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INSIDE

Access audits: Tips from 'the trenches'

By Felicia Ziomek, BSN, MBA, RN

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Do you have to be a crime scene investigator (CSI) to perform access audits? No, but it helps to think like one!

Regulations require health care providers to perform "access audits" to determine whether employees inappropriately access patient e-PHI (electronically protected health information). But where do we start? And how deeply do we investigate? The regulations don't give any specifics; they just indicate that these audits must be performed. I don't know all the answers, but I thought it helpful to share how I perform these audits. Over time, I'm learning ways to avoid "false positives" and cut down the time it takes to perform these audits.

If you haven't already done this:

1. Inventory all systems that contain PHI. I list each system vertically on a spreadsheet, and in horizontal columns list the following information:

a. Does the system have electronic PHI available in it? What kind?
b. Does the system have an audit log report? What data is included in the report, and who can request the report? How can it be pulled: by user ID; by account number; by medical record number; by access date?
c. How many days is the retention limit set to store the access audit trail-detailed information?
d. Who is my "super-user" contact for the system?
e. Does the application have auto-log off capability, and has it been enabled?
f. When did I last update the information in this list for this system?

TIP:

Do a risk assessment for records auditing

I was astounded that we have 30+ separate software systems that contain PHI, and I'm not done cataloging them all. Unfortunately, they're like silos. Their audit trails and audit logs aren't consolidated; they're all separate. Currently, I perform access audits for only the two most widely used systems, but I'm developing a schedule for the rest. I asked the US Office of Civil Rights (OCR) whether it's expected that we audit records from all 30+ systems that contain PHI, or whether it's acceptable to scale the breadth of access audits to just the most frequently used systems. In a recent discussion with OCR, they interpret the requirement to be that every system that contains PHI should be audited; but that there is no standard for how often each system is audited. A risk assessment should help determine the level of auditing that should be performed.

2. Turn on audit logging flags and retention limits (We set ours to 366 days).

TIP:

Test your audit log report.

The retention limit of one system I audit is initially set "off the shelf" at only two weeks (you can't view any access data older than this). In addition, many systems have logging flags that need to be changed from their "off the shelf" setting of "no" to "yes" (to record accesses to that particular function), so you'll want to set your retention limit and logging flags to your desired setting sooner rather than later. Thoroughly test whether your audit log report is actually capturing the account accesses it should, given how you've set the audit log flags. Sometimes software vendors don't thoroughly test their system's audit logging.

3. Establish VIP codes to be used somewhere in your Patient Registration system. These denote patient populations whose accounts you possibly want to audit. Our codes were established for billing purposes, but I use them to find patient accounts to audit. For example, I request a report of board members (B), employees (E), physician/family/child (P), and VIP (V) accounts from the prior quarter.

TIP:

Check for name recognition.

When I receive a list of the accounts associated with the VIP codes above (to choose which accounts to audit), I choose patients with the highest name recognition to employees—prominent members of the hospital and the community, and physicians many employees would recognize.

4. Ask your Information Systems department if they have a specific naming convention for the computer ID name that will appear on audit log reports. For instance, embedded in the computer name that appears on our reports LIM = Livermore Health Information Management department, PED = Pleasanton Emergency Department, P3W = Pleasanton 3-West Nursing Station. When physicians or their office staff accesses a patient record through our computer system "gateway," the computer name on that log entry is very different from those assigned to hospital departments.

5. **Ensure all users have a unique User ID established, including office staff.**

Physician office staff should not all be using the same User ID, or using the physician's user ID.

6. **Decide who will perform access audits in your hospital.**

Nurse Auditors are a good choice, because their auditing instincts are already established, and they're familiar with the roles of various employees in the clinical setting.

Getting ready

Reference materials to have packed in your "CSI briefcase" when you perform an access audit include:

1. **Calendar.** This helps you determine (for instance) it was acceptable that the Unit Secretary in Surgery accessed a patient PHI on a Monday when the patient had outpatient surgery the previous Friday, and was discharged late in the day.
2. **List of employees,** including their department name and position title.
3. **List of physician groups** and which physicians are affiliated with which groups. This helps you determine whether Physician #2 was covering for Physician #1's patient. Nobody is above the law; audit physicians and physician office staff.
4. **List of user IDs** and the name of the person (last and first) associated with that user ID. This will likely be a different list for each software system.
5. **List of function abbreviations** that appear on an audit log report, along with their descriptions. For example, function "PHRU180" is the Diagnosis Verification screen. A list of modifier abbreviations would also be helpful (DX = diagnosis, PX = procedure, CPT = CPT code).
6. **List of events** you might see on an audit log report and a definition of each. For example, R = read-only, U = update, C = create/add a record.

TIPS:

Request these lists well in advance, and verify that the number of people on the list is correct.

These special reports may be considered ad hoc reports and it can be challenging to get them right the first time. I had to get two of these lists corrected for my use because initially they didn't include all the names. The Human Resources and Physician Group "canned" reports include more data that I shouldn't have access to, so this required a special query be run.

Get these lists put in Excel format, and use the AutoFilter function (choose "Data", then "Filter", then "AutoFilter").

It will save time when you're determining which employee accessed the patient account you're auditing when the only info you have is user ID. Even if you receive files in PDF format, you can convert them to Excel, and eliminate the blank lines by sorting.

Timing is everything

Time your audits so that you've allowed enough time to deal with what you find, including meeting with affected directors, your compliance/privacy officer, and summarizing the outcome of the investigation. If you have regulatory time frames whereby you must report the breach to state officials (as we do in California) or now to federal officials (per the beach notification rules associated with the HITECH Act), be acutely aware of when the clock starts ticking and when the deadline is for reporting the breach to whichever agencies are required to be notified. Discuss the reporting requirement with senior management ahead of time, and solicit their input to the process.

After determining the accounts I'll audit, I run the audit log reports for those accounts. In addition to auditing the primary account for that patient, I also audit their related accounts. For example, if I'm auditing an outpatient surgery account, and there was an outpatient lab account for the same patient during that quarter, I'll audit that account too; the "snooper" could have searched for the patient by medical record number, and may have inappropriately accessed more than one account related to the same patient.

My audit log report includes user ID, date/time of access, location of access (individualized computer name), patient name, account number, medical record number, function they accessed, and whether the access was "read-only", "update", "create/add" etc. Not all system audit log reports will include the same data.

Timelines

For every patient account I'm auditing, at the top of the audit log report, I list the Census Event History for that account (date/time the patient was admitted to the Emergency Department (ED), admitted as an inpatient [and on which unit], transferred from one unit to another, and discharged/expired). If an e-mail was sent announcing the death of an employee and communicating funeral service details, I write that on my timeline because, unfortunately, these e-mails sometimes trigger unauthorized account accesses.

TIPS:

Know what employees' roles are, when it comes to accessing electronic records.

Unit secretaries often check patient accounts after discharge to ensure open orders are resolved. Registrars check accounts to ensure admissions, transfers, transitions, and discharges have been entered and are correct. In our ED, when it's slow in the middle of the night, registrars fax patient charts to their

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primary care physicians. Unit secretaries page consultants, scan EKGs into the electronic chart, and perform other clerical duties that require accessing the electronic chart. Look for 'footprints' (notes in the electronic chart); these account accesses were logged in our ED charting system along with what action the registrar took. I can audit registration entries to determine the User ID of the person who entered the admission, discharge, transfer (ADT) data, to verify the account access was appropriate. When I don't see an action logged, I add that employee's name to the list of employees to be interviewed about why they accessed that record.

Who covered her break?

Don't be surprised when you see (for example) a unit secretary assigned to 2-North access a patient account on 3-West, especially if the computer used was on 3-West. They cover for each other during absences and meal breaks.

One physician practice biller may support multiple physicians in the same practice.

To verify the biller legitimately needed access to a particular patient's account, find your biller on the list of user IDs, determine which physician practice they support, and verify one of the physicians in that practice is listed as the patient's admitting/attending/consulting physician.

Follow the evidence

When I saw an employee accessed a particular VIP account from a computer with an odd computer location, I contacted Information Systems (IS) and learned the computer was in our training room. I ran an audit log report for just that user for that day, found no other patient account accesses, and was suspicious the employee had used a training room computer to snoop. Since IS advised me there may be some instances when they didn't change the computer ID when they moved a computer, I went to the training room, found the computer in question, accessed an innocuous account, and ran the audit log report on my access to verify I'd found the correct computer.

"Where were you on the night of…?"

When I contacted this employee's supervisor and asked that they examine the timecard for that employee, I learned the employee was in orientation that day. I contacted the training supervisor, who explained that when she is teaching a class about certain software functions, she can teach only in the "live" environment (and she lectures them on privacy when she gets to that point in the class). Case closed, the access was legitimate.

I don't exempt any category of employee from scrutiny; anyone can inappropriately access a record. In what context was the access done? Did that person need to access that account on that date and time to do his/her job? Or was he/she merely snooping out of curiosity? For example, you can't assume that all coders have access rights. In one case, we found three coders had accessed a medical record, but only one coder had coded/abstracted it; the other two had accessed the record inappropriately. Does your audit log indicate how the employee accessed the patient's record (i.e., by keying the account number or by keying the patient's name)? If it's by keying the account number, that may indicate they're accessing the account for work purposes, versus searching by name.

"Who are you?"

It can sometimes be difficult to determine which employee is the one who accessed an account you're auditing. When employees change their last names (e.g., when they marry), sometimes there's a time lag before their names are changed in various computer system databases. I've found an employee's last name is different between our e-mail address book and the list of employees that Human Resources provided me. Sometimes I can find them by searching, using their first name. Sometimes employees are listed by their first name in the report from Human Resources, but listed by their middle name in a system user ID report. For example, they may be listed as Pete B. O'Riley in the list of employees, but listed as P. Baba O'Riley in the ED charting system and on the ED audit log report. Once I almost choked on my coffee when it appeared that a housekeeping employee had accessed a patient record. When I looked closer, I saw there were two employees with the same last name; one was a nurse on the same unit where the patient was being treated.

Chain of custody of the evidence

After I've compiled my list of employees with possible inappropriate accesses, I meet with the employee's director and provide them copies of the access audit logs. When I talk to the director I use the "presumed innocent" convention and I indicate there could be an explainable reason (of which I'm unaware) why their employee accessed the account. If the director can't explain why that employee needed to access that record on that date, they're asked to interview their employee. The director is instructed that if the employee admits they accessed the record inappropriately, the director should ask the employee if they shared the information with anyone else; if they shared the information, that's a higher level of inappropriateness. The director is asked to report back to me in seven working days with the result of the meeting with the employee. I summarize the final list of employees who performed inappropriate accesses and give it to the corporate compliance officer (CCO).

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"Won't get fooled again"

At my hospital, the CCO, together with Human Resources, determines the consequences of the inappropriate access. At some hospitals, an inappropriate access is grounds for immediate termination. If an employee states they did not access the record and someone else may have done so using their computer (because they don't always lock their computer when they're away from their desk), the employee may be given a written warning if it's against policy to leave a computer unsecured.

One of the more difficult groups to audit is the physicians. If physician A is the patient's known physician, but it is physician B whose user ID is on the Audit Log report, is that because physician A and physician B are in the same practice and physician B was covering for physician A that day? If physician B is not in the same physician practice as physician A and is not associated with the patient's current or prior accounts, does that mean the record access was inappropriate? Not necessarily, because the patient could have been treated by physician B only in the physician's office. Physician B may have never referred the patient to the hospital for testing; and therefore, may have never been attached to that patient in the hospital records.

After the access audit is completed, our CCO sends an e-mail to all employees, emphasizing that we take the privacy of our patients PHI very seriously, and as such, we perform periodic access audits. She indicates that inappropriate access of patient PHI is a violation of both California state law and federal law, a serious breach of training and policy, and could result in the loss of their job. In my department, employees are instructed to enter notes in account screens when they access accounts, to explain their need to access information in the account.

So, to meet the access audit regulatory requirements, be on the lookout for your own "Gil Grissom, CSI wanna-be" who can perform these nasty-but-necessary access audits. Tell them to stay open to hearing the little voice in their head saying, "Hmmm, that doesn't seem right." Over time, their investigative instincts will be honed. And, they should be able to perform these access audits in a manner where they, as the investigator, don't access the PHI themselves, leaving their own 'footprint' on the scene.

Cloning EHR: The review of systems

By Susan Welsh, MHA, CPC, CPC-I, PCS

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Electronic health records (EHR) will eventually become the norm. Congress, the President, the U.S. Department of Health and Human Services have all put forth initiatives to encourage providers to adopt electronic health records with an eye toward increasing interoperability (read "same platform/standards") for data exchange and decreasing the tremendous costs associated with a traditional paper record. With sales exceeding $3.03 billion in the last 12 months,[1] Iron Mountain, a records storage and management services provider, is very fond of the medical record in paper format. Every hospital and physician practice who must legally keep copies of medical records in storage (like that offered by Iron Mountain) for up to ten years is a little less in love with paper records.

In addition to the shear bulk of the traditional record, the paper record is searchable only by hand. Electronic records improve the ability of the practitioner to locate critical data in microseconds.

Critical data is the issue in the cloned record. First Coast, the new Medicare Administrative Contractor (MAC) for Florida and Puerto Rico,[2] defined cloned documentation:

> Documentation is considered cloned when each entry in the medical record for a beneficiary is worded exactly like or similar to the previous entries. Cloning also occurs when medical documentation is exactly the same from beneficiary to beneficiary. It would not be expected that every patient had the exact same problem, symptoms, and required the exact same treatment.[3]

For purposes of evaluation of the electronic health record let's take some of these concepts and look at some medical record documentation generated by an electronic health record. The concepts are:

> Patients having the same documentation from beneficiary to beneficiary
> Patients having the exact same symptoms

In Table 1 on page 12 illustrates the medical record entries for the review of symptoms (ROS) in five patients. In all cases, you cannot tell if the patient is a man or a woman (with the exception of patient #3), and with the exception of patient #2, you have no idea what is wrong with any of these patients.

The pattern is even more remarkable if you reformat the table and list the ROS as groups, one for each system, as in Table 2 on page 13. (Note: Patient #3 is missing from the gastrointestinal [GI] section. Patient #2 is missing from the genitourinary [GU] section. Patient #1 is missing from the musculoskeletal section. The missing information in some of the patient records represents information the physician took out because the patient had positive findings for that system. Rather than document those findings, the doctor just took out the negative findings.)

The problem of cloned documentation becomes readily apparent when reviewing the information for these five patients. Patient #1 has no musculoskeletal symptoms, but may have trouble with leg pain on walking. Patient #2 has no genitourinary symptoms, but does have problems with back pain. Patient #3 has two musculoskeletal symptoms and no gastrointestinal symptoms. However, the most disturbing findings are for patients #4 and #5. Neither patient has any problems in any system, which begs the question: Why are they seeing the doctor?

Not only is information cloned across patients, mistakes are also. Note in the HEENT (head, ears, eyes, nose, and throat) system, the same error is repeated for all five patients. The statement begins with "colon."

There is an even bigger problem with the documentation. Take a quick self-check test. Using any of the patients listed, go through each list of symptoms and ask out loud "Do you have (fill in the blank)?" for example, "Do you have fever, chills, night sweats or a change in your appetite?"

Give your "patient" time to respond. Forgetting for a minute that you are going to have to explain to most of your patients what 'orthopnea' (shortness of breath when lying down), 'hematochezia' (bloody stools), and 'dysuria' (painful urination) mean, how long does it take you to go through the list? It is an intensive Q&A, which may be off-putting to patients who have come in for a cold or the flu.

This brings up the problem that this documentation has in meeting the requirements of medical necessity. Is it appropriate to ask every patient if they have mood changes or problems sleeping? Is it appropriate to ask all of these questions of every patient who comes in the door, no matter what the nature of the presenting problem? Clearly First Coast's answer to that question is a resounding "No."

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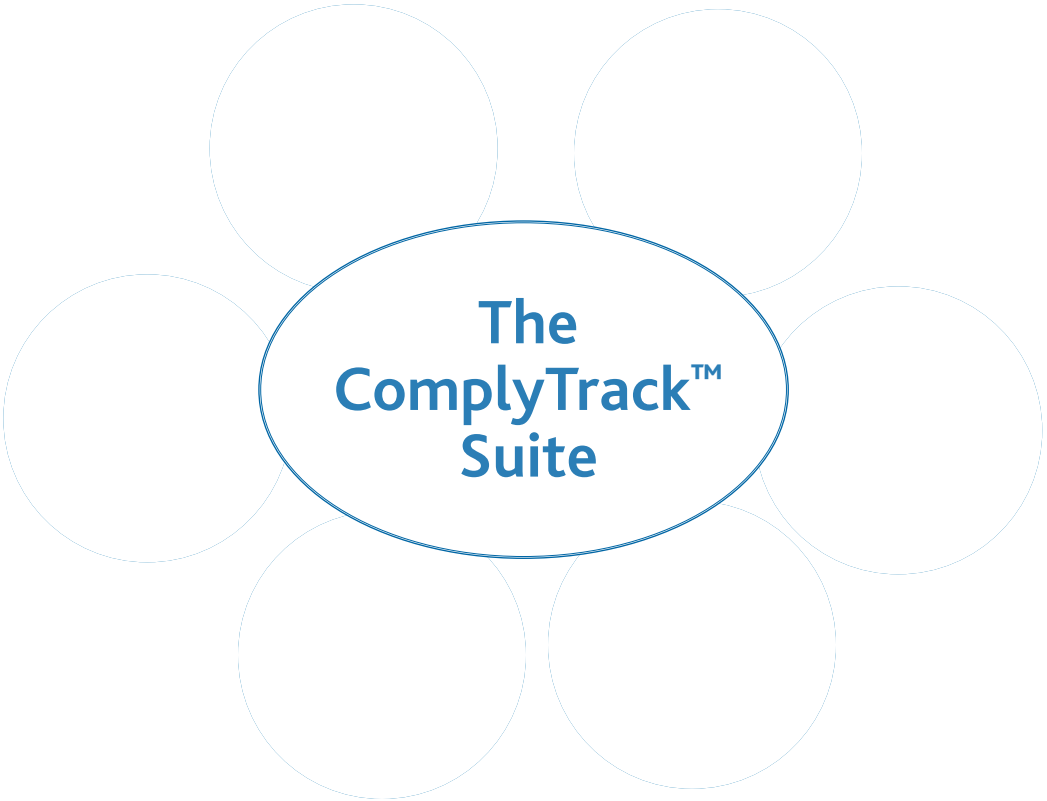

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The third problem with a template ROS is that the template doesn't change, except when you change it. It consistently puts the same information in each and every time. It becomes routine and, when something becomes routine, you can have problems with consistency. Although the template will give you a comprehensive ROS every time, it also adds specific elements to the record that may be contradicted in your other documentation. If you do not remove the proper statement, you could have a patient complaining of sleep problems in your history of present illness (HPI) and in the template ROS document, they have no complaint of sleep problems. If you don't add to the template, the patient could have a complaint of a mass or swelling and the template document would reflect a normal skin ROS, with no mention of the swelling or mass. In both cases, the inconsistency will be noted by an auditor and will call into question the validity of your documentation.

How do you fix this problem and still take advantage of the electronic health record's many improvements over the paper record?

Begin when you set up the choices on your electronic medical record. The problem with the documentation above is that the program automatically drops a complete ROS into each patient note. The physician then removes or changes information to "customize" it for each patient encounter. The problem is that a large amount of information remains the same from patient to patient. It may be true, but is it relevant to the encounter?

The temptation to hit all the bullet points in your documentation is great. You may want to, just be sure the comprehensive level of ROS is met, so you don't have to worry about this documentation requirement.[4] But CMS has brought out:

> Medical necessity of a service is the overarching criterion for payment in addition to the individual requirements of a CPT code. . . The volume of documentation should not be the primary influence upon which a specific level of service is billed.[5]

Medical necessity should be driving the gathering of your information in the encounter. The documentation of the ROS should represent the medically necessary and relevant information you need for the treatment and management of your patient.

When setting up your choices in the program, don't use the template ROS to drop in responses to every system question. Be sure your program can offer you a "pick list" of signs and symptoms for each system. Select the information that documents the patient's responses to your questions from that premade list of signs and symptoms, and be sure your program has a place for you to free text in anything unusual. On services where the treatment and management of the patient does warrant the billing of those higher level codes, remember to include the "All other systems normal" to achieve your comprehensive ROS after listing the problems and pertinent negatives. Only include information in the record that pertains to the current visit.

First Coast has another warning about cloned documentation in the same bulletin:

> Cloned documentation does not meet medical necessity requirements for coverage of services rendered due to the lack of specific, individual information. All documentation in the medical record must be specific to the patient and her/his situation at the time of the encounter. Cloning of documentation is considered a misrepresentation of the medical necessity requirement for coverage of services. Identification of this type of documentation will lead to denial of services for lack of medical necessity and recoupment of all overpayments made.[6]

The addition of information that increases your encounter documentation's resemblance to every other encounter does you no favors, increases the opportunity for contradictory information in the note, adds nothing of clinical relevance to your record, and may endanger your reimbursement.

1 http://moneycentral.msn.com/detail/stock_quote?Symbol=irm, 5/14/09
2 http://www.cms.hhs.gov/MedicareContractingReform/05_PartAandPartBMACJurisdictions.asp#TopOfPage
3 MedicareB Update, Third Quarter 2006, Vol. 4, No. 3
4 1995 Evaluation and Management Documentation Guidelines, AMA and HCFA (CMS) and the 1997 Evaluation and Management Documentation Guidelines, AMA and HCFA (CMS)
5 CMS Claims Services Manual, 30.60.1(A) Selection of Evaluation and Management Service: Use of CPT Codes
6 Ibid 1

Note: Tables 1 and 2 follow on pages 12 and 13

Table 1: Sample medical record entries of the symptoms of five patients

Patient	E&M	Category	Documentation
1	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
1	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
1	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea
1	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
1	ROS	GI	Patient denies nausea, heartburn, abdominal pain, melena, hematochezia, constipation
1	ROS	Endocrine	Patient denies polyuria, polydipsia, heat or cold intolerance, hypoglycemia
1	ROS	GU	Pateint denies dysuria, urgency, frequency, hematuria, nocturia, vaginal discharge
1	ROS	Skin	The patient denies rashes, itching, change in color or bleeding associated with a skin lesion
1	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
1	ROS	Psychology	Patient denies mood changes, sleep disturbance, No suicidal ideation.
1	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
Patient	E&M	Category	Documentation
2	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
2	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
2	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea, leg pain with walking
2	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
2	ROS	GI	Patient denies nausea, heartburn, abdominal pain, melena, hematochezia, constipation
2	ROS	Endocrine	Patient denies polyuria, polydipsia, heat or cold intolerance, hypoglycemia
2	ROS	Skin	The patient denies rashes, itching, change in color or bleeding associated with a skin lesion
2	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
2	ROS	Psychology	Patient denies mood changes, sleep disturbance.
2	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
2	ROS	Musculoskeletal	Low back pain. Otherwise joints within normal limits. Doing lots of heavy lifting while moving
Patient	E&M	Category	Documentation
3	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
3	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
3	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea, leg pain with walking
3	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
3	ROS	Endocrine	Patient denies polyuria, polydipsia, heat or cold intolerance, hypoglycemia
3	ROS	GU	Pateint denies dysuria, urgency, frequency, hematuria, nocturia, vaginal discharge
3	ROS	Musculoskeletal	Patient denies joint or muscle pain/swelling/stiffness.
3	ROS	Skin	The patient denies rashes, itching, change in color or bleeding associated with a skin lesion
3	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
3	ROS	Psychology	Patient denies mood changes, sleep disturbance.
3	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
3	ROS	Musculoskeletal	No joint swelling, no joint tenderness, good strength and normal sensation of all muscles
Patient	E&M	Category	Documentation
4	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
4	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
4	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea, leg pain with walking
4	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
4	ROS	Endocrine	Patient denies polyuria, polydipsia, heat or cold intolerance, hypoglycemia
4	ROS	GU	Pateint denies dysuria, urgency, frequency, hematuria, nocturia
4	ROS	GI	Patient denies nausea, heartburn, abdominal pain, melena, hematochezia, constipation
4	ROS	Skin	The patient denies rashes, itching, change in color or bleeding associated with a skin lesion
4	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
4	ROS	Psychology	Patient denies mood changes, sleep disturbance.
4	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
4	ROS	Musculoskeletal	No joint swelling, no joint tenderness, good strength and normal sensation of all muscles
Patient	E&M	Category	Documentation
5	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
5	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
5	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea, leg pain with walking
5	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
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5	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
5	ROS	Psychology	Patient denies mood changes, sleep disturbance.
5	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
5	ROS	Musculoskeletal	No joint swelling, no joint tenderness, good strength and normal sensation of all muscles

E&M = Evaluation and management
ROS = Review of symptoms

Table 2: The medical record entries of the same five patients, grouped by organic system, show evidence of cloning.

Patient#		System	Finding
1	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea
2	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea, leg pain with walking
3	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea, leg pain with walking
4	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea, leg pain with walking
5	ROS	Cardiovascular	Patient denies chest pain, palpitations, orthopnea, leg pain with walking
1	ROS	Endocrine	Patient denies polyuria, polydipsia, heat or cold intolerance, hypoglycemia
2	ROS	Endocrine	Patient denies polyuria, polydipsia, heat or cold intolerance, hypoglycemia
3	ROS	Endocrine	Patient denies polyuria, polydipsia, heat or cold intolerance, hypoglycemia
4	ROS	Endocrine	Patient denies polyuria, polydipsia, heat or cold intolerance, hypoglycemia
5	ROS	Endocrine	Patient denies polyuria, polydipsia, heat or cold intolerance, hypoglycemia
1	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
2	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
3	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
4	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
5	ROS	General	Patient denies fever, chills, night sweats, change in weight or appetite.
1	ROS	GI	Patient denies nausea, heartburn, abdominal pain, melena, hematochezia, constipation
2	ROS	GI	Patient denies nausea, heartburn, abdominal pain, melena, hematochezia, constipation
4	ROS	GI	Patient denies nausea, heartburn, abdominal pain, melena, hematochezia, constipation
5	ROS	GI	Patient denies nausea, heartburn, abdominal pain, melena, hematochezia, constipation
1	ROS	GU	Pateint denies dysuria, urgency, frequency, hematuria, nocturia, vaginal discharge
3	ROS	GU	Pateint denies dysuria, urgency, frequency, hematuria, nocturia, vaginal discharge
4	ROS	GU	Pateint denies dysuria, urgency, frequency, hematuria, nocturia
5	ROS	GU	Pateint denies dysuria, urgency, frequency, hematuria, nocturia
1	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
2	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
3	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
4	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
5	ROS	HEENT	colon Patient denies ears/eyes/nose drainage, changes in vision or hearing, eye or ear or throat pain.
1	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
2	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
3	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
4	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
5	ROS	Hematology	The patient denies history of easy bruising or problems with blood.
2	ROS	Musculoskeletal	Low back pain. Otherwise joints within normal limits. Doing lots of heavy lifting while moving
3	ROS	Musculoskeletal	Patient denies joint or muscle pain/swelling/stiffness.
3	ROS	Musculoskeletal	No joint swelling, no joint tenderness, good strength and normal sensation of all muscles
4	ROS	Musculoskeletal	No joint swelling, no joint tenderness, good strength and normal sensation of all muscles
5	ROS	Musculoskeletal	No joint swelling, no joint tenderness, good strength and normal sensation of all muscles
1	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
2	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
3	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
4	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
5	ROS	Neurology	The patient denies weakness, headache, dizziness, balance problem, slurred speech or numbness
1	ROS	Psychology	Patient denies mood changes, sleep disturbance, No suicidal ideation.
2	ROS	Psychology	Patient denies mood changes, sleep disturbance.
3	ROS	Psychology	Patient denies mood changes, sleep disturbance.
4	ROS	Psychology	Patient denies mood changes, sleep disturbance.
5	ROS	Psychology	Patient denies mood changes, sleep disturbance.
1	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
2	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
3	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
4	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
5	ROS	Respiratory	Patient denies cough, dyspnea, pleurisy
1	ROS	Skin	The patient denies rashes, itching, change in color or bleeding associated with a skin lesion
2	ROS	Skin	The patient denies rashes, itching, change in color or bleeding associated with a skin lesion
3	ROS	Skin	The patient denies rashes, itching, change in color or bleeding associated with a skin lesion
4	ROS	Skin	The patient denies rashes, itching, change in color or bleeding associated with a skin lesion
5	ROS	Skin	The patient denies rashes, itching, change in color or bleeding associated with a skin lesion

ROS = Review of symptoms

feature article

Meet Helen A. Bixenman, MBA/HCM, CHC

Compliance Officer, Banner Health, Phoenix, Arizona

Editor's note: This interview was conducted by HCCA CEO Roy Snell in October 2009. Roy may be contacted by e-mail at roy.snell@hcca-info.org. Helen Bixenman may be contacted by e-mail at helen.bixenman@bannerhealth.com.

RS: Please tell our readers a little about your background and what led up to you getting involved with the compliance profession.

HB: After receiving my undergraduate degree in biology, I was fortunate to work for the first private non-academic genetics laboratory in the United States, The Genetic Center of the Southwest Biomedical Research Institute (SBRI). While working for SBRI, I completed postgraduate training in the area of cytogenetics and became certified as a clinical laboratory specialist in cytogenetics. Being the first private genetics laboratory in the United States certainly had its challenges; however, the largest by far was being a certified Medicare laboratory. Because we accepted specimens across state lines, SRBI was required to comply with the Clinical Laboratory Improvement Act of 1967 (CLIA-67) and we were the first cytogenetic laboratory to be held to these standards. Providing laboratory services on a national level also required us to meet various state licensure and regulatory requirements. This experience expanded my clinical management responsibilities to include oversight of quality assurance and regulatory affairs.

RS: Well, how did you first get involved with regulations and compliance as a genetics laboratory professional?

HB: During the Medicare survey process it became clear that the majority of standards established under CLIA-67 for the traditional clinical laboratory could not be applied in the specialty area of cytogenetics. I discussed my concerns with my colleagues and, in general their response was that their laboratory was not required to follow CLIA-67 requirements. I began to have a captive audience when large reference laboratories added cytogenetics to their test menu and when the Clinical Laboratory Improvement Act of 1988 (CLIA-88) expanded DHHS' [Department of Health and Human Services] oversight to virtually all clinical laboratories. Because the CLIA regulations did not initially include the subspecialty of cytogenetics, genetic professional organizations identified the need for the development of high standards and self regulation. I was appointed to a task force established by the Association of Cytogenetic Technologists, with the specific charge of developing chromosome analysis guidelines. This task force formulated recommended standards after reviewing guidelines established by several states and regional genetics groups. The guidelines were then reviewed by a panel of expert consultants who where laboratory directors and well known in their respective fields. The guidelines were published in 1989 in a number of journals, played a role in establishing federal

standards for the subspecialty of cytogenetics, and continue to set standards for genetic services.

In 1990, SBRI was acquired by Genetrix, and the company was in a rapid growth phase that included numerous mergers and acquisitions. It was clear that they needed an individual to assist this process from a licensing and accreditation standpoint, and I was asked to add the responsibility of Director of Regulatory Affairs/Quality Assurance to my role as Managing Director of Cytogenetics and Molecular Genetics. In 1994, my role changed to Director of Laboratory Operations and Corporate Compliance Officer.

RS: I see that you have worked with the Arizona Hospital and Healthcare Association (AzHHA) as chair of the Health Care

Compliance Task Force. Please tell us about the task force.

HB: The purpose of the task force is to address issues related to state licensure, EMTALA, Medicare, and state and federal regulations that impact hospitals and their compliance programs. Membership is open to all AzHHA members and we meet bi-monthly. Our agenda includes two educational components: federal and state compliance updates and roundtable discussions. These sessions are led by outside counsel or AzHHA's Director of Regulatory Affairs and Policy. Occasionally, we invite the Arizona Department of Health Services Division of Licensing (ADHS), Arizona Health Care Cost Containment System (AHCCCS), our Medicare Administrative Contractor (MAC), or members to provide compliance updates. During 2009, our roundtable discussions have included education and discussion on Stark, the Employee Free Choice Act and 2009 labor relations issues, H1N1 update and preparations, and HITECH breach reporting and other HIPAA developments. We also allow time for members to discuss compliance related issues that they are facing.

Over the years we have established several work groups, subcommittees, or task forces that focus on HIPAA privacy, security, and transactions and code sets, discharging the uninsured and international patients, and Recovery Audit Contractor.

RS: Does the task force tackle quality of care as a compliance issue?

HB: We do address quality of care through our discussion of ADHS survey findings, disaster protocols, alternative standards of care, infection control, and nursing assessments. AzHHA has a separate patient safety steering committee whose mission is more directly focused on quality-of-care issues. As the federal government moves toward initiatives such as value-based purchasing and bundling, AzHHA is considering options for how best to meet member needs. This may entail refocusing the task force more closely on quality-of-care issues in the future.

RS: In your opinion, what impact has the task force had on compliance?

HB: When the task force started in 1997, we focused on the seven elements of a compliance program as described in the OIG's Compliance Program Guidance for Hospitals. Each meeting was dedicated to a specific element with members sharing their policies, practices, and processes. This collaborative effort allowed individual hospitals to benefit from the knowledge and experience of hospital compliance professionals throughout the state of Arizona. Continued sharing of successes, achievements, and near failures, and our regular education sessions allow hospitals to refine their programs on a regular basis. Our informal partnership with ADHS, AHCCCS and MAC allows us to work collaboratively on a range of issues.

RS: From your experience, if you had to name the top three compliance risk areas, what would they be?

HB: At a time of increased and expanding regulatory scrutiny, health care organizations need to proactively implement processes to ensure compliance with Medicare, Medicaid, and other payer guidelines, the accuracy of patient admissions, the adequacy of medical record documentation, accuracy of coding and billing, and compliance with established policies and procedures. Ongoing internal reviews, audits, and other evaluation techniques need to be conducted to monitor compliance with coverage and billing guidelines, identify problem areas, and initiate prompt corrective action and preventive measures to prevent future occurrences.

Keeping pace in a rapidly changing regulatory environment – the need to understand


ROY SNELL

what those changes mean to your organization, provide clarification of regulations to staff, develop and disseminate new policies, and revise existing policies all in a timely fashion.

Finally, I'd say monitoring the implementation and effectiveness of compliance policies and operational processes that have been developed in areas of compliance risk.

RS: You hold the Certified Healthcare Compliance (CHC) certification. Why did you seek certification?

HB: The profession of health care compliance is more than a job. For me, holding the CHC certification makes an important statement about my professional commitment to health care compliance.

RS: Do you have any recommendations for compliance colleagues who are new to the profession?

HB: Become involved with HCCA and explore all that it has to offer to enhance your compliance efforts. Network with other compliance professionals through local education and networking meetings, don't be afraid to ask questions of experts and leaders in our field, and most importantly, have patience. And when you are ready, earn your

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Medicare Fraud Strike Force Operations in Houston Lead to Charges Against Six Area Residents

On October 21, 2009 the U.S. Department of Justice announced that Medicare fraud charges have been filed against six individuals in the continuing operation of the Medicare Fraud Strike Force in Houston.

In an indictment unsealed on October 21, 2009, Bassey Monday Idiong, 30, owner of B.I. Medical Supply LLC, Linda Eteimo Ere Kendabie, 27, an administrative assistant at B.I. Medical, and Modupe Babanumi, 42, a patient recruiter for B.I. Medical, all of whom reside in the Houston area, were each charged with participating in a scheme to submit claims to Medicare for medically unnecessary durable medical equipment (DME) . In many instances , the DME was not given to the purported patients. This equipment included so-called "arthritis kits," which consist of sets of orthotic braces that are purportedly used for the treatment of arthritis-related conditions. *http://www.usdoj.gov/opa/pr/2009/October/09-ag-1132.html*

LA Medicare Fraud Strike Force Charges 20 in Health Care Fraud Cases Involving Durable Medical Equipment

On October 21, 2009 The U.S. Department of Justice announced that twenty defendants, most of them residing in the Los Angeles area, were charged in seven cases for allegedly participating in Medicare fraud schemes that resulted in more than $26 million in fraudulent bills to the Medicare program. *http://www.usdoj.gov/opa/pr/2009/October/09-crm-1131.html*

Indiana Home Health Agency Pays Nearly $2 Million to Settle False Claims Act Allegations

On October 20, 2009 the U.S. Department of Justice announced that Omni Home Care, a home health care agency in Evansville, Ind., and its parent corporation, Omni Home Health, have agreed to pay the United States $1.97 million to settle claims that it violated the False Claims Act between 2006 and 2008, by failing to obtain certain required physician approvals before submitting bills for home health services to Medicare. *http://www.usdoj.gov/opa/pr/2009/October/09-civ-1124.html*

Detroit-Area Physical Therapist Pleads Guilty in Medicare Fraud Scheme

On October 19, 2009 the U.S. Department of Justice announced that Solomon Nathaniel of Sterling Heights, Mich., pleaded guilty in U.S. District Court in Detroit to participating in a conspiracy to defraud the Medicare program. *http://www.usdoj.gov/opa/pr/2009/October/09-crm-1123.html*

Meet Helen A. Bixenman

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CHC credential and contribute personally to advance the field of health care compliance.

RS: How does HCCA best support the work you are doing and what could HCCA be doing to support your work and the profession even more?

HB: My interactions with HCCA have allowed me to grow intellectually, and my professional achievements are a direct reflection of HCCA. I believe we have an obligation as important members of the health care community to expand our scope of professional influence, and to find new and effective ways to support and encourage the highest standards of professionalism among not just our members, but in conjunction with all health care professionals, to continuously improve quality of care compliance.

RS: What is the one piece of compliance advice you would like to share with everyone?

HB: The success of a compliance program is a function of people, processes, and technology. By setting up the right processes and engaging all stakeholders, the accountability for compliance becomes part of the culture in the organization.

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- Demonstrates the hard work and dedication necessary to succeed in the compliance field

For more information about certification, please call 888/580-8373, email ccb@hcca-info.org, or visit our website at www.hcca-info.org.

Congratulations!! The following individuals have recently successfully completed the CHC certification exam, earning their certification:

Leigh Reynolds Adams
Susan J. Arpei
Kathleen A. Barber
Robert Louis Decarlo
Wendy E. Dell
Carol Sue Garcia
Sheila Kay Heward
Angela Marie Lott
Caterina Apollonia Russ
Natashia Dione Saunders
Gordon D. Smith
Michelle S. Stabb

Congratulations!! The following individuals have recently successfully completed the CHRC certification exam, earning their certification:

Karen Ann Murray
Alison L. Oville

Letter from the CEO

Should the Compliance Officer report to the General Counsel?

Recently, pharmaceutical giant Pfizer paid a $2.3 billion fine. Why such a big fine? In part, it's because they did not respond to repeated requests by the government to do things correctly. They also aggravated the government by not setting up a compliance and ethics program properly, in the government's view. The Office of Inspector General (OIG) told Pfizer that as a part of their latest settlement, they could not have the compliance officer (CO) report to the general counsel (GC.) The CO now has to report to the chief executive officer (CEO). The following is an excerpt from a major legal website that describes the OIG's reasons for forcing Pfizer to have the CO report to the CEO and not to the GC.

On September 10, 2009 www.Law.com reported :

> The change is intended to eliminate conflicts of interest, and prevent Pfizer's in-house lawyers from reviewing or editing reports required by the agreement, says Lewis Morris, Chief Counsel for the Inspector General's office. Officials at Pfizer did not respond to requests for comment.
>
> "The lawyers tell you whether you can do something, and compliance tells you whether you should," [Lewis] Morris says. "We think upper management should hear both arguments."

Although I agree with Lew's premise that the CO should not report to the GC, I would have made the point a little differently. If the lawyers were telling the CEO whether he/she "can do something" they obviously got it horribly wrong. If the Pfizer lawyers were telling their leadership that they "can do," what they did do..... they were off by $2.3 billion. For COs, it's not a matter of can vs. should. COs tell you what is legally appropriate and legally inappropriate, not necessarily whether or not you should or shouldn't do something. My guess is that the lawyers were telling the Pfizer leadership what they wanted to hear, as opposed to what the CO would tell them—what they needed to hear. COs don't do things like calculate the risk of getting caught. They don't discuss whether or not the regulation is fair. They don't break the law because everyone else is doing it. They ignore peer pressure. They are not responsible for the net profit or conflicted in any other way. They cut out the emotion. They don't promulgate excuses or rationalize behavior.

Most of all, and the main point of this article, is that COs should avoid conflicts of interest. They are not responsible for the profit ratios, product sales, or the public relations of the organization. They are not responsible for defending the organization. They state the facts and they stand their ground. That is why we have this new profession of Compliance in business today. It's not a matter of can or should. It's a matter of follow the law, end of story.

It's not just the OIG's perspective. Here is a Senator's viewpoint on the CO reporting to the GC. Actually, in this case, the company in question took this ill-fated reporting relationship to a whole new level. The GC and the CO were one and the same person. Senator Grassley once sent a letter to Tenet stating, "It doesn't take a pig farmer from Iowa to smell the stench of this conflict." He was referring to the GC managing the compliance program. The government eventually went after Tenet's GC personally, and Tenet paid multiple multi-million dollar fines.

The US Sentencing Commission has weighed in via the Sentencing Guidelines (USSG.) The USSG are a guide for judges to use when sentencing individuals and corporations. The USSG say that if you have a compliance and ethics program, you should get a break. If you don't have a compliance and ethics program, you should pay double or triple fines. Another provision in the USSG could make the fine a terminal experience for the offending company. The USSG say that the CO should be free of conflicts and be able to operate independently. In the November 2004 amendment to Chapter 8 of the USSG, they emphasized that the person responsible for the compliance and ethics program should have certain responsibilities.

USSG Chapter 8, November 2004 amendment

In order to carry out such responsibility, the new guideline mandates that such individual or individuals, no matter the level, must "be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority."

Pfizer is one of few health care organizations in the country to have the CO report to the GC. It's been beat into health care by the

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Social Networking

JOHN FALCETANO

Editor's note: John Falcetano, CHC-F, CCEP, CHRC, CIA is Chief Audit/ Compliance Officer for University Health Systems of Eastern Carolina and Secretary of the HCCA Board of Directors. John may be contacted at jfalcetano@suddenlink.net.

This Social Networking column is devoted to providing a list of recent topics being discussed on the Health Care Compliance Association's (HCCA) Social Network site, where our members and others can find answers to their questions and network with others online.

The Compliance and Ethics Social Network website functions like any other online community that share common interests. The site has multiple communities that members can access, such as auditing and monitoring, chief compliance/ethics officers, long-term care, hospital, research compliance, and other networks and forums. The Social Network site is a great way to make friends, talk with peers, and focus on a specific compliance topic. This month's topics include:

1. Ethics issues or just business
2. Budget benchmarking
3. Signs of an ethical culture
4. Laboratory charge structure
5. Obtaining authorizations at health fairs
6. Insurance companies and red flag rules
7. Inmates/prisoners and HIPAA
8. HIPAA and e-prescribing
9. Security, privacy and text messaging
10. Compliance and safety
11. Conducting business with debarred vendors
12. Coding tips
13. Training materials for boards
14. Medical record retention
15. Encrypting PHI

The Compliance and Ethics Social Network also has an added benefit of giving you access to many compliance-related documents through the Compliance and Ethics Social Network library. Here compliance professionals share their documents, presentations, and audit programs with the Social Network community. I encourage everyone to become involved with the Social Network. It is a great way to participate in the discussion, review the comments, or just talk with your peers. You can access the Social Network by going to the following link: **www.hcca-info.org/sngroups**

New medication therapy guidelines for Medicare Part D sponsors

By Diane R. Burman RPh, CHC, Margaret Shepherd RPh, Norbert Becker RPh, and Michael DeVincenzo, PharmD

Editor's note: Diane R. Burman is Senior Director, Compliance Integrity/Quality Assurance; Margaret Shepherd is Director, Clinical Services; and Norbert Becker is Clinical Pharmacist; all with PerformRx located in Philadelphia, PA. Michael DeVincenzo is a recent PharmD graduate. Ms. Burman may be reached by telephone at 215/937-5061 or by e-mail at Diane.Burman@PerformRx.com; Ms. Shepherd may be reached by telephone at 215/937-5414 or by e-mail at margaret.shepherd@performrx.com; Mr. Becker may be reached by telephone at 215/863-5670 or by e-mail at norbert.becker@performrx.com; and Mr. DeVincenzo may be contacted by e-mail at devincenzo.michael@yahoo.com.

Medication Therapy Management (MTM) is a key component of health care and has produced positive outcomes on medication use since its inception in 2006, as part of the Part D drug benefit. It has been a goal of the Centers for Medicare and Medicaid Services (CMS) to see MTM evolve and become a "cornerstone of the Medicare Prescription Drug Benefit." An extensive assessment of MTM programs was performed by CMS in 2008, which yielded the decision to increase access to MTM and reduce eligibility restrictions. Therefore, in order to provide MTM services beginning in 2010, CMS is instituting more specific requirements for all Medicare Part D sponsors (excluding Private Fee-For-Service [PFFS] plans). The impacted areas include enrollment, comprehensive medication reviews, targeted medication reviews, intervention, and outcomes-reporting.[1]

The first area deals with the method of enrollment and has been designed by Part D sponsors in the past as opt-in, opt-out, opt-in and opt-out, or other.[2] For the requirements in 2010, sponsors must enroll targeted beneficiaries using an opt-out method of enrollment only.[1] Simply put, everyone who is qualified will be automatically enrolled unless he/she opts-out. The enrolled beneficiaries, however, may refuse individual services and still remain in the program. Increased patient access, compliance, and enrollment to MTM services are greatly anticipated.

By targeting beneficiaries, Plan D sponsors will also be required to be more dutiful and will reach out to a greater population. Beneficiaries will have to be targeted for enrollment at least quarterly during each year, which is considerably more frequent than the current requirement to perform it annually.[1,2] However, this change should not propose a wide-spread problem, because more than 95% of MTM programs in 2008 have already been targeting beneficiaries at least quarterly.[1] It is also expected that sponsors perform an end-of-year analysis to identify current beneficiaries who will meet the eligibility requirements for the following year for the same plan. This prospective action should streamline the process and allow for fewer interruptions while providing MTM interventions.

Criteria for targeting

The targeting criteria for 2010 are more defined but will still target multiple disease states.

Diseases

Currently, the minimum number of chronic diseases that a participant can have is from two to five; and each Part D sponsor must specifically indicate the minimum number of chronic diseases a beneficiary must have for eligibility in their program.[2] In 2008, the majority of programs did require a minimum number of two or three chronic diseases. For 2010, sponsors cannot require more than three chronic diseases as the minimum number, and they must target at least four of the following seven core chronic conditions:

- Hypertension
- Heart failure
- Diabetes
- Dyslipidemia
- Respiratory disease (such as asthma, chronic obstructive pulmonary disease [COPD], or chronic lung disorders)
- Bone disease/arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis)
- Mental health (such as depression, schizophrenia, bipolar disorder, or chronic and disabling disorders)

Because the above mentioned requirements are the minimum, CMS encourages sponsors to target any additional disease states in order to meet the needs of their patients.

Drugs

The next component of the targeting criteria states that a sponsor cannot require more than eight Part D drugs as the minimum number of multiple covered Part D drugs.[1] Thus, sponsors can set the threshold number anywhere between or equal to two to eight. Although over 85% of sponsors in 2008 already did target beneficiaries with a minimum threshold of eight or fewer Part D drugs, the past requirement for the threshold could be any number of drugs from two to fifteen.[1,2]

Annual costs

The last area of targeting beneficiaries focuses on annual costs of Part D medications. Subsequently, the cost threshold for 2010 will be decreased from $4,000 to $3,000. Thus, sponsors must target beneficiaries who meet the aforementioned targeting criteria (i.e., number of disease states and drugs) along with those who are likely to incur an annual cost of at least $3,000 for Part D medications.[1]

Interventions

The next focus of the updated 2010 requirements deals with the minimum level of interventions that must be made by individual sponsors. The updates include the minimum requirements to provide specific services such as comprehensive medication reviews (CMR), targeted medication reviews, and offering interventions targeted to prescribers. The various interventions may be performed independently or in combination, which may produce a more coordinated effort. Pharmacists or other qualified health care providers may conduct these interventions, which must include an interactive component as well as continued monitoring and follow-up. As discussed earlier, patients may refuse certain interventions and services without having to disenroll from the program.[1]

There are many "lower touch" or passive interventions that may also be provided. These interventions can encompass things such as educational newsletters, drug utilization review (DUR) edits, refill reminders, and/or medication lists. These passive interventions, however, cannot be the sole offerings. In fact, less than 2% of providers in 2008 offered only passive interventions as their sole offering, and most programs already provide services such as an annual CMR. This information supports the current viewpoint that an annual CMR is essential to improve outcomes with MTM.[1]

The first intervention required by CMS for 2010 is to offer a CMR at least annually to all targeted individuals in the program. The CMR must include three components:

1. A review of medications to assess usage and to detect any drug related problems.
2. An offer to provide an interactive, person-to-person consultation to each beneficiary. This consultation will be performed by a qualified provider and can be either face to face or via other interactive methods, such as the telephone. This interaction should provide the sponsor with additional information that may be outside of the claims data such as OTC medications, herbal supplements, health status, adverse events, or any other health related issues.
3. A process in which the sponsor will provide the beneficiary with an individualized overview or "take away" of the consultation. This may include a personal medication record, a reconciled medication list, action plans, monitoring recommendations, education, and/or self-management, etc.[1]

The second intervention required for 2010 is to perform ongoing monitoring, no less often than quarterly, in the form of targeted medication reviews for all individuals in the MTM program. The monitoring will assess medication use and whether any unresolved issues need attention. The assessment will also determine if any new drug problems have arisen or if the individual has had a transition in care since the CMR. It is required of the Part D sponsor to evaluate the reviews and determine if a follow-up intervention is necessary with the beneficiary and/or prescriber. If so, then the follow-up intervention should be interactive, but can be provided via the mail or other means.[1]

The third intervention required for 2010 is to offer interventions targeted to prescribers. This is required in order to resolve any drug-related issues, and/or to improve any other issues that may facilitate the patient's medication use. These interventions may be faxed or mailed, or even interactive when deemed appropriate.[1]

There are slight exceptions for targeted beneficiaries who are residents in a long-term care (LTC) setting. For this patient population, the sponsor does not have to offer the interactive CMR component. They do, however, still have to perform quarterly drug reviews and offer interventions to the patients' prescribers.[1]

The last topic for the new requirements focuses on outcomes measurement and reporting. Currently, sponsors are required to provide CMS with data on a semi-annual basis to determine if the plans are meeting their standards.[2] Nonetheless, specific processes to measure outcomes have never been rigidly put in place. The new requirements state that Part D sponsors must measure and report:

the number of CMRs,
the number of targeted medication reviews,
the number of prescriber interventions, and
the change(s) in therapy directly resulting from the MTM interventions.[1]

Continuous evaluation and subsequent improvement of each program is expected among each sponsor. Recently, an MTM monitoring contract was granted to CMS through 2010 to help the agency monitor and evaluate MTM programs. Other agencies and alliances responsible for health care quality and patient safety may also assist CMS in recognizing additional areas that could be measured and reported by Part D sponsors. A few probable areas of evaluation may include drug utilization, beneficiary health, financial impact, and customer satisfaction.[1]

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Three-day Payment Window Rule: A source of confusion, noncompliant billing, and additional revenue

By Frank X. Smith

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Compliance officers and departments are sometimes labeled as the "no" people. They tell CEOs, COOs, and CFOs what they can and cannot do and when they should or should not do it. Here is an opportunity to do what you do best: mitigate risk while increasing the net revenue for your hospital. It seems many hospitals have indiscriminately bundled outpatient services provided to patients within three days of an admission with inpatient claims. In some cases, efforts to be compliant have had the opposite effect, and have resulted in lost revenue for the hospital.

A historical perspective

The Three-day Payment Window Rule, which has been in effect since 1991, has its genesis with the inception of the Medicare program in 1966. At the beginning of the program, Medicare implemented an administrative policy that dictated bundling services provided the day prior to admission with the inpatient claim and billing to Part A. With the advent of the Prospective Payment System in 1983, the diagnosis-related group (DRG) weights and standardized amounts were developed to include the cost of services provided the day before admission, because they had historically been included in the inpatient costs.

The expansion of includable preadmission services with the Part A admission, from one to three days, began with Section 4003 of Public Law 101-508, which established a three-part phasing process into the current rule. It should be noted as it was in the Conference Report which stated that "[n]othing in this provision requires the Secretary to take special action to adjust the DRG relative weights to reflect the additional services that would be covered by the DRG payment under this provision."

The first phase, effective from November 5, 1990, (the enactment date of Public Law 101-508) through September 30, 1991, provided that any services furnished during the day before the date of admission, regardless of whether the services were related to the admission, were included with the inpatient claim.

The second phase, which became effective on January 1, 1991, and is ongoing, includes bundling diagnostic services (including clinical diagnostic laboratory tests) that are furnished during the three days immediately preceding the date of admission.

The third phase, which became effective October 1, 1991, and is ongoing, includes bundling other services related to the inpatient admission that are furnished during the three days immediately preceding the date of admission.

On January 12, 1994 the Centers for Medicare and Medicaid Services (CMS) published an interim final rule with comment period. In it they defined other services related to the admission "as those diagnostic services in connection with the diagnosis (that is, the principal diagnosis) that require the beneficiary to be admitted as an inpatient." CMS considered expanding the term to include secondary diagnosis but recognized that secondary diagnosis can include complicating events that do not occur until after admission and therefore concluded that it is more accurate to use only the principal diagnosis to identify those preadmission services that are related to the reason for admission. The preadmission services that are considered for bundling must be provided by the admitting hospital or by an entity that is wholly owned or operated by the admitting hospital. Also, CMS at this time requested input from providers to further develop criteria for services "related to the inpatient admission."

In the Federal Register dated February 11, 1998 which was the final rule, CMS agreed with commenters who responded to the interim final rule within the comment period that certain services should not be subject to the provisions of the payment window. CMS "determined that Part A services (such as home health, hospice, and skilled nursing facility services), ambulance services, and chronic maintenance renal dialysis should be excluded from the payment window."

Further, CMS reiterated its definition of "services as being related to the admission *only* when there is an exact match between the ICD-9-CM diagnosis codes assigned for both the preadmission services and the inpatient stay" (emphasis added). This definition clarified the term "related to the inpatient admission."

Implementing the regulation

The Federal Register was followed by changes to the Medicare Claims Processing Manual. The current Medicare Claims Processing Manual, Pub 100-04, Chapter 3, Section 40, 3.C Implementing the Regulation, states "Effective March 13, 1998, we defined nondiagnostic preadmission services as being related to the admission only when there is an exact match (*for all digits*) between the ICD-9-CM principal diagnosis code assigned for both the preadmission services and the inpatient stay" (emphasis added).

It is important to determine whether the policies and processes at your facility conform to the latest Three-day Payment Window Rule phase and the clarifications concerning ownership and related services. As noted above, there were several phase-in periods:

the inclusion of all services (November 5, 1990 – September 30, 1991),
the inclusion of diagnostic services (effective January 1, 1991, and ongoing), and
the inclusion of inpatient-related services (effective October 1, 1991, coinciding with the end of phase 1, and ongoing). The definitions for ownership and related services were not clarified until seven years later.

Inpatient and outpatient coding

Some providers automatically bundle into the inpatient claim all the outpatient services they provided to patients within three days of inpatient admission. This is an excessively conservative attempt to be compliant with billing rules, but it is, in essence, anything but compliant. There are specific coding guidelines for inpatient and outpatient coding. The findings of an inpatient stay that are arrived at a day or more after admission cannot change what was done in the outpatient setting. Because of the coding guidelines, matching outpatient and inpatient primary diagnoses will rarely be the same. Consider the impact on reimbursement in the following examples, where it is presumed that the patient does not meet the Chapter 3, Section 40.3 criteria for bundling.

Case 1: A patient's outpatient services are bundled with the inpatient claim and the claim happens to be an outlier case. The provider will be paid on the outlier ratio of cost-to-charges for those outpatient services, rather than on the APC rate net of coinsurance. The provider payment is incorrect and the provider may be over- or underpaid.

Case 2: an individual's outpatient service, including an outpatient surgical procedure, is bundled with the inpatient claim, and the outpatient surgical procedure increases the inpatient MS-DRG. For example, if an outpatient has a cholecystectomy performed, complications arise during recovery, and subsequently the patient is admitted, the surgery is bundled with the inpatient claim, with the additional surgical procedure code 51.22 cholecystectomy. The MS-DRG is revised to MS-DRG 909, Other O.R. Procedures For Injuries w/o CC/MCC [without complications and comorbidities], weight 1.1342. The provider payment is incorrect and most likely the provider is overpaid. However, under the Three-day Payment Window Rule provision, the surgical services are to be unbundled and billed to Part B with an assignment of MS-DRG 921, Complications of Treatment w/o CC/MCC, weight .6109, and the inpatient admission is billed to Part A.

Besides the difference in reimbursement amounts due to bundling the outpatient services that do not meet the criteria set forth in the claims processing manual, in each case there is a shift of payment services from the Part B fund, where the Program payment is reduced by the coinsurance borne by the patient, to the Part A fund.

Process reviews and interpretation

When reviewing your hospital's processes, there are operational processes and interpretation issues that need to be understood in order to deal with this rule correctly.

Operationally, obtaining the outpatient primary diagnosis happens in two different manners. First, when an ambulatory patient arrives for outpatient ancillary services other than emergency services, the patient provides a script from the ordering physician that contains the primary diagnosis for the service, which is entered in the hospital's registration system. This differs from the patient who arrives at the emergency department (ED) for emergency services. The primary diagnosis for

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the emergency service will be obtained sometime subsequent to the provision of service, when the ED chart is reviewed and coded. If the patient is admitted to the hospital before the ED record is coded, many providers bundle the emergency services into the inpatient claim. This automatic process bundles services that may not have a five-digit match between the outpatient primary and inpatient primary diagnoses. Depending on how current the ED coding is, the facility may be bundling a majority of emergency claims when very few should be bundled.

Emergency department services appear to have been bundled with the inpatient claim more than any other preadmission testing services (e.g., surgical, therapeutic). This observation is based on an analysis of more than 177,000 Medicare discharges where 89% of the discharges had preadmission ED encounters. These encounters were not coded by the providers. While it is beyond the scope of this article to speculate how this happened, it does raise a question about whether emergency services were automatically bundled by these providers.

CMS guidance

When reviewing examples of encounters that should be unbundled, we have encounters that are clinically similar but did not meet the five-digit match criteria. Again, consider the following example.

Case 3: If the ED's primary diagnosis is 789.00 abdominal pain, the patient is subsequently admitted the day of or up to three days after the ED visit, and the primary inpatient diagnosis is identified as 577.0 acute pancreatitis, should the hospital unbundle the outpatient non-diagnostic charges because there is not a five-digit match?

In this scenario, we have a sign and a symptom presented in an outpatient setting that is also present in the inpatient primary diagnosis. One might think they are related, but direct correspondence from CMS guides that these services should be unbundled, and the nondiagnostic services should be billed separately to Part B because the outpatient and inpatient primary diagnoses did not have a five-digit match.

Another example is this question posed to CMS: "In our experience, the principal diagnosis on the emergency department visit and the principal diagnosis of the inpatient admission seldom have an exact match. For example, if the patient is seen in the ED for chest pain and is admitted on the same day to rule out a myocardial infarction that is later found to be present on the inpatient admission, there would not be an exact match between the principal diagnoses. Would the outpatient nondiagnostic services be unbundled and billed to Part B?" CMS again responded "yes" to billing Part B for the ED.

Testing and coding reviews

Review your procedures to ensure compliance with the latest guidelines in the Medicare Claims Processing Manual. First, a quick test is to see if all emergency records are coded prior to bundling and claims submission to Medicare. Second, test your bundled emergency records and see if the ED primary diagnosis meets the five-digit match with the inpatient primary diagnosis. If your processes do not meet these criteria, you should implement new procedures immediately. Implementing the procedures to comply with the Medicare Claims Processing Manual may require additional manpower in your Health Information Management (HIM) department; however, the additional revenue will likely exceed the expenses incurred, and you eliminate the risks inherent in noncompliant billing procedures.

If you are going to retroactively review your claims, you have until December 31, 2009, to address services provided after October 1, 2007, through September 30, 2008. For services provided October 1, 2008 through September 30, 2009, you have until December 31, 2010, to unbundle and rebill the claims.

Where the records have been previously coded, a review for the five-digit match can be done quite easily. Remember to capture all ED encounters that have been bundled. There can be cases where the patient came to the ED more than once in the three days prior to admission. If the records have not yet been coded, the personnel coding the records should not have access to the inpatient record or claim information to help ensure impartiality when coding.

Once the coding has been completed, we recommend that you test the coding findings. All documentation for services, both inpatient and outpatient coding, should be reviewed to make sure that the codes for both are correct before making the decision to unbundle. For those cases that have a four-digit match, we recommend reviewing all related documentation and findings to ensure accuracy. For all others, we recommend that you follow your internal guidelines for ensuring coding accuracy.

Remember, when you are performing a retrospective review, once you have identified those services that should have been unbundled, the inpatient claim needs to be adjusted prior to submitting the outpatient claim. Once there is an indication the claim is to be adjusted, the outpatient claim can be submitted. Some cases will result in a payment

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Enforcement of Medicare Secondary Payer regulation

By Jeanne Potter, BS, RHIT, CCS-P, CHC

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The Center for Medicare and Medicaid Services (CMS) is the federal agency responsible for administering the Medicare program. CMS releases new or revised guidance for physicians, beneficiaries, and other agencies on a daily basis, and misinterpretation of Medicare regulations often results in overpayments or billing errors. Because the reimbursement released by Medicare is supported by federal funds, blatant acts of Medicare fraud are currently handled by the federal policing agencies and court system, such as the Office of Inspector General (OIG) or Department of Justice (DOJ).

In the past, recoupment of overpayments resulting from waste, abuse, or fraud in the Medicare program was mostly directed to medical providers, because the financial well being of these organizations depended on reimbursement from state and federal governmental agencies, such as Medicare and Medicaid. In addition, recoupment could easily be deducted from the current and future bills that will be processed for payment. It was obvious, however, that the recoupment process in the Medicare offices was hindered by a lack of financial resources, auditing personnel, and authority. This all changed with the introduction of the Health Insurance Portability and Accountability Act (HIPAA) in 1996.

HIPAA increased the civil, criminal, and monetary penalties to entities that have been found guilty of committing Medicare fraud. In addition, OIG initiated large-scale audits to identify forms of waste, fraud, and abuse that resulted in overpayments to medical providers. In 2004 alone, OIG recouped $18 for each dollar they spent in recovery efforts. In 2006, OIG recouped $2.2 billion from health care fraud and abuse investigations, which was a dramatic increase from the $1.47 billion collected in 2005. The OIG audits worked quite well for CMS; therefore, federal funding to the audit program has been increased in the hopes that recoupment to the Medicare program will increase as well.

The Medicare Secondary Payer (MSP) regulation for medical providers has been a recurring topic in the OIG's annual Work Plan for many years. MSP guidelines would be in effect if a patient's medical treatment should be primarily covered by liability insurance (such as workers' compensation, auto, or homeowner's) or a group insurance policy. This regulation has been in effect for more than 20 years; however, the reimbursement topic was not a hot item until after the DOJ filed a lawsuit against Provident Life and Accident Company in 1988 for failing to comply with the MSP regulation. The lawsuit was settled for $27 million in 1993. At that time, DOJ made a recommendation to CMS to continue all efforts to recoup Medicare payments made in error as the primary carrier. Unlike most of the items discussed in the OIG Work Plan, this regulation pertains to any entity that plays a role in MSP, such as patients, insurance companies, employers, and even attorneys.

Since the Provident case, there have been a myriad of lawsuits directed to non-medical providers that were filed based on the MSP regulation. Three of these cases are:

Daniel C. Fanning vs. United States of America.[1] This lawsuit was filed by a single beneficiary on behalf of approximately 1,800 lawsuit settlement recipients who were receiving Medicare recoupment letters. The settlements were paid to patients who were implanted with faulty orthopedic bone screws. Medicare submitted the recoupment letters in an attempt to recover federal payments made for medical care pertaining to the faulty screws. Mr. Fanning believed he should not be liable for reimbursing Medicare after receiving his settlement. His lawsuit was not successful, and the MSP regulations were cited in the explanation for the decision.

Baxter International vs. United State of America.[2] This lawsuit was similar to the *Fanning vs. United States of America* case, in that it was in response to a settlement paid to recipients of faulty breast implants who were Medicare beneficiaries. The manufacturer was found liable in this case, because the company was found to be negligent for paying out settlements without regard to the Medicare MSP regulation.

Pollo Operations vs. Edna Tripp.[3] This lawsuit was filed against the Medicare beneficiary after she made attempts to collect her full injury settlement from Pollo Operations without reimbursing Medicare for the medical expenses previously paid. As with the other examples, the courts cited the MSP regulation as the reason for upholding this decision.

DOJ reported that 1,486 new MSP cases were filed in one US region alone during calendar year 2003, in addition to more than 2,000 pending cases already on file. The

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Enforcement of Medicare Secondary Payer regulation

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number of cases collected has only increased in the past years. In an effort to increase recoupment efforts related to the MSP regulation, CMS announced on October 2, 2006 that a new agency would be handling overpayments for non-medical providers—the MSP Recovery Contractor (MSPRC).[4] Although OIG continues to target fraud and abuse committed by medical providers, the MSPRC is responsible for submitting recovery letters to the beneficiaries, insurance companies, employers, attorneys, or other entities.

When an individual or entity is identified as having received a settlement or similar payment for medical services previously paid by Medicare, the MSPRC sends a letter demanding payment from the individual or entity within an allotted time frame. If payment is not received within this time frame, the MSPRC has the authority to charge interest for the monies owed. If the MSPRC is still not successful in collecting payment after interest has been added to the balance, the matter could be referred to the DOJ for legal action or the Department of Treasury (DOT) for monetary collection.

CMS is hoping the MSPRC will be just as successful in recouping erroneous Medicare payments as OIG has been, although they may not see the benefits immediately. The OIG audits took a few years to show remarkable results; therefore, it would be realistic to assume the MSPRC might require similar time to establish the program. If the MSPRC is as effective as the OIG audits, the health care industry may soon witness an onslaught of recoupment efforts made against non-medical providers, such as Medicare beneficiaries, attorneys, or liability insurance companies.

In addition to the creation of the MSPRC, CMS has initiated a process to match workers' compensation data from the states and workers' compensation agencies against the list of eligible Medicare beneficiaries.[5] This process will identify if a Medicare beneficiary has filed a workers' compensation claim in the past. This data will then be compared against the bills processed by Medicare in an attempt to identify bills for which Medicare should have been the secondary carrier. In addition to analyzing the databases, workers' compensation agencies are being encouraged to contact Medicare on the workers' compensation claims filed and settlements awarded, in a proactive effort to reduce the amount of erroneous MSP payments released. This process will capture the MSP scenarios that resulted in Medicare overpayments that have not been previously identified by Medicare.

In an effort to put more responsibility onto the entities receiving the settlements, Congress passed the Medicare, Medicaid, and SCHIP

Extension Act of 2007. This regulation shifts the responsibility of identifying when a claimant is a Medicare beneficiary onto the liability insurance and group health insurance carriers. The carriers will be obligated to submit "required information" regarding their claimants to Medicare and daily monetary penalties will apply in the event of non-compliance. To add teeth to the bill, Congress reserved $35,000,000 for CMS to implement the law over the next three fiscal years. Insurance companies can no longer keep their heads in the sand about their role in MSP regulation. MSP will no longer just be "Medicare's problem."

It's a little over a year since the Medicare, Medicaid, and SCHIP Extension Act was passed, and CMS has already used this regulation to file an unusual case. Attorneys are not safe from the Act's requirements, nor does the settlement have to reach monumental amounts for Medicare to develop an interest in recouping the reimbursement made.

A recent decision was made to deny an attorney's motion to dismiss charges made by CMS in an effort to recover payment after the attorney's client received a $25,000 settlement. Although CMS's overpayment was calculated to a miniscule $11,367.78, a statutory claim was still filed against the party deemed to be the "entity responsible for making the primary payment." The attorney was deemed to be the primary party, although he followed what was assumed to be "proper protocol" by communicating the distribution of funds to the patient and the settlement details to Medicare. He initially assumed his duty to the government was complete; that is, until he received the letter from Medicare demanding payment.

CMS cited specific rules when denying the attorney's motion to dismiss the suit. These rules are:

42 U.S.C. § 1395y (b) (2) (B) (ii) stating that "[a] primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made…"

42 U.S.C. § 1395y (b) (2) (B) (iii) stating that the government may "bring an action against any or all entities that are or were required or responsible…to make payment with respect to the same item or service… under a primary plan."

Cox v. Shalala, 112 F.3d 151, 154 (4th Cir. 1997) holding that the government "may recover…from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity."

42 C.F.R. §411.24(g) that "CMS has a right of action to recover its payments from any entity, including beneficiary provider, supplier, physician, attorney, State agency or private insurer that has received a primary payment."

It is important to note the courts clarified that the government can recover overpayments "from any entity that has received payment from a primary plan, including an attorney…" As of February 2009, this case is still pending; however, it is important to note the rules the government has referred to in the decision to deny the attorney's motion to dismiss. The final decision on this case can make a remarkable impact on how liability settlements are handled for current or soon-to-be Medicare beneficiaries, regardless if the overpayment is unsubstantial.

Recognizing the financial impact on the Medicare program, the government is now taking drastic steps to increase collection efforts for recouping Medicare payments that it should not have made as the primary carrier. The recoupment efforts against any entity are expected to dramatically increase with the addition of MSPRC, workers compensation data match efforts, and the Medicare, Medicaid, and SCHIP Extension Act of 2007. Even if a patient or attorney does not contact Medicare about a workers' compensation settlement, it is quite likely that Medicare will find out from the workers' compensation agency or after analyzing the agency's database. Being proactive here may pay dividends, as CMS states, "This would avoid Medicare making a mistaken payment and eliminate the need to recover from the workers' compensation carrier or responsible party."

1 See http://www.usdoj.gov/osg/briefs/2003/0responses/2003-1327.resp.html
2 See http://www.usdoj.gov/osg/briefs/2003/0responses/2003-1341.resp.html
3 See http://bulk.resource.org/courts.gov/states/Fla.Dist.Ct.App.3/3d03-0781.pdf
4 MSPRC available at: http://www.msprc.info/index.cfm?content=main
5 See WC Data Match: http://www2.cms.hhs.gov/WorkersCompAgencyServices/10_wcdatamatch.asp

Covenant Medical Center settles Stark Law violation for $4.5 million

By Gabriel L. Imperato, Esq., CHC

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On August 25, 2009, Covenant Medical Center (Covenant), a non-profit medical clinic in Waterloo, Iowa, agreed to pay the US government $4.5 million to settle allegations that it violated the False Claims Act (FCA). The case was not brought by a whistleblower, but was instead initiated by a competitor hospital's complaints to the federal government, including Iowa Senator, Chuck Grassley, the Internal Revenue Service, and the Department of Justice.

Covenant's settlement is the largest health care fraud settlement ever in the Northern District of Iowa. The allegations of health care fraud involved Covenant's improper financial arrangements with five employed physicians, who were allegedly paid in excess of fair market value for their performed tasks on behalf of Covenant. This is one of the few cases where the amount of compensation to an employed physician (an exception to the Stark Law prohibition) formed the basis for False Claims Act liability. Covenant expressly denied any wrongdoing and alleged that the government was unable to produce evidence that it had participated in any wrongdoing or illegal conduct.

Violations of the False Claims Act

The Stark Law prohibits improper compensation arrangements between hospitals and physicians, although there is an exception for employed physicians who refer patients, as long as their compensation is consistent with fair market value in the local marketplace. An arrangement is considered improper if a hospital pays a physician above fair market value and/or the arrangement is not commercially reasonable. The objective of the Stark Law is to ensure that physicians' medical judgments are not influenced by improper financial incentives, allowing them to make sure that decisions are made solely in the patients' best interests.

Violations of the Stark Law create liability under the civil False Claims Act when a hospital submits claims for payment to a government-sponsored health care plan or program such as Medicare. By submitting a claim for payment to a government-sponsored health care plan, the hospital is in effect certifying on its billing form that it has not violated any health care fraud law, such as the Stark Law. A hospital that knowingly submits a false claim for payment in violation of the Stark Law may have violated the False Claims Act. Here, the government alleged that Covenant submitted false claims for payment, because its referral arrangement with several physicians violated the Stark Law with the excessive compensation to the physicians.

These physicians were among the highest paid hospital-employed physicians, not only in Iowa, but in the United States. Conversely, Covenant claims that their physician compensation plan "was based on work personally performed by the physicians, and reflected their exceptionally high level of productivity."

Physician overcompensation

Investigations into Covenant for physician overcompensation began in 2005, when Cedar Valley Medical Specialists (CVMS), a for-profit medical clinic, expressed concerns to the US Senate Finance Committee, then chaired by US Senator Charles Grassley of Iowa, and to the US Department of the Treasury. CVMS obtained Internal Revenue Service 990 forms, which showed that in 2002, Covenant's five highest paid physicians made between $633,000 and $2.1 million a year. Two of the highest paid Covenant physicians were orthopedic surgeons Dr. Gary Knudson and Dr. Richard Naylor. In 2002, Knudson was paid $2.14 million and Naylor was paid $1 million for their services. Also, Dr. Victor Lawrinenko, a gastro-intestinal specialist, earned $2.1 million. Covenant claimed that the physicians were specialists that worked in understaffed areas and that their compensation was less in subsequent reports. Covenant also claimed that the physicians' compensation was based on a formula that accounted for the amount of business brought into the hospital by each physician and subtracted overhead expenses.

All Iowa hospitals are classified as nonprofit organizations, which exempts them from paying taxes on income, property, or sales. Though not required, they are expected to make up the tax difference by providing large amounts of charitable health care to needy people. In 2002, the same year Covenant paid some of its top physicians more than $2 million in compensation, reports showed

that Covenant provided less than $2 million in charity care. Generally, Iowa hospitals' charitable health care services constitute 3% of their patient revenues. However, according to the Iowa Hospital Association, Covenant's charitable health care service constituted only about 1% of its patient revenue, one third of the state average.

According to the IRS, the $633,000 to $2.1 million Covenant paid their top physicians was much greater than the highest paid physicians at another hospital in Waterloo, Allen Hospital, whose yearly physician compensation ranged from $230,000 and $360,000. Similarly, physicians at Covenant were receiving compensation that was several times higher than physicians at other hospitals in Des Moines, Cedar Rapids, University Hospitals and Clinics in Iowa City, as well as the Mayo Clinic in Rochester, Minnesota. At University Hospital in Iowa City, the state's biggest and best-known hospital, the highest paid physician made $417,000 in 2003. Similarly, the internationally acclaimed Mayo Clinic paid its top physician only $624,000 that same year.

The US Attorney for the Northern District of Iowa, assured the public that "we are actively working with our investigative partners to ensure Medicare funds are properly spent, and we will continue to aggressively pursue all types of fraud in order to protect federal health care dollars."[1] Additionally, the Internal Revenue Service has said that it is now making the question of excessive salaries a top priority in its regulation of nonprofit organizations. Covenant's settlement should serve as a warning to other nonprofit organizations that pay excessive salaries, because additional instances of excessive compensation are likely to be investigated by the federal government.

The author would like to acknowledge the significant contributions of Broad and Cassel law clerk, Vanessa Lee in the preparation of this article.

1 Press release from the US Attorneys Office Northen District of Iowa, August 25, 2009. Available at: http://www.usdoj.gov/usao/ian/press/August_09/8_25_09_Covenant.html

Screening physician contracts for private business use: An IRS Private Letter ruling

By Davis Sherman

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The Internal Revenue Service (IRS) issued Private Letter ruling (PLR) 200926005, released June 26, 2009 describing and applying the "facts and circumstances" pertinent to review of a professional services agreement between a hospital and one of its physician groups.[1] The reason for reviewing the agreement was to determine whether the agreement created the type of "private business use" that is generally not permitted in hospital facilities financed with tax-exempt bonds. All non-profit organizations that have borrowed the proceeds of tax-exempt bonds to pay for their facilities need to know when impermissible "private business use" arises and may need to self-report private business use on Schedule K in the organization's annual Form 990 return. The obligation to self-report begins with the Form 990 return covering any fiscal year beginning in 2009. The first such Form 990 filings will likely fall due in late 2010 or early 2011, depending on extensions.

Private business use—definition, limits, and enforcement

Broadly speaking, "private business use" means use of capital assets (buildings and equipment) financed with tax exempt bonds, either by a tax-exempt organization in an unrelated trade or business or by a taxpayer in a trade or business, unless permitted through an exception or safe harbor provided under the Internal Revenue Code and regulations or a Revenue Procedure. This article focuses on the latter category—specifically, on private business use that may arise when physicians who use bond-financed hospital buildings and equipment in their business as physicians, then also enter into contracts with the hospital. Many other "facts and circumstances" can give rise to private business use, but they are beyond the scope of this article.

Why worry about private business use? Tax-exempt organizations that have borrowed proceeds of tax-exempt bonds will have entered into binding loan covenants designed to protect the tax-exempt status of the bonds. The covenants limit the amount of private business use to the rather minimal amount allowed by the Internal Revenue Code and related regulations. Under the IRS's general rule, the permitted amount of private business use of a bond-financed asset can be up to 5%. Methods for calculating the precise percentage of private business use, whether based on space, time, or other allocations, can be found in the regulations. As a practical matter, however, the effective limit is often less than 3%, because transaction costs associated with issuing bonds are often paid with up to 2% of bond proceeds (as allowed by another IRS regulation), but the 2% cost-of-issuance allowance is deducted from the overall 5% private business use allowance.[2]

Violation of the loan covenants limiting private business use could lead to the IRS declaring that the interest payable on the bonds no longer qualifies as tax exempt. IRS has applied this extreme sanction relatively rarely, because it punishes not only the organization that allowed improper private business use of bond proceeds, but also creates havoc for innocent bondholders. Instead, the IRS favors imposing sanctions that may include a mandate to end the private business use, refund some or all of the bonds, or pay a settlement amount in a closing agreement, or a combination of all three. Currently, the IRS has no practical way of policing the loan covenants against private business use, short of a resource-intensive bond issue-by-bond issue audit of post-issuance compliance. IRS has initiated a random audit program, in part to assess the extent of non-compliance in various sectors of the tax-exempt bond market, specifically including health care bond issues. However, by redesigning the annual Form 990 return to be filed for fiscal years beginning in 2009 and thereafter, the IRS has prospectively shifted the burden of detecting and reporting non-compliance to each tax-exempt organization. Fortunately, the self-reporting requirement reaches back only to bonds issued in 2003 and afterwards.[3]

Service agreements and private business use

With this overview of the private business use limits in mind, let us turn back to a description of private business use that may arise in the context of badly drafted agreements between health care providers and physicians. Before analyzing the recent PLR about physician agreements, it may help to review broad categories of use of tax-exempt bond-financed assets that do not constitute private business use. For example, Internal Revenue Code §141(b)(6)(A) itself states that use as a member of the general public is not taken into account. Patients and their visitors do not "use" tax-exempt bond-financed facilities, because they are not there to make money in a trade or business. Nor do the organization's employees, because they are generally

working to carry out the organization's charitable purpose. Nor does private business use arise from use by certain incidental service providers, such as individuals or businesses holding contracts for janitorial, office equipment repair, hospital billing, or similar services, according to the regulations. The regulations also tell us that private business use does not arise from the mere granting of admitting privileges by a hospital to a doctor, even if conditioned on the provision of de minimis services (such as on-call obligations), if those privileges are available to all qualified physicians in the area.

On the other hand, private business use generally does arise when a hospital provides personal office space or treatment areas in a tax-exempt bond-financed building to a physician (other than an employed physician). Any arrangement giving ownership or leasehold rights or other special legal entitlements to a taxpayer creates private business use.[4]

Safe harbor guidance for management contracts

To span the wide gap in guidance between these examples of uses that do and do not give rise to private business use, the IRS has promulgated regulations and revenue procedures and has issued a handful of Private Letter rulings, including the PLR released this June. The primary source for guidance remains Treas. Reg. §1.141-3, captioned "Definition of Private Business Use" and Rev. Proc. 97-13, discussing so-called "management contracts." The regulations, and particularly Rev. Proc. 97-13, focus on types of contractual arrangements between tax-exempt organizations that are the direct users of tax-exempt bond proceeds and financed assets on the one hand, and on the other hand, certain users who benefit indirectly from special legal entitlements to use the bond-financed assets. IRS uses the term "management contract" to describe several types of contracts where the user of the bond-financed assets is a service provider who performs services involving all or any function of a facility, such as a hospital. Examples of management contracts include:

- contracts for provision of management services for an entire hospital,
- contracts for management services for a specific department of a hospital, and
- incentive payment contracts for physician services to patients of a hospital.

Management contracts of this general type may result in private business use of assets financed with tax-exempt bonds based on all of the facts and circumstances.[5]

Rev. Proc. 97-13 was intended to provide operating guidelines or safe harbors for types of management contracts that would not result in private business use. To put it another way, Rev. Proc. 97-13 was not intended to answer the question whether any particular management contract results in private business use. Instead, it only identifies five sets of facts and circumstances, so-called safe harbors, that describe permissible arrangements. The five safe harbors vary from one another primarily in the length of the contract term that is permitted, and in the degree to which compensation is determined by a periodic fixed fee versus by a formula based on a percentage of gross revenues, a capitation fee, or a per-unit fee. Longer contracts require a larger proportion of periodic fixed-fee compensation.[6]

Navigating outside safe harbors

The release of PLR 200926005 on June 26, 2009 underscores the proposition that other arrangements outside the six safe harbors may also be permissible. PLR 200926005 gives the IRS's blessing to a proposed form of professional services agreement (the Agreement) that a non-profit hospital wanted to use as its model contract for physicians in various specialties. The Agreement does not fit within any of the five safe harbor provisions set down in Rev. Proc. 97-13, but comes close to the safe harbor for contracts where all the compensation for services is based on a percentage of fees charged or a combination of a per-unit fee and a percentage of revenue or expense fee. Nevertheless, the IRS ruled that the Agreement does not result in private business use of tax-exempt bond financed assets based on its analysis of all of the facts and circumstances.

What were the salient facts and circumstances? First comes compensation. Under the Agreement, the physicians would agree to devote a significant portion of their time to patient care services in the hospital. The hospital would pay all expenses incurred as a result of the physicians performing professional services and would bill the patients or their insurance companies. The physicians would be paid a percentage of the net professional patient billings. The percentage varies—a base percentage for the first X dollars of net professional patient billings and different percentages for additional incremental dollar amounts of billings.

In sum, almost all of the compensation under the Agreement would consist of a percentage of fees generated by the physicians, adjusted for items such as insurance discounts and certain bad debts. The compensation formula specified in the Agreement steers clear of what the regulations generally prohibit: compensation based, in whole or in part, on a share of net profits from the operation of the facility. None of the expenses of the hospital or the physicians incurred in performing medical services would be taken into account in determining the amount of base compensation.

Second, the Agreement provides a mechanism

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to ensure that aggregate compensation would remain objectively reasonable. The Agreement gives the hospital the right to review a physician's compensation against the most current Medical Group Management Association Physician Compensation Survey for physicians practicing the same medical specialty in comparable locations.

Third, the Agreement provides for incentive compensation, up to a specified maximum percentage of base compensation. The incentive compensation amount is pegged to specific quality, learning, and customer goals. The quality goal is based on national quality standards and evidence-based clinical best practices established by national health organizations. The learning goal measures continuing medical education attainments, effective communication among medical staff, and adaptation to new medical technology to support quality and patient satisfaction. The customer goal targets measures of customer service and patient satisfaction. IRS noted that none of these incentive goals are based on the number of patients treated, or productivity, or net profits of the hospital or service line.

Fourth, the IRS noted that the Agreement's initial term is greater than two years, and its renewal and termination provisions, although outside the safe harbors, were specifically geared to addressing difficulties experienced by the hospital in attracting and retaining qualified physicians. The Agreement would automatically renew for additional terms unless either party gives 90 days notice prior to the end of the term or the Agreement is terminated for cause. IRS accepted the hospital's assertion that these terms and renewal provisions of the Agreement were justified by the poor economic climate, sub-par provider payment history, and history of difficulty in recruiting and retaining qualified physicians in an area outside of a large metropolitan area.

Finally, the IRS noted the absence of conflict-of-interest factors that might interfere with the hospital's ability to terminate the contracts. Following the precept set down in §5.04 of Rev. Proc. 97-13, the IRS examined the proposed Agreement for circumstances substantially limiting the hospital's ability to enforce the Agreement or terminate it. It noted that the physicians would not have more than 20% of the voting power of the hospital board, and would not be related parties for purposes of control.

Conclusion

What can we learn from PLR 200926005? First, contracts outside the five safe harbors do not necessarily give rise to private business use. Structured carefully, they may comply.

Second, cautious practitioners and hospital managers may not want to execute contracts outside the safe harbors on the basis of their own internal analysis of the facts and circumstances. Instead, like the hospital in the PLR, they may want, or may be advised by bond counsel, to seek a Private Letter ruling or other guidance from the IRS, which can be slow and expensive.

Third, practitioners can forecast a need for careful review of all management contracts as part of the organization's overall effort to determine whether it has private business use of its tax-exempt bond-financed facilities, and if so, how much to report on Form 990, Schedule K.

Fourth, organizations and their compliance staff may wish to begin the review of their management contracts well before the deadline for filing the first revised Form 990, Schedule K in 2010 or 2011, so that there is time to correct any problems that come to light.

1 The primary sources discussed in this article are IRS Private Letter Ruling 200926005, (June 26, 2009); the Internal Revenue Code of 1986, as amended, particularly Code §141(b); Treas. Reg. §1.141-3 (as amended in 2001); Rev. Proc. 97-13, 1997-1 C.B. 632, as modified by Rev. Proc. 2001-39; IRS Form 990 Instructions (posted December 19, 2008); Form 990, Schedule K (posted December 19, 2008); and Form 990, Schedule K Instructions (posted December 23, 2008).
2 See Code §141(b)(3); Treas. Reg. §§1.141-3(a), 1.145-2. The 5% limit applies only to bond-financed assets and the aggregate limit will be higher when substantial amounts of other funds were also used to pay for the asset.
3 See Form 990, Form 990 Instructions and Form 990, Schedule K Instructions, Part I and Part III, pp. 2-3
4 See Treas. Reg. §1.141-3(b) and Rev. Proc. 97-13
5 See Treas. Reg. §1.141-3(b)(4); Rev. Proc. 97-13, §3.03
6 See Rev. Proc. 97-13, §5

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Strategies for reducing relator attorney fees in False Claims Act qui tam actions:

By Melissa (Lisa) Thompson, JD, MPH; and Frederick Robinson, JD

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The Fraud Enforcement and Recovery Act of 2009 (FERA) expanded the reach and eliminated certain defenses under the federal False Claims Act (FCA),[1] thereby increasing the risk that a company will become involved in a *qui tam* case that may require a significant amount of money to resolve, including payment of the attorney fees, costs, and expenses of the whistleblower or relator.

Imagine that your company was involved in a *qui tam* action that has now settled, and it is your job to review the relator's attorney bills and negotiate a separate settlement. Before you write the check, however, be aware that under the FCA, recovery is limited to reasonable expenses necessarily incurred plus reasonable attorneys' fees and costs. This article will provide information to help you review relator attorney bills and develop a strategy for challenging the amount of a FCA fee award, with the goal of reimbursing relators for the reasonable fees, costs, and expenses to which they are entitled, and not more.

Background: the False Claims Act

The FCA allows the United States to seek treble damages and civil penalties against any person who knowingly presents a false or fraudulent claim for payment to the federal government. The FCA also allows private citizens, known as relators, to bring a *qui tam* action on behalf of the government. A number of states have enacted their own whistleblower statutes, modeled after the federal FCA, and it is not unusual for a relator to bring suit under both state and federal laws.

To commence a federal *qui tam* action, a relator files a complaint *in camera* with the applicable federal court and serves a copy on the government, along with a written disclosure of substantially all material evidence and information that the relator possesses. The government then evaluates the case to determine whether to intervene. If the government decides to intervene, it will assume primary responsibility for handling the case going forward.

If the *qui tam* case results in either a judgment or a settlement, the FCA allows a relator to share a percentage of the government's eventual recovery. The relator is also entitled to receive from the defendant, "an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs."[2]

Recovering attorney fees and costs

To recover fees and costs under the FCA, a relator must document the appropriate number of hours expended and the hourly rates. Relators cannot simply remit a single amount for payment; they have to be able to produce documentation sufficient to back it up. Typically, relators' attorneys will submit copies of their bills to the defendant, and the parties will attempt to mutually agree on an amount without involving the court. Under this scenario, a defendant has three basic options:

- pay the bills as submitted,
- attempt to settle for a reduced amount, or
- if the parties are unable to agree, be prepared to go to court.

These choices are not mutually exclusive. In fact, even after a fee request is presented to a court, the parties may settle the amount and pay the adjusted bills before a judgment is rendered.

Legal research conducted early in the process will help in developing an effective strategy and determining whether a basis exists for obtaining a reduction. It is also important to understand how judges handle attorney fee awards in the applicable jurisdiction so that this information can be used to negotiate a reduction in the bills or, in the alternative, to challenge them in court.

Courts typically will determine the appropriate amount of attorney fees by calculating the number of hours reasonably expended multiplied by a reasonable hourly rate.[3] This is called the "lodestar" method. When submitting fee requests, attorneys for relators should—but do not always—exercise "billing judgment" with respect to the hours worked. In this regard, courts will want to see that the attorneys have made a good-faith effort to exclude any hours that are excessive, redundant, or otherwise unnecessary, much as a lawyer in private practice should eliminate such time entries before submitting a bill for payment.

Under fee-shifting statutes such as the FCA, hours that are not properly billed to attorneys' clients are also not properly billed to their adversaries.[4] As will be explained below, certain categories of billing entries are particularly suspect and may be a basis on which to seek reductions in the bills.

Reducing the bills using overall percentage deductions

Some billing entries are so vague that meaningful review is virtually impossible. Courts have reduced attorney fees to account for incomplete and imprecise entries such as "legal research," "met w/client," "trial prep," and the like.[5] To account for vague entries, some courts analyze the bills on a line-by-line basis and eliminate individual items. More often, however, courts will reduce the total amount billed by an overall percentage.

"Over-lawyering" is another recognized basis for reducing legal fees.[6] An example of this is when multiple attorneys bill for the same task. While there are certainly appropriate situations for more than one attorney to bill, such as where a junior attorney with more knowledge of the internal workings of a case accompanies a senior attorney to a hearing or deposition, or where a multi-attorney conference is necessary. This is not always the case.

Another type of over-lawyering occurs when senior-level attorneys bill for tasks that should have been performed by junior-level attorneys. Even where attorneys hail from smaller firms that may lack associate-level resources, logic and practice suggest that when a senior-level attorney bills for work that an associate or paralegal can perform, the bills should be adjusted accordingly. Another area to target for a reduction in fees is when excessive hours are billed for work such as "review of documents produced by client," "deposition preparation," and other similar items that are potentially open ended in time.

Courts have cut other categories of entries by a percentage as well. For example, some courts will reduce excessive attorney time billed to "travel" by 50%. Others have scrutinized expenses. When there is insufficient documentation of expenses, such as a bill that presents a total charge for copying without specifying the price per page, some courts will apply a percent reduction to those charges as well.

Accordingly, if the bills contain any of the following types of entries, a case could be made that an overall percentage reduction should apply:

- imprecise, vague entries
- multiple attorneys billing for the same work
- fees billed at an inappropriately high level for the task
- extreme numbers of hours billed to work such as "research regarding…," "document review," or "trial preparation"
- excessive attorney time billed at full rates for travel
- insufficient documentation of expenses

Subtracting the hours not properly billed

Certain categories of attorney fees and expenses should not be submitted for payment at all. For example, a relator's attorney bills may contain entries for work unrelated to the *qui tam* claims, such as unrelated employment matters; time spent on unsuccessful claims; or work on tasks that are not necessary to the case, such as communications with the media. Fees and expenses for these claims are generally not compensable.[7]

Similarly, the relator's lawyers may try to charge for time spent negotiating the amount of the relator's share with the government, which also should not be compensated. Courts have reasoned that legal bills should be reduced dollar-for-dollar for entries relating to relator's share negotiations, because the defendant had no right to participate in the discussions between the relator and the government, particularly where there was nothing to suggest that the defendant prolonged the process or could have hastened its conclusion.[8]

When a lawyer bills for de minimis tasks or work that could be performed by a non-lawyer (e.g., copying documents, indexing files, filing a pleading with the court, setting up conference calls) this should also raise a red flag and may be a basis for reductions.

An argument can be made, therefore, either in discussions with relators' counsel or before the court, that the number of hours and the total fee should be reduced dollar-for-dollar to account for entries such as:

- work unrelated to the claims
- time billed for unsuccessful claims
- unnecessary work
- time spent negotiating relator's share of the recovery
- entries involving de minimis work
- lawyers billing for non-lawyer tasks

These deductions comprise precisely the type of "billing judgment" the relator's counsel should have exercised prior to submitting the bills for payment in the first place.

Determining a reasonable hourly rate

Hourly fees for attorneys vary significantly. To determine whether the rate sought by relator's counsel is reasonable, courts will look at whether the amount sought is typical of the prevailing rates in the community, for attorneys with similar levels of skill, experience, and reputation.[9] Some courts allow a rebuttable presumption that an attorney's usual billing rate is reasonable as long as it is in line with other attorneys providing similar services in the community, again looking at

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skill, experience, and reputation.[10] Other courts put the burden on relators to prove the fee is reasonable.

To prove their hourly rate is reasonable, relator's counsel will normally provide affidavits from other lawyers practicing in the community who have similar billing rates. To counter this, it is important to research typical billing rates in the community. If the rate will be argued in court, or potentially to bolster negotiations, affidavits should be used to support the defendant's position as well. Because billing rates apply across the board, even a small reduction in the rate can have a large effect on the overall total.

Fee determinations by the court

If a relator is not interested in compromise or if prior settlement negotiations fall apart, the issue will be decided by the court. After thoroughly analyzing the bills in light of the laws in the applicable jurisdiction and the judge's track record with attorney fee awards, if it appears that reductions are in order and the relator is balking, a company may be want to consider seeking the court's ruling, rather than simply writing a check.

As always, there are risks and benefits to putting the decision in a court's hands. One risk to consider is that a court can actually increase or "enhance" the amount of the attorney fees awarded, although this is supposed to be reserved for "rare" and "exceptional" situations.[11] The primary factors normally considered are the amount of time required for the case and the results obtained.

As a final matter, the total amount of a company's legal fees spent defending the case can be relevant to the reasonableness of a plaintiff's fees.[12] This can go either way. If a defendant's fees in the case are less than the amount being sought by the relator, there is an argument to be made that defendant's legal fees are an appropriate benchmark for the work that was reasonably required in the case. Where a defendant's fees are much greater that those of the relator, however, this could negatively impact the potential for a defendant to obtain any significant reduction of the fee request in court, and should be factored into the strategy.

Conclusion

When a company is in the unfortunate position of being responsible for a relator's legal fees in a qui tam action, it is important to evaluate the bills carefully to identify potentially problematic entries that could provide ammunition for reductions. Certain entries can provide a basis for arguing an overall percentage reduction should apply, such as imprecise, vague entries or tasks evidencing over-lawyering. Other entries may appropriately be subtracted out altogether; for example, work unrelated to the *qui tam* claims, time spent negotiating relator's share of the recovery, and entries involving de minimis tasks. Attorney billing rates should also be scrutinized and, if reduced, can have a significant impact on the overall total.

Develop an understanding of how the applicable jurisdiction and judge normally handle fee disputes. Assess the risks and benefits of going to court if the parties are unable to settle on an amount. Finally, remember that the burden is on the relator to prove the fees and expenses are reasonable. Bills not properly billed to clients are not properly billed to adversaries in a fee-shifting action such as the FCA. If relator's counsel have not exercised proper billing judgment prior to submitting the bills in the first place, reductions should be in order and able to be achieved.

1 31 U.S.C. §§ 3729-33.
2 31 U.S.C. § 3730(d)(1).
3 Hensley v. Eckerhart, 461 U.S. 424, 433 (1983).
4 Id. at 431 (quoting Copeland v. Marshall, 641 F.2d 880, 891 (D.C. Cir. 1980)(en banc)).
5 H.J. Inc. v. Flygt Corp., 925 F.2d 257, 260 (8th Cir. 1991).
6 See Kline v. W. City of Kan. City, Mo., Fire Dep't, 245 F.3d 707, 709 (8th Cir. 2001); Alexander v. Gerhardt Enterprises, Inc., 40 F. 3d 187, 194 (7th Cir. 1994).
7 See Hensley, 461 U.S. at 435 (time spent on claim distinct from successful claims should be excluded).
8 United States ex rel. Taxpayers Against Fraud v. General Electric Co., 41 F.3d 1032, 1044-46 (6th Cir. 1994); Miller v. Holzmann, 575 F. Supp. 2d 2, 26-27 (D.D.C. 2008).
9 Blum v. Stenson, 465 U.S. 886, 896 (1984).
10 See, e.g., Miller v. Holzmann, 575 F. Supp. 2d at 11-12.
11 See id. at 11.
12 See Am. Travelers Life Ins. Co. v. AIG Life Ins. Co., 354 F.3d 755, 761 (8th Cir. 2004).

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Three-day Payment Window Rule: A source of confusion, noncompliant billing, and additional revenue *...continued*

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reduction due to the adjustment of an outlier or an MS-DRG revision, but we have seen this in a small minority of the claims we have adjusted. The majority of inpatient claims adjustments have a positive impact or no impact at all on reimbursement.

Regardless of whether you perform this review concurrently or retrospectively, when the outpatient claim is submitted for payment, you need to include FL-17PS09, which indicates the services are provided within three days of admission but the services are not related (See Medicare Claims Processing Manual, Chapter 25, Section 75.2). You need to work with your clearinghouse to ensure they can submit the claim with this code.

Implementing this review into current operations is much easier than a retrospective review. With the retrospective review, additional steps to re-register the outpatient are necessary to track the claim through payment.

Being fully compliant with the Three-Day Payment Window Rule mitigates risk and increases your net revenue. It is a regulation that hospital compliance officers cannot afford to overlook.

New medication therapy guidelines for Medicare Part D sponsors

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In order to provide MTM services beginning in 2010, all Part D sponsors must comply with the above requirements. The new guidelines are quite thorough but most sponsors already meet many of the standards and should not be overburdened. The guidelines, which will result in increased access, enrollment, and compliance to MTM programs, are anticipated to improve overall health care and medication management.

1. Centers for Medicare & Medicaid Services (CMS). Department of Health & Human Services. March 30, 2009. Call Letter 2010, p 68-73
2. Centers for Medicare & Medicaid Services (CMS). Department of Health & Human Services: Medicare Prescription Drug Benefit Manual, Chapter 7 – Medication therapy management and quality improvement program. Pub. 100-18, Sep 5, 2008.

Survey results: Facebook, Twitter, LinkedIn and compliance

By Adam Turteltaub

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When it comes to the use of Facebook, the Marines have made a retreat, banning its use in the workplace.

A number of companies have taken the same approach, but what are they doing about employee use of social networking sites outside of the workplace? Just because someone uses these sites at home doesn't mean the risks have evaporated. There is still tremendous potential to post proprietary information as well as a slew of inappropriate content.

Further, the risk is not likely to go away. The explosion of social media usage on sites such as Facebook, Twitter, and LinkedIn is a force that will need to be reckoned with for some time. Facebook alone counts more than 250 million active users.

And, notably, corporate use of these sites is growing. The HCCA has a feed on Twitter (HCCA_News), a group on LinkedIn, and even a Facebook presence.

An ostrich approach clearly isn't sustainable given the risks and opportunities, but what should companies do? To help determine what is being done by employers, the Health Care Compliance Association and Society of Corporate Compliance and Ethics conducted a survey among compliance and ethics professionals in late August 2009. Just under 800 responses were received from individuals at for profit (both public and private), non-profit, and governmental institutions.

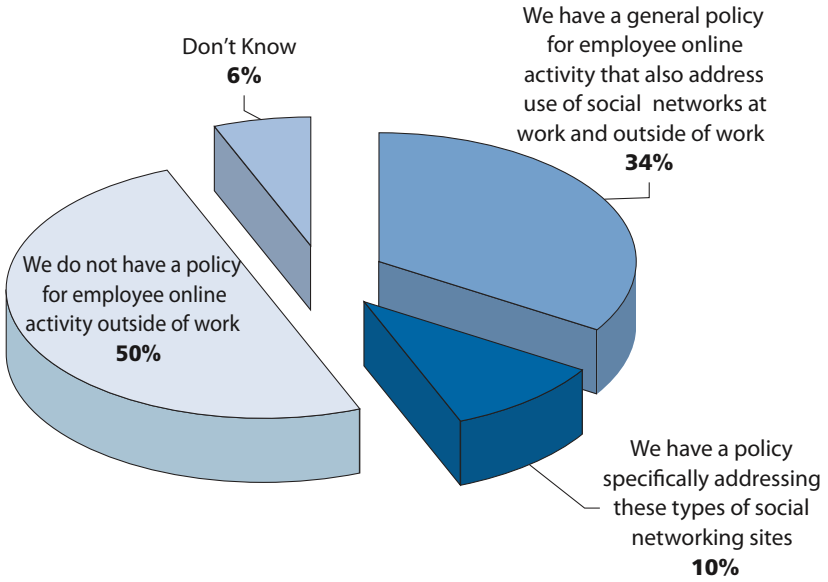
The results indicate that there is far from a consistent approach either to policy making or monitoring of employee behavior. Although some companies have set out a specific policy for their employees' online activities outside of work, half have not. Monitoring tends to passive more than active, this despite the fact that one quarter of respondents reported that their employer has had to discipline an employee for activities on Facebook, Twitter, or LinkedIn.

Detailed findings

What an employee does online outside of work remains largely his or her business. Half (50%) of respondents reported that their company does not have a policy for employee online activity outside of the workplace. Of those companies that do have a policy, 34% include it in a general policy on online usage, and just 10% specifically addressing the use of social network sites.

Mirroring the lack of a usage policy, roughly half of the respondents reported that their companies do not have an active monitoring system in place. About half (53%) reported that their company either doesn't monitor, hasn't had an issue, or has a passive system in place—they act when they are apprised of an issue. An informal monitoring process was reported by 8% of respondents. Where there is monitoring, it tends to be the provenance of the security department (24%), rather than compliance (2%). Another 14% of respondents didn't even know who handled monitoring, or if anyone did.

Does your company have policies specifically addressing employee use of Facebook, Twitter, LinkedIn and other social networking sites?



Despite the lack of formality in processes, companies are finding themselves needing to discipline employees for online behavior at social networking sites. About one quarter (24%) of respondents reported that an employee had been disciplined in their organization for activities on Facebook, Twitter, or LinkedIn. Interestingly, the percentage was much higher in the not-for-profit sector (33%) than in the for-profit sector (13%). And, once again, demonstrating a lack of development of processes in this area, 37% of respondents did not know if there had been an incident leading to discipline in their organization.

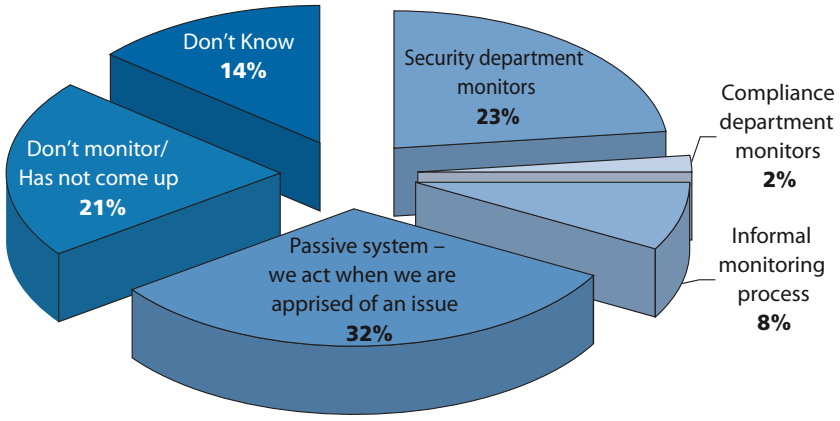
Conclusions

As is often the case with technology, the use of it tends to grow faster than the systems to manage its use. While social network usage has exploded, only about half of companies have put in place policies to govern employee usage of it.

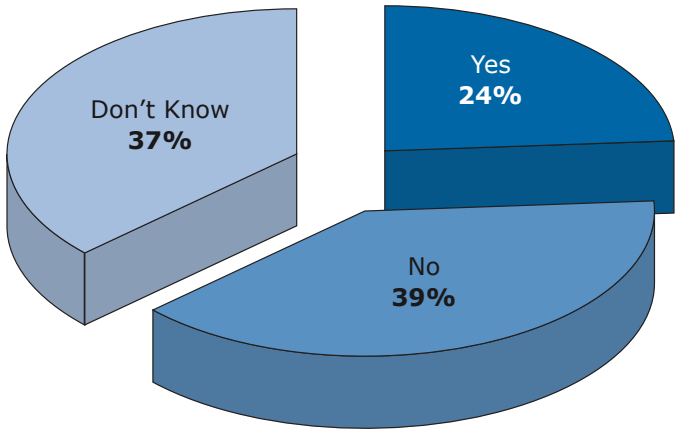
Although the data indicates that many organizations have had to discipline employees for improper activity online, the fears may outweigh the actual risks. A survey asking about discipline regarding improper e-mail usage would likely yield much higher numbers.

Nonetheless, the lack of formal processes for monitoring the usage of social networks could mean that there is much going on that organizations are, as yet, unaware of. In the long term, that may lead to more rigorous policies and procedures for managing social network usage.

How is employee activity monitored on Facebook, Twitter, LinkedIn and other social network sites?



Has your organization ever disciplined an employee for his or her activities on Facebook, Twitter, or LinkedIn?



Detecting and controlling fraud and abuse in managed care organizations

By Peter N. Francis, PhD

Editor's note: Peter N. Francis is a former Medicaid Program Integrity Director and Inspector General in Arizona. He provides auditing and consulting services to health care organizations and government agencies. He may be contacted via e-mail at petefrancisconsulting@cox.net.

Managed care is now a significant portion of the health care market in the United States, both in the government and commercial sector. As managed care has grown, payers have struggled to design fraud and abuse detection and control systems that are both suitable to managed care and cost effective and affordable. Detection and control systems built for Fee For Service (FFS) delivery systems are not often a good match to managed care. Thus, payers need alternative new strategies, especially if they are to meet the growing demand for improved fraud control engendered by federal health care reform efforts.

One common approach to controlling fraud and abuse in managed care has been to rely on managed care entities to police their own networks and to report problems to payers. This approach has been spurred by several circumstances and events:

Most payers do not have the resources and funding to oversee and monitor both FFS and managed care systems. Thus, there has been little choice but to rely on managed care entities to assume responsibility for controlling fraud and abuse.

Payers often have not had sufficiently accurate, complete, and reliable encounter data to mine for billing irregularities and anomalies. Without useful encounter data, payers have relied on managed care entities to maintain oversight over subcontractor payments.

Many health care entities, including managed care organizations, have been required over the past several years to develop fraud and abuse control and corporate compliance programs. These programs can lull payers into complacency, even if it is not known if the programs are effective.

The relative absence of high-profile fraud cases and program losses in managed care provides no compelling reason to reconsider the current approach. Lacking evidence to the contrary, payers may assume that fraud and abuse in managed care is adequately controlled.

The relative lack of high-profile fraud and abuse cases in managed care may be less an endorsement of the current approach than an indication that traditional detection systems are not well suited to managed care. Fraud continues to be a hidden crime that is only uncovered when detected. FFS detection methods, such as use of software to mine claims data, will not detect most of the kinds of fraud schemes that are unique to managed care.

On the contrary, the lack of high profile cases and the generally low level of fraud and abuse reporting in managed care should raise concerns. Although payers have relied heavily on managed care entities to control fraud and abuse, their faith in managed care organizations may, in some cases, be misplaced. There are ample reasons why managed care entities may not be willing or able to fulfill their fraud and abuse control responsibilities:

Lack of financial incentives

In most contracts with managed care organizations, fraud and abuse control is one more requirement that carries no financial incentives. Little or no reward is earned for investing time and resources in fraud control above the minimum level of effort needed to meet contract requirements.

Maintaining network relationships

Fraud and abuse control can conflict with other legitimate organizational goals. Managed care organizations must maintain networks and relationships with subcontractors that can be threatened and undermined by aggressive or intrusive oversight. In some rural or underserved areas, subcontractors may be hard to find and even harder to replace. Fraud and abuse control efforts that extend beyond "a wink and a nod" could threaten these relationships.

Legal liability

Fraud and abuse control and enforcement increases legal liability for managed care entities. Actions are subject to legal challenge and can lead to expensive and protracted litigation. In some cases, it may be less costly to ignore a problem than to risk the legal costs of taking action.

Corporate image

Effective fraud and abuse control can be bad for an entity's corporate image. No managed care chief executive wants to read a news story about either a dispute the organization may be having with a subcontractor or an action it may be taking against employees involved in misconduct. Fraud and abuse makes for bad

headlines, which is reason enough to avoid the problem in the first place.

Inexperience

Many managed care organizations may not have well-trained and experienced fraud and abuse control and compliance experts on staff who can develop and maintain an effective and professional program. Without these experienced and capable employees, the organization will struggle to be effective, even if its intentions are otherwise.

Costs

Fraud and abuse control may be viewed by some corporate executives as an overhead cost that, if not restrained, could potentially make the organization less competitive in the marketplace. Good fraud control requires a commitment of resources which, at least in the short term, may be viewed as bearing little fruit for the organization.

A better approach

Of course, questioning reliance on managed care entities to control fraud and abuse begs the question: What's the alternative? Is there a better approach that payers can take to ensure the integrity of their managed care delivery systems?

Although there are no easy answers, three strategies may offer opportunities to enhance the current approach, which relies heavily on self-policing:

Create a credible audit threat

The threat of a meaningful audit, even when the likelihood of audit is remote, keeps many individuals and organizations honest. This is the strategy that has been used successfully by the IRS for many years. The problem in health care is that many payers, in an effort to achieve broader audit coverage, conduct predictably superficial and shallow audits of fraud control or compliance programs. Managed care entities can easily prepare for and "pass" these audits, even if they have minimally effective or even ineffective programs. Payers should consider replacing the more numerous audits of this type with a less frequent audit that is meaningful and intensive. These audits would entail more testing of fraud prone areas, and a more in depth analysis of each element of the organization's fraud control program.

Strengthen sanctions and penalties

Audits must be backed up by enforcement actions when significant problems are identified. Payers should consider whether their current contracts with managed care entities provide sufficient sanctions to enforce effective fraud and abuse control. Can financial penalties be imposed if programs are not effective? Can enrollment be capped? Can the payer refer the managed care entity to federal or state enforcement authorities for possible civil or criminal prosecution? Without the option of strong sanctions, payers run the risk that managed care entities will ignore requirements and do little to address program deficiencies.

Conduct periodic risk assessments

Payers should also consider conducting annual risk assessments of managed care delivery systems that cut across organizational boundaries. The purpose of these risk assessments would be to identify emerging problem areas that pose a current threat. Fraud and abuse control efforts too often lag the real world, putting payers in the constant and difficult position of playing "catch-up." While closing one loophole, a new one is opening that may not be discovered until considerable financial damage has been done. Conducting periodic risk assessments represents a proactive way for payers to ensure that managed care fraud control programs are coordinated across the entire delivery system to address current, not past, vulnerabilities.

Payers do not have to abandon the current approach to controlling fraud and abuse in managed care. Reliance on managed care organizations for self-policing has many built in efficiencies and serves the common interest. Managed care organizations are closest to their subcontractors and enrollees, and are in the best position to detect potential problems early. Rather than abandoning the current approach, payers should consider supplementing the self-policing done by managed care organizations with more effective auditing and risk assessment activities.

New payer initiatives of this type may be welcome news to compliance officers who work in the trenches. With the stakes now higher, managed care organizations may be more motivated to invest adequate resources in their programs, make them an important priority, and provide the upper management support they deserve. Compliance officers and their staff may not have to work so hard to marshal the resources needed to maintain viable and effective programs.

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enforcement community for 13 years. The fact that Pfizer didn't get the message before the $2.3 billion settlement is a matter for the record books. The question you have to ask yourself is: Is this applicable to health care or business in general?

Certainly the USSG apply to all industries. You could pull out the name Pfizer and replace it with any company's name: say your own, and the logic still holds up. The idea that the CO should be free of conflict has nothing to do with health care. If the government finds this to be a conflict of interest for Pfizer, they could find it a conflict of interest for you. Senator Grassley's comments are also not health care specific. All these arguments made by all these people apply to all organizations. Independence of the CO is a universal concept.

If you defy this logic and continue to have the CO reporting to the GC, then you will have to explain a few things. Why did you ignore the USSG? How can your CO be responsible for defending others from your organization and report to someone who defends your organization from others? Lew Morris makes a great point. The leaders of the organization need to hear from both sides and the CO needs to be independent.

The University of California decided that their CO would be hired by and report to the Regents. Many organizations from many industries are moving the CO from reporting to the GC, to reporting to the CEO with a dotted line to the Board. In fact, some of the most experienced COs are refusing to accept job offers, because the company has the CO reporting to the GC. I get about three or four of these calls a year from COs. They are not just concerned about the reporting relationship, but rather the implication that if the organization would do this, there may be more problems. They don't think it works, and they don't want to be there when the company finds out it doesn't work. Keeping this reporting relationship could hurt your recruitment of an effective CO.

I recently returned from a meeting of 470 compliance professionals from around the country. I would guess that there were COs from 30 to 40 different industries. In fact, there were probably people from about a dozen countries in attendance. Because of the recent Pfizer settlement, the GC/CO reporting relationship issue was discussed in many sessions. Many were asked if they reported to the GC, and many did. They were asked if they thought it was appropriate, and few thought it was appropriate. In fact, much of the discussion centered on their frustration over their lack of independence and how they could correct the problem. Many felt they could not approach the subject without angering people. The point is that the profession thinks it's a bad idea, and those expecting compliance professionals to do their job will be taking this into consideration.

And don't forget the cynics. The cynics believe that the reason that many GCs insist that Compliance report to them is so they can keep them under their thumb. Some cynics believe that CEOs want the CO to report to the GC to keep a lid on the CO. In my 13 years in this business, almost all investigators I have met believe that it is done to keep a lid on things. One technique I have seen investigators use is to interview employees until they find one who will say "I think they have the CO reporting to the GC to prevent the CO from doing his job." They seem to always find one, and it makes them feel as though there is an attempt to cover up wrongdoing. This GC reporting to the CO relationship may be the best possible way to raise the aggravation level of enforcement authorities.

What I don't understand is why the GCs want to expose themselves to this. It is rare for a GC to be prosecuted by an investigator when GCs are doing their job defending the company. But if the GC is managing the compliance and ethics program and can be proven to have blocked remedial action of a known problem, they become part of the problem. That is what happened to the GC at Tenet. If I were the American Bar Association or any other thought-leadership group for GCs, I would be recommending that the CO should not report to the GC.

The greatest line I have ever heard related to this issue was used by more than one investigator I know. They start the initial investigation with two questions. Usually present are a table full of the key leaders from the company. The investigator asks, "Who here is responsible for defending the company." The GC raises their hand. Then they ask, "Who here is responsible for defending others from this organization?" The GC raises their hand again. It is at that moment that the investigator's mind is made up. Rightly or wrongly, it has happened before and it will happen again.

The bottom line is: Why do you have the CO report to the GC? What is the advantage? Is that reason/advantage worth the potential negative consequences? Actually, the real bottom line is: Do you want to have an effective compliance and ethics program? If you do, you would not have the CO report to the GC, regardless of what the government, Senators, or the investigators may tell you. Independence for the CO is a key to the success of any compliance and ethics program. A CO without independence is like an auditor who is unable to audit, or a risk manager who can't perform a risk assessment, or a lawyer who doesn't know the law. It just makes no sense.

New HCCA Members

The Health Care Compliance Association welcomes the following new members and organizations. Please update any contact information using the Member Center on the website, or e-mail Karrie Hakenson (karrie.hakenson@hcca-info.org) with changes or corrections.

Alabama

Linda Coogan, Medical West
Kathryn Ford

Alaska

Renae Axelson, Geneva Woods Pharmacy
Sidney G. Delaney, Anchorage Community Mental Health Services
Christy L. Klepinger, Providence Alaska Medical Center
Pam Miller, Behavioral Health Consulting Services
Rita Roach, Tanana Valley Medical Surgical Group
John Wray, Bartlett Regional Hospital

Arizona

Toby Anchie, St Joseph's Hospital
Thea R. Clemons, Little Colorado Behavioral Health Centers
Valli Goss, Arizona Attorney General's Office
Jill Hirneisen, Scottsdale Healthcare
Sue E. Hoopmann, Catholic HealthCare West
Timothy F. Hughes, Banner Medisun Inc
Cynthia Johnson, Univ Physicians Healthcare
Stephanie Kaul, Banner Health
Christine A. LoBianco, Banner Health System
Trina D. MacPhail, Sierra Vista Regional Health Center
Janeth G. Mattox, Maricopa Integrated Health System
Kathleen Morken, Evercare AZ
Tracy Patterson, NextCare, Inc.
Alex Robison, Protiviti Inc.
Alicia C. Rosales, Cancer Treatment Center of America
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Gregory Cohen, Physician Compliance Network, LLC
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Betty M. Hong
Margo Kaatz, Presbyterian Intercommunity Hospital
Farnaz Kashefi, Ensign Service Center
Debra Kaufman, Cedars Sinai
Priscilla Knolle, Stanford Hospital & Clinics
Michelle Knowles, A-Med Health Care
James R. Krausz, Loma Linda Univ Health Svcs
Larisa Kravchuk, Arnold Greenberg MD Inc
Todd Krim, SoftScript, Inc.
Greg Krug, Genomic Health Inc
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Ellen Minden, Sutter Health
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David Phillips, UnitedWestLabs Inc.
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Sergey Sergeyev, THE Clinic, Inc.
Nancy Smith, ProTransport-1
Debra Stanley, Redwood Regional Medical Group
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March 15–18 Boston, MA

June 7–10 San Francisco, CA

August 16–19 Chicago, IL

October 25–28 San Francisco, CA

November 15–18 Orlando, FL

CERTIFICATION EXAM OFFERED FOLLOWING EACH ACADEMY

REGISTRATION FOR EACH ACADEMY IS LIMITED TO 75 ATTENDEES

> **"I just wanted to say thank you for helping to coordinate and present such an educational and useful compliance academy. If I knew how much I was going learn and how many ideas I would leave with to improve our compliance program I would have attended much sooner. The academy helped to energize and inspire me to take our compliance program and myself as a compliance professional to the next level."**
>
> *Michael Scudillo, Chief Compliance Officer, Universal Institute, Inc.*

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Managed Care
Compliance Conference

February 21–23, 2010

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HCCA'S MANAGED CARE COMPLIANCE CONFERENCE provides essential information for individuals involved with the management of compliance at health plans. Plan to attend if you are a compliance professional from a health plan (all levels from officers to consultants), in-house and external counsel for a health plan, internal auditor from a health plan, regulatory compliance personnel, or managed care lawyer.

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