (CIA). The final rule does address the preemption of state databases: the new federal rule will preempt state collection which has historically required an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under the rule.⁵ However, it does not clearly address the collection of information for those under a CIA. It is likely that the Office of the Inspector General will revisit the CIA requirements, but as of now, this remains up in the air. With some CIAs requiring quarterly posting of payments, it is possible that there will be multiple public sites with discrepant information that will add to any confusion that occurs. For teaching hospitals and for physicians themselves, understanding and resolving these differences may become important and time consuming.

What happens to the assessment and management of conflicts of interest moving into the future? As noted above, just relying on self-disclosures can no longer suffice. Up to now, self-disclosure was not completely reliable and was fraught with errors,⁴ but it was essentially all there was. Going forward, just relying on what is publicly disclosed will not satisfy the institution's needs. Institutions will need to be able to both collect disclosures and to verify these disclosures through public data.

Best practices will move organizations to develop policies and procedures that actively collect disclosure information from affected individuals, to actively monitor publicly available information, and to resolve apparent discrepancies caused by a myriad of confounding variables, such as inconsistent reporting periods. In addition, we believe that because self-disclosure is associated with significant errors of omission, a best practice will include presenting the public information to the physician at the time of their providing a self-disclosure. This will improve the accuracy of the disclosure and allow for identification of disputed information so it can be flagged and followed up. Organizations will have more control of the information and be able to reconcile discrepancies, identify and eliminate problem areas, and respond quickly to both public and regulatory inquiries. This represents a significant change from current practice and will require an investment in personnel and systems. How big an investment this will require remains to be seen. Although PPSA may make it easier than it is today to gather public disclosure information, it may still be more than many organizations wish to take on alone. ■

1. 78 FR 9457
2. Goldman, L: "Ignore at your peril what others know about your organization." *Compliance Today*, June 2012, pp 32-35
3. Okike K, Kocker MS, Wei EX, et al: "Accuracy of Conflict-of-Interest Disclosures Reported by Physicians." *N Engl J Med* 2009;361:1446-74.
4. Weinfurt KP, Seils DM, Tzeng JP, Lin L, Schulman KA, et al: "Consistency of Financial Interest Disclosures in the Biomedical Literature: The Case of Coronary Stents." *PLoS ONE*: 3(5); May 7, 2008. Available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0002128>
5. 42 CFR § 403.914(a)

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by Wendy Wright, CHC, CPC, CPMA, CEMC

SNF Advance Beneficiary Notice: Avoiding financial liability and Medicare sanctions

- » Skilled nursing facility (SNF) residents must be notified when non-covered services are initiated, reduced, or terminated.
- » A properly executed SNFABN will protect the nursing facility from financial liability.
- » When notifying residents of financial liability, facilities must explain to residents orally and in writing.
- » Non-compliance with program instructions increases the risk of facility sanctions under Medicare.
- » Proper staff education and training on administering SNFABN is essential to ensuring compliance with Medicare guidelines.

Wendy Wright (wrightw@caromonthhealth.org) is Manager of Corporate Responsibility at CaroMont Health, a health care system with seven affiliates, including a skilled nursing facility and rehabilitation center, in Gastonia, NC.

Confusion regarding the requirements for notifying Medicare beneficiaries of their eligibility for services during a Part A stay has left many skilled nursing facilities (SNF) facing potential financial liability and possible violations of resident rights. According to the Centers for Medicare & Medicaid Services (CMS), facilities are required to notify beneficiaries or their authorized representative of their impending financial liability prior to services being initiated, decreased, or terminated.¹ Form CMS-10055 Skilled Nursing Facility Advance Beneficiary Notice² (SNFABN) was developed to provide beneficiaries with advanced notice of future non-covered extended care services. The purpose of this form is to help beneficiaries make an informed choice about whether or not they want to receive these items or services, knowing that they might have to pay for them out of pocket or with other insurance benefits.



Wright

Triggering events

CMS has identified certain triggering events that require a SNFABN to be obtained from a resident or authorized representative. These events include:

- ▶ initiation of services such as physician-ordered extended care services or items that do not meet medical necessity;
- ▶ a reduction in frequency of physician-ordered items or services; and
- ▶ a proposal to terminate physician-ordered items or services.

One of the main triggering events that impacts nursing facilities is when services are reduced or terminated and the resident remains at the facility, continuing to receive custodial care, or in other terms, non-Medicare covered long-term care services. Under section 70 of the Medicare Claims Processing Manual,³ custodial care is listed as a statutory exclusion, and when services are reduced to custodial care, a SNFABN should be executed. This is a situation where facilities may fail at notifying residents of their financial responsibility for the non-covered services, leaving

the facility open to financial liability and sanctions under the Medicare Conditions of Participation (CoP).

Executing the SNFABN

When executing the SNFABN, the facility must insure that the execution occurs in advance of the services being rendered and in a timely manner. CMS requires that when a triggering event happens, the facility must notify the resident “well enough in advance” for the resident to make other arrangements. SNFABNs given the same day may not be considered timely, and Medicare can investigate an allegation made by the resident in these situations. Some facilities choose to notify their residents (or their authorized representatives) during the care plan meeting that is held to discuss the resident’s progress with their goals. Many facilities typically hold care plan meetings five days prior to changing the resident’s status, at which time the SNFABN will be executed. This meets Medicare’s requirements for timely notification.

Not only is timely notification required when executing a SNFABN, but the notification must be easily understood and in a language that the resident or authorized representative can comprehend what is being asked of them. For this purpose, the CMS-10055 SNFABN form has an “Items and Services” section and a “Because” section and is fully customizable. The form is used to explain to the resident what types of items and services are being changed or withdrawn, why Medicare will not cover these items and services, and an explanation that financial responsibility

will be the duty of the resident. When outlining the non-covered items and services, significant information detailing exactly what items or services will not be covered should be included. It is not advisable to use diagnosis codes, abbreviations, or technical language the resident may not understand. Also, when stating the reason for the change in the “Because” section, the word “because” is required to be incorporated into the statement. If the Medicare contractor determines that the language included in these sections is not comprehensible, the SNFABN will not be valid.

When executing the SNFABN, the resident or authorized representative will likely ask

about the cost of such items or services.

This is the opportunity for the facility to give an estimated cost of the non-covered items or services.

Understanding that a final cost may not be easily provided, the facility must estimate fees to the best of their ability. On the SNFABN form, the

facility may provide an estimate for each item or service, or an aggregate cost for multiple items or services on the “estimated cost” line. The lack of this information will not void the SNFABN, but the facility must be prepared and willing to answer any inquiries about cost from the resident.

When the facility anticipates that the resident no longer meets Medicare Part A requirements for skilled services, the resident must choose one of two options:

- **Option 1:** The resident may disagree with the facility’s determination that services be terminated or reduced and can choose to continue to receive the services and

Not only is timely notification required when executing a SNFABN, but the notification must be easily understood and in a language that the resident or authorized representative can comprehend...

demand that the facility bill Medicare for an official determination.

- **Option 2:** The resident agrees with the facility's determination and the resident chooses not to receive the non-covered items or services.

The facility cannot pre-select either option prior to the resident or authorized representative signing the form. If option 1 is selected, once the official determination from Medicare is received and the carrier agrees with the facility's determination that the resident does not meet the criteria for skilled-level care, the resident will be personally and fully responsible for payment of the services. The facility is unable to bill the resident for these services until the official determination is received. If the resident will continue to receive custodial care, this should be outlined on the SNFABN and verbally explained to the resident or authorized representative that the level of care the resident is receiving is not considered a Medicare covered service.

What if a facility cannot obtain a SNFABN?

Some residents may not be capable of understanding financial liabilities and may have an authorized representative who handles the resident's finances, but lives out of town. In this case, the SNF administrator should make telephone contact with the resident's authorized representative and inform them of the change in status or decrease in services. The date the administrator spoke with the authorized representative should be noted in the margin of the SNFABN and the SNFABN should be mailed to the authorized representative with instructions to return the form to the facility as soon as possible.

Once the facility has received the signed copy of the SNFABN, the facility should retain the form in the resident's records and immediately mail a copy of the executed form to the authorized representative for their records.

Some Medicare carriers will accept the date of when the conversation occurred as the date of execution, whereas other carriers may only recognize the date in which the form was signed. It is suggested that facilities contact their Medicare carrier to clarify what their requirements are on the executed date. The facility cannot shift financial liability to the resident when the facility is unable to obtain a SNFABN.

Educate staff on requirements

On at least an annual basis, facilities should provide training for their staff which includes reviewing the requirements for proper execution of SNFABNs. A facility can tailor the training to include situations in which confusion has arisen around the requirements for notifying patients of termination of benefits. It is particularly important for staff members who are involved in the resident's care to be able to identify triggering events or situations in which an SNFABN is needed. By providing proper education and training on these requirements, the facility will ensure protection from sanctions under the Medicare CoP.

Conclusion

SNFs can protect their residents and themselves from financial liability with a properly executed SNFABN. Residents or their authorized representatives must be notified when services initiated, reduced, or terminated will result in Medicare non-coverage. Notifying the resident or the authorized representative, both orally and with the CMS-10055 form, in a timely manner will ensure the resident is informed and allow them to take part in the decision-making for their care and any financial liabilities. 🗨️

1. 42 C.F.R. § 483.10 Resident's Rights
2. The form is available at <http://www.cms.gov/Medicare/Medicare-General-Information/BNI/downloads/CMS10055.pdf>
3. Medicare Claims Processing Manual, 100-04, Chapter 30, Section 70. Available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf>

by Jason T. Lundy

RAC update

- » CMS issued a Ruling on March 13, 2013 that modifies treatment of Part B billing for RAC-denied claims.
- » ALJs had been making “partially-favorable” awards for Medicare Part B payments on claims that were denied Part A payment due to lack of medical necessity for inpatient admission.
- » Providers may now re-bill RAC-denied claims for Part B inpatient payment at any stage of the RAC appeals process.
- » Providers have to withdraw the appeal for Part A payment on the corresponding claim re-billed to Part B.
- » CMS also issued a proposed rule to formalize the treatment of Part B billing, and comments on the proposed rule were accepted until May 17, 2013.

Jason T. Lundy (jlundy@polsinelli.com) is a Shareholder in the Chicago offices of Polsinelli PC.

Shortly after our May 2013 issue went to press, CMS issued a new ruling that affected information presented in the article on page 31 of that issue. This is a brief update to that article.

On March 13, 2013, the Centers for Medicare & Medicaid Services (CMS) made a significant ruling relating to the availability of Medicare Part B payments for inpatient claims previously denied by RAC contractors.



Lundy

Pursuant to the RAC audit program, a RAC denial takes back the Medicare payment from a provider. Most of the time, denials are based on a RAC contractor’s decision that the *inpatient* admission was not medically necessary for the service, and therefore, the claim is ineligible for Medicare Part A payment. Those decisions meant that the provider received *no* Medicare payment for the patient’s treatment and services, even for claims where the medical treatment and services were not disputed as medically necessary, and therefore eligible for another category of Medicare payment. Providers have vigorously argued that an inpatient admission RAC denial should not also

eliminate permissible Medicare payments for the services, and Administrative Law Judges (ALJs) started accepting those arguments by awarding “partially-favorable” decisions at Level 3 RAC appeals. ALJs ordered consideration of Medicare Part B payments for denied claims as if services were rendered at an outpatient or “observation level” of care. Those ALJ decisions were at odds with CMS’s traditional billing policy regarding Part B inpatient claims for services beyond those listed in the Medicare Benefit Policy Manual (MBPM). The new Ruling CMS-1455-R allows providers to submit Part B inpatient claims for a more expansive range of services upon denial of Part A claims during RAC appeals.

Under the new ruling, a provider may submit Part B inpatient claims for services beyond those listed in the MBPM when: (1) a Medicare review contractor denies the Part A inpatient claim upon finding that the inpatient admission was not reasonable and necessary; (2) the Part B services would have been payable to the provider if the beneficiary was treated initially as an outpatient; and (3) the billed services do not require outpatient status (e.g., outpatient visits, Emergency Department visits, and observation services).

The ruling allows providers to submit claims for Part B payment as long as the provider withdraws its appeal on the corresponding

Part A claim. The ruling applies to Medicare claims denied by RAC auditors after March 13, 2013, or Medicare claims in a pending RAC appeal at any level as of March 13, 2013. Going forward from this ruling, the scope of RAC appeals will be limited to review of Part A inpatient claims, and ALJs are no longer permitted to order Part B payment or remand for consideration of Part B payment.

The ruling also sets forth the time period within which a provider must bill the Part B claims. Generally speaking, providers must submit Part B claims within 180 days of receipt of an appeal dismissal notice, final or binding unfavorable appeal decision, or determination of a Part A inpatient claim for which there is no pending appeal and for which the hospital does not appeal. Further, Part B inpatient and outpatient claims filed later than one year after the date of service will not be rejected as untimely, provided the denied Part A inpatient claim was timely filed.

Along with this ruling, CMS concurrently released a proposed rule on the Part B inpatient billing matter. The proposed rule is similar to the March 13 ruling, but has some key differences, especially relating to time restrictions for the Part B re-billing. CMS accepted comments on the proposed rule up to May 17, 2013. ☐

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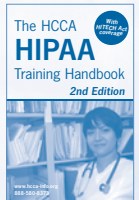
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Quality fraud: Two pathways to trouble

Alice G. Gosfield (page 27)

- » Exclusions, civil money penalties, and false claims charges have been imposed for provider quality failures in the past.
- » The OIG and Department of Justice now have a more refined and developing focus on quality process failures by hospitals and physicians.
- » Provider quality reporting is a separate basis for false claims liability.
- » It is only a matter of time until whistleblowers hone in on these two new targets.
- » Providers can take proactive steps to avoid trouble.

Complying with the new HIPAA Omnibus Rule: Part 2

Adam H. Greene and Rebecca L. Williams (page 31)

- » The definition of business associate has been broadened.
- » Business associate agreements are required for all qualifying, downstream subcontractors.
- » Direct and vicarious liability for non-compliance has been increased in scope.
- » Patient rights to access and restrict PHI disclosures are expanded.
- » Enhanced enforcement of noncompliance due to willful neglect is likely.

Billing compliance under the Incident To provision: What's the risk?

Kelly C. Loya and Cara Friederich (page 39)

- » Medicare designed the Incident To concept to reimburse physicians for all care received in the office in addition to the physician's direct services.
- » Services billed Incident To require the physician to be present in the office during the entire service.
- » Government audits suggest concerns about the misuse of the Incident To provision.
- » Using non-physician practitioners for more than Incident To services makes good business sense.
- » Educating staff regarding the Incident To requirements is essential to compliance.

Navigating security concerns with clinician tablet usage

Rebecca L. Frigy (page 55)

- » More and more clinicians are using tablets and handheld devices at the point of care.
- » Handheld devices are often lost or stolen.
- » Because these devices are often not password protected or encrypted, unauthorized access to PHI is a security risk.
- » Personal use of tablets and sharing them with family members also present security risks.
- » Health care organizations should take steps to address these security risks.

Project management methodologies for an effective compliance program

Brian Santo (page 53)

- » Compliance programs can achieve sustained success through leveraging project management approaches.
- » The core of any project is the project management plan.
- » Consistent auditing and monitoring will promote an active approach to compliance program management.
- » A project manager must receive corporate buy-in on a project management approach.
- » Oversight, auditing and monitoring, and training are continuous elements of an effective compliance program.

Surviving the ongoing focus on medical necessity and short stays

Kelly Saunders, Cheryl Golden, Nancy Toll Perilstein, and Joanna Haller (page 56)

- » Create a multi-disciplinary "short stay work group" to address accurate level of care.
- » Review Medicare claims prior to submitting them and promptly correct those not meeting the requirements for medical necessity.
- » Verify that the patient's status in the billing system matches the status ordered by the physician.
- » Verify accurate policies and procedures are in place and reflect current practice.
- » Assess the hospital's denied claims, particularly current cases related to pre-pay reviews, to mitigate risk.

ICD-10: Payer and provider implementation strategies

Susan Haseley and Jeffrey Strauss (page 67)

- » ICD-10 impacts virtually the entire enterprise in both payer and payee organizations.
- » It is a massively complex undertaking that affects huge numbers of health care industry workers.
- » ICD-10 will yield significant benefits to patients, payers, and payees—including long-term savings.
- » Successful implementation depends on the collaboration of payers and payees to ensure that everyone has the same understanding of how the ICD-10 codes are used.
- » Create a structured, strategic blueprint for implementation that will deliver the best results and create the least disruption.

Conflict of interest management after the Physician Payment Sunshine Act

Leon Goldman (page 73)

- » The PPSA public database will not replace institutional self-disclosure.
- » Both public disclosure information and locally self-disclosed information will need to be monitored.
- » Organizations will need a process/system to collect public disclosures, compare to self-disclosed data, and resolve/explain discrepancies.
- » Presenting publicly disclosed information to the clinicians during their self-disclosure process will help improve the accuracy of their reports.
- » Having an easily downloadable, searchable, and aggregated database may change how disclosures are managed.

SNF Advance Beneficiary Notice: Avoiding financial liability and Medicare sanctions

Wendy Wright (page 77)

- » Skilled nursing facility (SNF) residents must be notified when non-covered services are initiated, reduced, or terminated.
- » A properly executed SNFABN will protect the nursing facility from financial liability.
- » When notifying residents of financial liability, facilities must explain to residents orally and in writing.
- » Non-compliance with program instructions increases the risk of facility sanctions under Medicare.
- » Proper staff education and training on administering SNFABN is essential to ensuring compliance with Medicare guidelines.

RAC update

Jason T. Lundy (page 80)

- » CMS issued a Ruling on March 13, 2013 that modifies treatment of Part B billing for RAC-denied claims.
- » ALJs had been making "partially-favorable" awards for Medicare Part B payments on claims that were denied Part A payment due to lack of medical necessity for inpatient admission.
- » Providers may now re-bill RAC-denied claims for Part B inpatient payment at any stage of the RAC appeals process.
- » Providers have to withdraw the appeal for Part A payment on the corresponding claim re-billed to Part B.
- » CMS also issued a proposed rule to formalize the treatment of Part B billing, and comments on the proposed rule were accepted until May 17, 2013.

HCCA's 2013 Upcoming Events

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

June 2013

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2	3 Basic Compliance Academy — SOLD OUT Scottsdale, AZ	4	5	6 WEB CONFERENCE: Managing Business Associates through HIPAA Compliance CHC Exam	7	8
Research Compliance Conference Austin, TX			CHRC Exam			
9	10	11	12	13	14 Pacific Northwest Regional Conference Seattle, WA <small>Flag Day</small>	15
16 <small>Father's Day</small>	17 WEB CONFERENCE: All Aboard the HIPAA Omnibus — An Auditor's Perspective	18	19 WEB CONFERENCE: Social Media in the Healthcare Setting: So Much Not To "Like"	20 WEB CONFERENCE: Physician Alignment: A Legal and Fair Market Value Compliance Update CHPC Exam	21 West Coast Regional Conference Newport Beach, CA <small>Solstice</small>	22
23	24 Health Care Privacy Basic Compliance Academy San Diego, CA	25	26	27	28 Cascade Range Regional Conference Portland, OR	29
30						

July 2013

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	1	2	3	4	5	6
				HCCA OFFICE CLOSED Independence Day		
7	8	9	10 <small>Ramadan</small>	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

Research Compliance Conference

June 2–5 • Austin, TX

AHLA/HCCA Fraud & Compliance Forum

September 29–October 1 • Baltimore, MD

Clinical Practice Compliance Conference

October 13–15 • Philadelphia, PA

Basic Compliance Academies

June 3–6 • Scottsdale, AZ — **SOLD OUT**

August 5–8 • New York, NY

September 16–19 • Las Vegas, NV

October 21–24 • Denver, CO

November 11–14 • Orlando, FL

December 2–5 • San Diego, CA

Research Basic Compliance Academies

November 4–7 • Chicago, IL

Health Care Privacy

Basic Compliance Academies

June 24–27 • San Diego, CA

November 4–7 • Chicago, IL

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Cascade Range • June 28 • Portland, OR

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