Same-Day Surgery®

Covering Hospitals, Surgery Centers, and Offices for More than 30 Years

December 2011: Vol. 35, No. 12
Pages 125-136

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Don't want a $1 million fine? Pay attention to regulated drugs

[Editor's note: In this issue of Same-Day Surgery, we put a special focus on compliance with regulated drugs. We've talked with some of the top pharmacy consultants in the country to find out foolproof systems for avoiding diversion and theft. These stories will help you decide where to focus your time and energy, while avoiding liability.]

A hospital-affiliated clinic and surgery center in Oklahoma have been fined $1 million in a settlement over claims that they failed to comply with federal regulations regarding record-keeping and inventory of regulated drugs, according to a media report.[1]

The parent company of the clinic and surgery center notified officials at the state and federal levels when they realized there were discrepancies in their inventories following the transfer of narcotics to the surgery center from the clinic, according to the report. Upon identifying inconsistencies, the clinic disclosed the discrepancies to the state Board of Pharmacy and the Drug Enforcement Administration (DEA). Investigators found that St. Anthony had not complied with all of the inventory and documentation requirements of the Federal Comprehensive Drug Abuse Prevention and Control Act.[1] No further details were released. Failure to comply with the federal requirements is subject

Next month we kick off our 35th year with salary survey results

Next month's issue marks the start of our 35th anniversary year of *Same-Day Surgery,* which we launch with the results of our annual salary survey .

With our annual salary survey results, you'll find out how your salary compares to your peers, and youll also find out what surgery programs are doing to stand out and attract staff. Don't miss this special issue of *Same-Day Surgery!*

This year we'll explore the new thresholds that outpatient providers are crossing including surgery on obese patients and the elderly. We'll also discuss how you can use new trends, such as social media, to your benefit. How can you market your facility in new ways? Also, we'll discuss how transparency is changing the job of the outpatient surgery manager. How can data be used as a marketing tool?We look forwared to serving you for the next 35 years.

to civil penalties of up to $10,000 per violation.

A spokesperson for the parent company was quoted as saying they are committed to improving their regulatory compliance efforts and that corrective actions have been taken.

"We're facing in this country a terrible epidemic to controlled substances, including substances dispensed at medical facilities," says **Sanford Coats**, JD, U.S. attorney in the Western District of Oklahoma in Oklahoma City. "Tracking is absolutely critical."

According to **Robert Troester**, executive assistant to the U.S. attorney in the Western District of Oklahoma, a situation becomes problematic not when there is a "single isolated missing form, but a systemic failure to keep control of documents and inventory."

The incident involving the Oklahoma healthcare providers is not isolated, Coats says. While most healthcare providers probably have good compliance programs in place, "some have been sloppy or haven't given it the due attention it needs," he says.

The federal fine comes at a time of increased focus on narcotics. Michael Jackson's death, blamed on propofol, has raised public concern about that drug, while there has been growing recognition of propofol abuse by medical providers. The DEA is considering designating propofol as a controlled substance. In the meantime, some hospitals and surgery centers already are accounting for items such as propofol as though they were designated as such.

Sheldon S. Sones, RPh, FASCP, president of Sheldon S. Sones and Associates, a safe medication and pharmacy consulting firm in Newington, CT, says, "Although it is important to remain compliant with federal and state requirements, I feel it is equally important to insulate the facility's stakeholders from the pain of controlled drug diversion issues. Thus, orchestrating a system that is both compliant and is structured appropriately is the end goal." *(For information on how to avoid drug diversion, see guest column, p. 128.)* Consider these suggestions:

• Have a pharmacist consultant review your policies and practices.

OA Center for Orthopaedics, in Portland, ME, addressed the issue of compliance with a team that included **Linda Ruterbories**, ANP, director of surgical services and program development, a staff nurse who was a compliance specialist, the PACU supervisor, and an anesthesiologist who subcontracted with

EXECUTIVE SUMMARY

The recent fine against a hospital-affiliated clinic and surgery center in Oklahoma has made outpatient surgery managers look again at regulation of their narcotics to ensure compliance with federal and state laws and to avoid diversion.

- Spot check narcotics waste, and look for patterns. Be alert to odd behavior by staff members.
- Consider security measures such as dead bolts, cameras, and links between the medication room and your facility's alarm system,
- Have two nurses count narcotics, and count them at the beginning of shifts, end of shifts, and when new staff members join a shift.

Same-Day Surgery® (ISSN 0190-5066) is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, NE, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Same-Day Surgery®, P.O. Box 105109, Atlanta, GA 30348.

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m. to 6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Outside U.S.A., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. Back issues, when available, are $83 each. (GST registration number R128870672.)

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This activity is intended for outpatient surgeons, surgery center managers, and other clinicians. It is in effect for 24 months after the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

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the facility. Sones was hired to review the facility.

He told the managers that they needed to change their procedures regarding samples of pregabalin. "Obviously, because they are a controlled substance, they needed to go into the Pyxis system and be dealt with in a different manner than before," Ruterbories says. Also, the staff had not been considering injectable Brevital to be a controlled substance. "Brevital is like propofol in a way, in that you wouldn't expect someone to abuse it or deviate from using it in the manner for which it was intended, but if it's a controlled substance, it needs to be treated as a controlled substance," Ruterbories says.

Traditionally, the staff members would pull narcotics from the Pyxis at the request of the anesthesiologist, who would document how much was used. Staff would waste the remainder. Sones recommended that they give the anesthesiologist a box with all of the anticipated medications for the day and have the anesthesiologist document specific patient use or, alternatively, draw the medications through the Pyxis on a patient-by-patient basis. He said either approach has to ensure thorough documentation of who received what, by whom, and when. Ruterbories points out that medications can be kept in locked anesthesia carts during business hours. Anesthesia staff, as well as others, should be monitored for any behavior changes that might indicate diversion, experts suggest.

• Spot check narcotics waste.

Nurses handle this responsibility at OA Center for Orthopaedics. They look at individual patient records and report any physicians or nurses about whom they have questions, Ruterbories says. "We're looking to establish patterns obviously," she says. *(See "Anesthesia Medication Reconciliation 2011 template" with the online issue. For assistance, contact customer service at (800) 688-2421.)*

Incorrect narcotic counts and patients who don't receive relief after being given pain meds might be signs of diversion, says **Bonnie Brady**, RN, CNOR, administrator at Specialty Surgical Center of Sparta, NJ. *(For more information on narcotics counts, see story, p. 127.)* "I have heard of substituting saline for narcotics," Brady says.

Be alert to odd behavior of your staff, Ruterbories advises. Atypical behaviors might include anxiety, belligerence, sweating, tremors, and compromised medical decisions. Random drug testing is one approach to such behavior, Ruterbories says.

• Consider security measures.

A few years ago at OA Center for Orthopaedics, thieves stole an anesthesia badge that was in an unlocked container and used it to enter the medication room and force open the Pyxis system. "Any system is only as good as the criminal trying to get into it," Ruterbories says. "They took all our narcotics."

The room is now locked down from 7 p.m. to 7 a.m. and is tied to the center's alarm system. Additionally, the administrators installed dead bolt locks that require a key. "It's not 100% foolproof; someone could find the key," Ruterbories says.

Centers also could consider installing a security camera in the medication room, which might deter thefts.

• Review your system of ordering narcotics.

At OA Center for Orthopaedics, the medical director "has to sign the DEA form so he's aware of all the narcotics we're ordering," Ruterbories says. The nurse compliance officer works with him on the ordering and obtaining of narcotics, she says.

Brady says. "Regulated drugs that are delivered should not be lying around when delivered but handed to a dedicated staff member to count and lock up."

At Specialty Surgical Center, any two nurses can count narcotics, Brady says. "That prevents any one nurse from being in total control of the count," she says. "Drugs are counted at the beginning and end of the shift and anytime there is a new staff member coming on at night."

REFERENCE

1. Associated Press. St. Anthony pays $1 million fine over non-compliance with federal drug inventory control rules. July 29, 2011. Accessed at http://www.therepublic.com/view/story/b14c290896454a8ba8a58a311043b5e9/OK—St-Anthony-Fine.

SOURCES

• **Sheldon S. Sones**, RPh, FASCP, President, Sheldon S. Sones and Associates, 15 Coachmen Lane, Newington, CT 06111. E-mail: Shelsones@aol.com. Web: www.Sheldonsones.com. Sones is a safe medication and pharmacy consultant to more than 110 ambulatory surgery centers in the Northeast. ■

Daily counts help avoid diversion

Daily counts of regulated drugs are one step to ensure compliance and to avoid diversion, says **Sheldon S. Sones**, RPh, FASCP, president of Newington, CT-based Sheldon S. Sones and Associates, a safe medication and pharmacy con-

sulting firm.

"We ensure that daily counts are performed at the location of controlled drug distribution as well as the larger 'safe,' which is counted on dispensing as well as monthly," says Sones, who points out that state requirements might differ.

Additionally, expect anesthesia providers to document clearly in the anesthesia record their controlled drug administration trail, he says. *(For more on the narcotics trail, see story, below.)* Consider these additional suggestions from Sones:

• Anesthesia providers should attest to drugs drawn for the work day and returned with another licensed individual.

• Records of controlled drug received should be retrievable and organized in such a way as to permit review of invoices.

• All discards of controlled drugs should be in a "real time" manner with witnessed signatures. Furthermore, the discards should be done in a manner that renders them "nonretrievable"

• Pharmacy consultant oversight should be performed on a monthly or quarterly basis with a review and attestation of compliance and accurate inventory. ■

Can you trace the narcotics trail?

To avoid diversion, address storage, documentation, and quality assurance, suggests **Sheldon S. Sones**, RPh, FASCP, president of Newington, CT-based Sheldon S. Sones and Associates, a safe medication and pharmacy consulting firm.

Drugs drawn for the day should have a trail that validates who took what drugs and when. "Likewise, on return to the main storage areas for the day, the same documentation should exist," Sones says. "Daily inventories of all stocks should be validated, and the federally required 'Biennial Controlled Drug Inventory' should be retrievable and in good stead."

The emphasis is on the word "trail," Sones says. He asks, "Can you identify what was delivered through your front door, who used what, and that what remains in stock is a quantitative `match'?"

• Ensure your records are in order.

The anesthesia record and the PACU record should be explicit as to what was administered, by whom, and when, Sones says. "One of the things we do on our routine visits is what I call a 'correlation' where we tag anesthesia records and compare them to controlled drug usage records to ensure the 'match.'" Sones says. "It speaks volumes to the commitment that the facility has to ensure compliance and control."

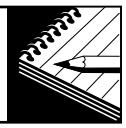
• Don't try to be solve the crime.

When looking for signs of potential diversion, "abnormal behavior of individuals with access to controlled drugs, casual documentation, illegibility, and even sometimes patient `under-response' to heretofor routine dosing are all reasons for suspect," Sones says.

If an issue is identified, communicate the problem to the administrator, clinical director, medical director, the Drug Enforcement Administration (DEA) registrant, which is the person who holds the DEA license; management company (if there is one), he says. "Basically, go up the leadership chain," Sones says.

Also, contact the legal authorities including state officials and DEA, he advises. "The facility should not take extraordinary detective-type efforts on its own," Sones says. "The facility, however, should aggregate data, information, and have a log of information gathered." ■

GUEST COLUMN



Substance diversion can and will happen

By **Christopher M. Dembny**, RPh
President
Dembny Pharmacy Consultants
Richardson, TX

Controlled substance diversion is one of those things that every administrator thinks "could never happen to me. I don't have any thieves or drug abusers working here." In my 20 years of being a pharmacist consultant for surgery centers, I've heard that more times than I can count.

We know that the national average is that 10% of the population has a problem with some type of substance abuse, and that the incidence is higher among those who have easy access. If you're in the healthcare industry long enough, you will have an experience with a person diverting controlled substances.

There is no way that we can completely prevent diversion. People who want drugs badly enough will find a way to steal them. It is our job to put systems

in place to discourage this and to detect it as quickly as possible when it happens. The little secret that few people know is that drug abusers will often target ambulatory surgery centers BECAUSE their systems to prevent diversion are not as well-designed and maintained as larger hospitals. Surgery centers rarely have automation (Pyxis, Omnicell, etc.) and have fewer people involved in the oversight of controlled substances. For someone who has a desire to steal controlled substances, this situation can make the drugs at a surgery center "low-hanging fruit."

That being said, every outpatient surgery program center should put as many safeguards and checks and balances in place to make it harder to steal and easier to detect. A good thief will always look for the easiest point of access. Some of these thieves have a lot more experience finding weak spots than we do at preventing and identifying them. Because of this, we need to make sure to close the holes in any areas that involve the movement of controlled substances:

- ordering and receiving drugs from wholesalers;
- daily administration to patients and wastage;
- transfer of drugs to another registrant;
- reverse management of drugs sent for destruction.

The area with the best potential for large scale diversion is the ordering and receiving drugs from wholesalers. Abusers can obtain large quantities of controlled substances by intercepting drugs in this first step of their journey through the facility.

Safeguards that should be put in place in this area include:

- A different person should receive the drugs than the person who ordered them.
- Someone other than those two people (preferably a consultant pharmacist) should validate that every controlled substance that is received is added to the continual inventory. This step is done by reviewing the controlled substance invoices and checking off, line by line, that every controlled substance that is invoiced has a matching entry that it was added to the continual inventory. This step shouldn't be very difficult because invoices for Schedule II drugs (CII) under the Controlled Substances Act for the United States are required by the Drug Enforcement Administration (DEA) to be maintained separately. Also, invoices for drugs in schedules CIII-V must be maintained in a separate file.
- Many facilities will keep a log of all the DEA 222 forms received and when they are used to order controlled substances. This step will prevent someone from stealing a DEA 222 form and using it to procure CII drugs. With the advent of the controlled substance ordering system (CSOS), the need for this step will diminish as people order CII's online through this system.
- At the end of each month or quarter, someone should review the documentation from the wholesaler to ensure that there are invoices present for all controlled substances shipped from the wholesaler to the surgery center. These are the invoices mentioned above that a third person has validated have been added to inventory. This step is accomplished either by a summary of controlled substances shipped from the wholesaler (generated by the wholesaler) or a review of the invoices paid by accounts payable (AP). Note that we want the ones from AP. Someone could steal drugs by destroying the pharmacy copy of the invoice, but they still have to send one on to be paid or it sends up a red flag from the supplier.

In summary, we should be able to validate that every controlled substance shipped to the surgery center has been added to the continual inventory. Nothing should be able to be removed from the supply chain as it moved toward the center.

- The volume of controlled substances that move through the system by daily administration to the patients also creates movement of drugs that can be falsified and drugs removed from the system. Controlled substance policies should be in place and be followed for the day-to-day tracking and administration of controlled substances, AND they should be followed. *(See more information, p. 130.)*
- Any transfer of controlled substances to another registrant (borrowing by another surgery center, hospital, or physician) is carefully documented and validated. This should happen rarely, but when it does, it needs to be documented correctly, including a DEA 222 form if schedule II drugs are involved.
- Another way drugs leave the facility is through reverse management channels for expired medications.

A log should be maintained of drugs that are removed from inventory because they are expired. These drugs should be signed out of the regular inventory and into the expired inventory when they are removed from regular stock. The expired drug log also should contain space for information to document the return and/or destruction by a wholesaler or reverse management company. In this way, there is a reproducible audit trail that can be followed from

— removal of drugs from current stock;
— addition to expired drug inventory;
— transfer from expired drug inventory to reverse management company;
— documentation of destruction by reverse man-

agement company.

In summary, people WILL steal controlled substances. If you haven't experienced it yet, you will. Anyone who has been in healthcare very long knows of instances of this happening. We need to do all we can to make sure that our facility doesn't fall victim to theft of controlled substances.

The potential problems caused by this theft are many. A lawsuit because of poor patient care delivered by an impaired caregiver is one of many potential consequences. Scrutiny from the DEA is another. We need to remain vigilant and put systems in place that will deter and detect controlled substance diversion. *(Editor's note: Dembny is a consultant pharmacist who has been consulting for ASCs for 20 years. He is consulting for 75 ASCs. He can be reached at cdembny@tx.rr.com.)* ■

Ensure these steps for controlled substances

By **Christopher M. Dembny**, RPh
President
Dembny Pharmacy Consultants
Richardson, TX

Controlled substance policies should be in place and be followed for the day-to-day tracking and administration of controlled substances. Here are my recommended steps:

• Two people should count controlled substances at the beginning and end of each shift (often each day in the ambulatory surgery center environment).

• There must be a reproducible audit trail for all drugs that leave the inventory of the facility and are administered to the patient/wasted.

• For each controlled substance that is administered/wasted, the Drug Enforcement Administration (DEA) requires documentation of:

— date and time of administration;

— name of patient;

— drug and dosage form administered;

— dose administered;

— amount of drug wasted (if any);

— signature or electronic signature of the person administering the controlled substance;

— signature or electronic signature of the person witnessing waste of controlled substance (if any);

— name of the practitioner who ordered the controlled substance.

These records must be maintained separately from patient charts and must be readily retrievable. Someone should go back and validate these entries with an eye for diversion. This retrospective review is done in many states by the consultant pharmacist. *(See signs of potential diversion, below.)*

There should be a reproducible audit trail that anyone can follow. The time to see if this trail is easy to follow is not when the DEA or other regulatory agency comes to visit. Managers need to know that they can track all controlled substances leaving their inventory. This process can be labor intensive, but it the best way to ensure that drugs are not just walking out the door with staff. Drugs also can be diverted as they are transferred out of the facility. *(For more information on diversion, see "Warning! Some drugs diverted for murders,"* Same-Day Surgery, *July 2011, p. 69.)* ■

Potentials Signs of Diversion

• Messy paperwork that is hard to follow

• Altered entries in the documentation

• Late entries. Example: controlled substance documentation for the 10 a.m. case that wasn't entered until 3 p.m.

• One person's signature that appears on the paperwork more times than everyone else's

• A significant amount of controlled substance wastage

• Unusually large doses

• Controlled substances administered to patients who didn't have painful procedures

• The same person always doing the beginning and/or ending count

• Audit trail not complete and reproducible. For example, if 12 fentanyl 2 ml amps left the inventory on a given day, there should be documentation that 12 amps were administered/wasted. Without this validation, drugs can just disappear, and no one will notice it. Surgery centers often administer a large amount of controlled substances. Someone patient enough to steal just a few dosage units per day can get away with it for a while.

Source: Christopher M. Dembny, RPh, President, Dembny Pharmacy Consultants, Richardson, TX.

Same-Day Surgery Manager

Lessons learned with new ASC opening

By **Stephen W. Earnhart**, MS
CEO
Earnhart & Associates
Austin, TX

We just opened our newest ambulatory surgery center (ASC) in Texas this week. We think it is our 206th, but we could be off on that number. While it is an ASC, there is some useful information for our hospital readers here. Please read on!

The center is a six-OR single-specialty center with an anticipated 8,000 cases in year one. We certainly will exceed that number in year two, as the total count for the physician investors current volume exceeds 15,000 cases in four area hospitals and two other surgery centers. There is no hospital investor. They were not invited by the docs.

While opening a new surgery center is not a big deal anymore, there are issues around this center that intrigued me. These issues offer lessons to other surgery centers, as well as surgeon offices and hospital outpatient departments, about how to achieve cost savings. Let's start with obvious:

• **Equipment.**

We will have spent a little over $2 million on equipment and instrumentation at this site. We came in under budget by about $200,000 because the surgeons (seven different practices) all agreed to a common set of major equipment systems and agreed to change their instrumentation needs, which is not an easy accomplishment, as many of you know. There was a lot of compromise, and a lot of vendors were upset, but the result was a huge savings for the ASC.

I always wonder, in these terrible economic days, why hospitals don't do the same. The money they could save by being firm on the systems they purchase and maintain would be enormous. Granted they would lose some surgeons that didn't get what they wanted, but they probably would lose them anyway if that is the way they function.

• **Staffing.**

We did not want to anger the local hospitals and other surgery centers (they might read this!) where the surgeons operate by cherry picking their staffs, but we had several applicants from those institutions anyway. Most of the applicants were from the hospitals.

Since Earnhart & Associates is managing this center for a long time, we were as picky as the surgeons about whom we hired. We wanted hungry staff! Of the 25 FTE positions we hired, only two or three came from the hospitals. The majority of the staff are new RNs and a few experienced scrub techs.

Most of the hospital staff members that applied did not want to be cross-trained (a requirement), wanted a full retirement plan year one (come on — it is a new center!), wanted the current salary they had at the hospitals where they had been for 15 years plus (and a bump even to that!), and they wanted facility-paid health insurance for entire family, not just the employee-paid. In other words, they wanted status quo and no risk. The surgeons gave us a clear understanding that they would much rather train new, energetic staff who were interested in growing their careers rather than staff that were at the end of their careers and had no interest in making the new center a success.

This information is a lesson to some: Often we have to take a chance when we are making change in employers. The new staff at the surgery center has no call, no emergency cases, no weekends, generally healthy patients, and no big hospital hassle. Often tradeoffs must occur!

• **Physical building.**

Due to size of the new center, we had to buy a building, tear it down, and start from scratch. Again, in these economically interesting times, you would think that cities would embrace a new tax source. Oh, no. They put up as many roadblocks as possible. Again, some people just do not get it. In spite of the city and the length of time it took to get permits, we still came in under budget on the building and opened two weeks early.

We were able to do our first case 12 days after our certificate of occupancy, which meant we beat our old record of 18 days. Thus, the city will get its revenue regardless.

• **Vendors.**

I know that I am usually hard on vendors in my column, but I have to hand it to these ladies and gentlemen: They really helped us obtain the best pricing, and they gave us outstanding service! I asked one of the reps why he was going out of his way to help us stay in our budget, and he told me it was because we were trying to be budget-conscious! That was cool.

• **First patients.**

Anesthesia cancelled our very first case. Medically

necessary. A bummer for some, but I was delighted! We were setting the marker that patient safety was a huge issue for us.

Our second patient — well, really our *first real* patient — was 45 minutes late. Of course. That was even with the two pre-op calls and directions. He finally showed up, and his "responsible adult" took off as soon as the patient walked in the door. That was fun getting his ride home to come back to the center. The patient did, however, get into the operating room 4 minutes early (yes – I track that), had general anesthesia, and was discharged an hour later. So in spite of everything, the system still works.

Once again it proved to me why I love my job so much! Nice job by everyone.

[Earnhart & Associates is a consulting firm specializing in all aspects of outpatient surgery development and management. Contact Earnhart at 13492 Research Blvd., Suite 120-258, Austin, TX 78750-2254. E-mail: searnhart@earnhart.com. Web: www.earnhart.com. Twitter: @SurgeryInc.] ■

Is your patient dealing with high out-of-pocket?

Make it clear you're there to help

More often, outpatient surgery staff members find themselves in the unenviable position of telling patients about out-of-pocket responsibilities running into the thousands of dollars.

Offering patients an immediate discount if they pay upfront is one good approach, according to **Gail Melingonis**, director of patient access at the University of Connecticut Health Center in Farmington. "Let's say a self-pay patient is going to have surgery, and their out-of-pocket estimate is $10,000. We'll give them that dollar amount, and say, 'If you pay us today, we will give you a 30% discount,'" she says.

Financial counselors must be clear that the $10,000 is an *estimate* of charges, and that there might be additional charges if procedures are added and that the 30% discount would apply to the entire balance in that case, says Melingonis.

If an insured patient has a large unmet deductible, of $2,000 for example, financial counselors do try to collect the entire amount. If the patient says they will not pay anything on the deductible, procedures or surgery isn't held up, however, says Melingonis. "If the patient says they can't pay the entire deductible, we ask them how much they would be comfortable with. We aim for at least half," she says. "If they offer us $20, we may ask for more. If they can't, we would take whatever they offer."

More accurate estimate

If self-pay patients can't pay an account balance, financial counselors meet with them to see if they qualify for some type of assistance, whether a public program or the hospital's charity care program.

"If they really don't qualify for anything, we tell them that we could set up a payment plan," says Melingonis.

This step isn't done at the point of service, however, because at that point, the actual charges aren't yet known, she says. "We would rather have them get the final bill before we set them up on a payment plan," says Melingonis. "Otherwise, we may over or under estimate what the monthly plan amount should be."

When financial counselors quote a price to a patient, they rely on the CPT code for the procedure that the doctor is planning to perform, she says. If the patient is having a knee arthroscopy, for instance, financial counselors estimate charges based on the CPT code, the fee schedule, the facility fee, and the number of hours the patient will be under anesthesia.

Based on that information, a self-pay patient might be quoted a price of $7,000, but that amount might change because the physician ended up doing a repair during the procedure, she says. "Some patients will call us very frustrated and want to know how much they're going to get charged," says Melingonis.

Financial counselors contact the patient's physician's office to find out exactly what they are planning to do, which gives them more accurate information to base the estimate on. "We try very, very hard to give as much information as we possibly can and make the patient feel that we are helping them," says Melingonis. "They are already being hit because they have a medical issue. I don't want to hit them again with a financial issue."

Deductibles explained

Financial counselors offer to contact the patient's insurance company to find out how much of the deductible has been met. In some cases, patients don't even realize they are responsible for a large deductible before insurance will consider paying anything at all, Melingonis says.

"We find this comes up most often at the begin-

ning of the year, or when insurance takes effect," she says.

Occasionally, an overwhelmed patient will ask a financial counselor, "Why is it so expensive?" In this case, says Melingonis, staff state, "These are deductibles your insurance company set. If you went to any other facility or were treated by another physician, you are still going to have this expense before insurance will consider paying anything."

When patients express dissatisfaction with their insurance policy, they also can be advised to speak with their employer's human resources/benefits manager about their plans.

SOURCE

For more information on helping patients with out-of-pocket responsibilities, contact:

• **Gail Melingonis**, Director of Patient Access, University of Connecticut Health Center, Farmington. Phone: (860) 679-4542. Fax: (860) 679-1636. E-mail: melingonis@nso2.uchc.edu. ■

The worst IT threats can come from inside

Imagine the havoc if one day your organization's critical data just … *disappeared*.

It could happen, says **Eric Chiu**, founder & president of HyTrust, a company in Mountain View, CA, that specializes in access control for data. It likely would be caused by someone employed or formerly employed at your organization, he says.

Information technology (IT) security often focuses on the threat of outsiders hacking into your system, but your own employees could pose the biggest threat of all, Chiu warns. He cites a recent incident in New Jersey that he says illustrates the threat posed by insiders: A former employee of the Japanese pharmaceutical company Shionogi was able to hack the organization and effectively take down its virtual infrastructure, which caused $800,000 in damages to the company.

"Insider threats are on the rise, whether from malicious or disgruntled employees, data leaks, or mistakes and other unintentional issues," Chiu says. "The breach at Shionogi is a great example of how vulnerable virtualization infrastructure and the cloud can be. Critical systems like e-mail, order tracking, financial, and other services were impacted, having been virtualized without the proper controls in place. This was because a disgruntled admin was able to delete the corporate servers with a simple click of a button."

EXECUTIVE SUMMARY

Employees can compromise information technology (IT) security if you do not take the right precautions.
Willful acts by employees can be even more damaging than data theft by outside hackers.
A recent case in New Jersey shows how easily a data system can be breached.
The virtualization layer used in many systems can be especially vulnerable.
Virtual infrastructure often is not protected as well as physical servers.

To add insult to injury, he was able to do this remotely while sitting at a booth in a Georgia McDonald's, using the restaurant's wi-fi connection, Chiu says.

The $800,000 in damages and multiple days of downtime at Shionogi could have been prevented with the right automated controls in place, he says. IT administrators, such as the man charged with the Shionogi crime, are primary threats because they must be privileged users with extensive access to the system and its controls, he says.

"They have credentials and back doors that they have put in place, and in this case, he was able to log in using those credentials long after he had been fired from the company," Chiu says. "He proceeded to delete all of the servers and virtual machines that the company ran on, which put the company out of business for a week and cost them almost a million dollars in damages."

The damage can be even worse, Chiu notes. In the Shionogi case, the vandal did not use an especially sophisticated method but rather manually deleted 90 virtual machines from the system one at a time. A more determined hacker could destroy 20,000 virtual machines in five minutes using a program code, he says.

That "virtualization layer," in which data is stored and managed on "machines" that exist only within the system, is a major trend in IT, Chiu says, and it creates vulnerabilities. "Insider threats are not new, but what is new is that about 50% of servers are running on top of virtualization. You can do much more in terms of attacking or stealing data by going through the virtualization layer," Chiu says. "If you want to steal patient information, it can be as easy as going in through the virtualization layer, copying the virtual machine, and putting it on your laptop. You don't have to go through an elaborate program of sniffing the system for weak points if you can access that virtualization layer."

The virtual infrastructure must be secured just like the physical servers, and that step is where most companies are falling short, Chiu says. In his experience, Chiu says, more than 80% of companies do not have proper controls for securing the virtualization layer. *(See the story below for more on considering the risks of virtualization.)*

"We're seeing just the tip of the iceberg because most of these breaches go unpublished," Chiu says. "For every public one like Shionogi, there are probably hundreds that we don't hear about."

SOURCE

• **Eric Chiu**, Co-founder and President, Hytrust, Mountain View, CA. Telephone: (650) 681-8100. ■

Focus on threats, not just ROI of virtualization

The vulnerabilities of a virtual infrastructure are real, but they often are overlooked while healthcare leaders focus on the return on investment (ROI), says **Eric Chiu**, founder & president of HyTrust, a company in Mountain View, CA, that specializes in access control for data.

"Healthcare companies are not focused on the security aspects of virtualizing patient health information but are focused on the ROI aspects," he says. "They're treating the virtual environment the same way they did the physical data center, so they're securing networks and applications, but they're not securing the underlying technology that all of those applications are sitting on top of."

Chiu says it is only a matter of time before a hospital or health system reports a major breach through its virtualization layer. "Only about 15% of these kind of breaches are done because of a conflict like someone being fired. Most of it is done for personal gain or wanting to expose information like was done with Wikileaks," Chiu says. "The admins can go in and, with the access and free rein they have in the environment, they can steal all sorts of data and never be detected." ■

Quarter of providers report breach in past year

About one-quarter of healthcare respondents reported that their organization has experienced a security breach in the past year, according to survey results from the Healthcare Information Management and Systems Society (HIMSS) in Chicago.

An internal breach of security continues to be the primary concern raised with regard to the security of electronic medical information.

Slightly more than one quarter of respondents (26%) noted that their organization has experienced a security breach in the past 12 months. This is similar to the 23% of respondents who noted this situation to be the case in 2010, according to the 22nd Annual HIMSS Leadership Survey. (The full survey report is available online at http://tinyurl.com/3ecjd8m.)

For the past several years, an internal breach of security has been identified as a primary concern regarding the security of electronic medical information among survey respondents, the report says. This ranking was also the case in this year's survey, when it was identified by 36% of respondents.

Another one-third of respondents (30%) reported that compliance with HIPAA security regulations/CMS security audits was a primary concern with regard to the security of electronic medical information. Rounding out the top three is inadequate funding/support for the security process, which was selected by 17% of respondents respectively. These were also top concerns identified in last year's study.

Only 4% of respondents indicated that they don't have any concerns about the security of electronic medical information at their organization, identical to what was reported in the 2010 survey. Respondents were least likely to report that lack of compliance with a business associate agreement was a primary security concern, identified by 3% of respondents. ■

Flu outbreak points to risk from ill co-workers

Working while sick led to outbreak

In the first weeks of the 2009 H1N1 pandemic, a physician became ill at a Chicago hospital and tested positive for the virus. Then other healthcare workers became ill and tested positive — an outbreak that began at a time when the virus was not widespread in the community.

An investigation, reported in *Infection Control and Hospital Epidemiology*, revealed an interesting pattern: The transmission was occurring among co-

workers, not from or to patients. Even if healthcare workers took precautions to protect patients, they were getting each other sick.[1]

Prevention of influenza transmission "is not about patient to provider, it's about transmission from person to person. You really need to take a comprehensive approach to preventing the transmission of influenza," says **David Kuhar**, MD, medical officer with the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC).

The transmission might have stemmed in part from a misguided sense of devotion to their jobs. More than half (55%) of the infected healthcare workers reported coming to work one or more days after developing flu-like symptoms. "This paper serves as a reminder as to what we should be doing for infection control for influenza," says Kuhar. "There need to be institutional strategies to prevent transmission of influenza. Showing up to work sick is not good for your coworkers and your patients."

The study's authors note that health care workers had "multiple exposure opportunities" to their ill co-workers. "For example, some [healthcare worker] cases reported traveling to a clinic together by car prior to illness onset. In addition, resident physicians attended daily morning reports and noon conferences," the authors said.

In fact, two healthcare workers who developed H1N1 reported always wearing an N95 respirator or surgical mask when entering a patient room with a patient with respiratory illness.

The hospital ultimately controlled the outbreak with some strict infection control measures. Access to the hospital was restricted to a single entrance near the Emergency Department. Healthcare workers were required to wear surgical masks in most clinical areas. The hospital also cancelled all non-essential meetings and asked employees to report to the employee health staff for screening for influenza-like illness.

By mid-May, 83% of the hospital's 1,721 employees had been screened for symptoms. About 95% of those received prescriptions for oseltamivir for prophylaxis. The outbreak then subsided.

At this early stage of the H1N1 pandemic, no vaccine was available. But the CDC recommends vaccination as the primary method of preventing transmission of influenza. However, the CDC also emphasizes other measures, such as ensuring that healthcare workers do not report to work while sick.

"All health care personnel should be getting their vaccine, but there is more to do: identifying patients who are ill, practicing appropriate hand hygiene, taking sick leave when appropriate," says Kuhar. "All of these things are important in reducing the transmission of influenza. Ultimately, you need a comprehensive approach."

A July 22, 2001, advisory from the American Hospital Association (AHA) gives the push toward mandatory vaccination of healthcare workers another surge of momentum. The AHA stated: "To protect the lives and welfare of patients and hospital employees, the American Hospital Association's Board of Trustees recently approved a policy supporting mandatory patient safety policies that require either influenza vaccination or wearing a mask in the presence of patients across health care settings during flu season. This policy aims is to achieve the highest possible level of protection."[2]

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1. Magill SS, Black SR, Wise ME, et al. Investigation of an outbreak of 2009 pandemic influenza A virus (H1N1) infections among healthcare personnel in a Chicago hospital. *Infect Control Hosp Epid* 2011; 32:611-615.
2. American Hospital Association. AHA endorses patient safety policies requiring influenza vaccination of health care workers. *Quality Advisory* 2011. Accessed at http://bit.ly/s41vL2. ■

CNE/CME INSTRUCTIONS

Physicians and nurses participate in this CNE/ CME program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to **www.cmecity.com** to take a post-test; tests can be taken after each issue or collectively at the end of the semester. *First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.*
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

COMING IN FUTURE MONTHS

- Innovative marketing strategy tied to sports
- Drug shortage strategies that pass accreditation
- Tool to boost hand-washing among your staff
- Latest trends in outpatient surgery liability

CNE/CME OBJECTIVES

- **Identify** clinical, managerial, regulatory, or social issues relating to ambulatory surgery care.
- **Describe** how current issues in ambulatory surgery affect clinical and management practices.
- **Incorporate** practical solutions to ambulatory surgery issues and concerns into daily practices.

CNE/CME QUESTIONS

1. After a theft of regulated drugs at OA Center for Orthopaedics, what security measures were added?
   A. The medication room is now locked down from 7 p.m. to 7 a.m.
   B. The medication room is tied to the center's alarm system.
   C. The administrators installed dead bolt locks that require a key.
   D. All of the above

2. If a diversion issue is identified, who should be notified, according to Sheldon S. Sones, RPh, FASCP, president of Sheldon S. Sones and Associates?
   A. The administrator
   B. The clinical director
   C. The medical director
   D. Drug Enforcement Administration (DEA) registrant
   E. All of the above.

3. According to the FBI, how did the man accused of illegally tampering with the data system of Shionogi obtain access?
   A. He used a Shionogi user account to access a Shionogi server and then took control of a piece of software that he had secretly installed on the server several weeks earlier.
   B. He used a weakness in the employee access format that he had discovered but not reported.
   C. He repeatedly tried to access the system at high speed until the system was overwhelmed.
   D. He worked with a friend still employed at Shionogi to obtain a valid entry password.

4. In a study of an outbreak of pandemic H1N1 in 2009 at a Chicago hospital, the hospital-based transmission was mostly:
   A. from patients to health care workers.
   B. from health care workers to patients.
   C. from health care workers to their coworkers.
   D. from visitors to patients.

SDS ACCREDITATION UPDATE

Covering Compliance with The Joint Commission and AAAHC Standards

Unintended retentions of foreign bodies increase in 2010, even higher in 2011

What strategies will stop this sentinel event?

In 2010, the number of unintended retentions of a foreign body jumped to the highest level since The Joint Commission started tracking statistics in 1995: 133 reported events. Already, through the third quarter of 2011, there have been 136 incidents reported to the agency.

Root causes showed some jumps in communication and leadership.

"Healthcare facilities are facing ever increasing competition and reduction in reimbursement, and so more time and effort is being devoted by leadership in efforts to meet the competition, reduce costs, and stay competitive," says **Stephen Trosty**, JD, MHA, CPHRM, ARM, president of Risk Management Consulting Corp., in Haslett, MI. "This can sometimes require so much time and attention from the leadership, that other areas of concern can take a backburner to the key issue of survival and growth."

Trosty suggests the following to avoid retentions of foreign bodies:

• There should be a process to ensure two independent counts of needles and other related objects used during surgery before the surgery begins.

Two independent counts should be placed into the chart, with the appropriate numbers, name of the people, and times that the counts were conducted, Trosty says. "This could become a liability if there is a foreign body left in a patient since the chart could become evidence used by the plaintiff either to show that the counts were not done or that the before and after figures did not agree," he says. "But it also can become a positive for the facility, in case of a lawsuit, if the proper procedure was followed and the before and after counts agree."

If the independent counts do not agree, there should be a system to conduct a third count to be sure there is an accurate and correct count, Trosty says.

• Before the patient is closed, there should again be two independent counts of the needles and other related material to be sure that the before and after counts agree.

This information should be documented in the medical record, Trosty says. "If there is a discrepancy between the two counts, a third one should be conducted in order to have an accurate post-operation count," he says.

If the numbers for before and after do not agree, an effort should be made to find the missing needle(s) before closing the patient, Trosty advises. "This also should be documented," he says.

• Have a process in place to determine the number of needles before and after surgery and to provide for a mechanism to try to find any missing needle(s) prior to concluding the operation/closing the patient, Trosty says. "But this has to be done without putting the patient into jeopardy," he adds.

• Any member of the team should be able to call a timeout if the counts are not done, before or after the surgery, as a way to double-check that the counts have been done and the existing proce-

Financial Disclosure:
Executive Editor **Joy Dickinson** and Board Member and Nurse Planner **Kay Ball** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.Consulting Editor **Mark Mayo** reports that he is an Administrative Consultant to USPI Chicago Market. **Steven Schwaitzberg**, MD, Physician Reviewer, discloses that he is on the speakers bureau for Stryker Corp. and Merck & Co., he is a medical advisor to Surgiquest, and he is a stockholder in Starion Instruments.

dure has been followed.

To avoid this sentinel event, keep up with new technology for avoiding unintentional retentions of foreign bodies, says **Marsha Wallander**, RN, assistant director of accreditation services at the Accreditation Association for Ambulatory Health Care (AAAHC). Wallander points to surgical sponges imbedded with an identity tag that can be detected with a wand. *(For more information, see "Procedures, technology can prevent retained items,"* Same-Day Surgery, *September 2010, p. 106.)* Additionally, there are devices made of clear plastic with individual numbered pouches to aid visual sponge counting, Wallander says.

"Organizations need to be acutely aware seeing what safety devices helps, are newly available, and assess them to see if they are useful or advantageous to their setting," she says. (For more information on retained items, see Resource below.)

SOURCE/RESOURCE

For more information, contact:

• **Stephen Trosty**, JD, MHA, CPHRM, ARM, President, Risk Management Consulting Corp., Haslett, MI. Telephone: (517) 449-1285. E-mail: strosty@comcast.net.

For the latest information on retained foreign object after surgery, go to The Joint Commission's web site: http://www.jointcommission.org/sentinel_event.aspx. ■

EHRs can help you comply with NPSGs

However, study notes challenges remain

Electronic health records, or EHRs, can be valuable tools for managers as they strive to comply with The Joint Commission's National Patient Safety Goals. That's a clear message communicated in a recent commentary in *The Journal of the American Medical Association*;[1] however, the authors take care to not only outline some best practices for EHR use, but to also review some of the challenges presented.

Take, for example, patient identification. "Wrong-patient errors occur in virtually all stages of diagnosis and treatment. Reliably identifying individual patients is especially challenging in high-volume practice environments with limited continuity of care," the authors wrote.

One of the authors, **Ryan P. Radecki**, MD, Department of Emergency Medicine, East Carolina University/Brody School of Medicine, Greenville, NC, says, "At least once a shift, you will not know the patient's name, or the name will not mean anything to you."

The authors cited a study of physicians that used eye tracking, which showed that physicians often fail to adequately confirm the identity of patients prior to order entry. "Eye tracking involves placing a small camera above the top of the computer screen that picks up the pupils, and you can see where the eyes are looking," Radecki explains. "In the case of EHR users, you can see if their eyes look to a particular portion of the screen, and you can see if they're performing the desired task or not."

Naturally, the goal should be for clinicians to reliably identify patients when accessing records and entering orders, the authors say. What's the best way to do that? "It's tricky. It really depends on what your interface for the EHR is," says Radecki. "If you put a picture of the patient where you sign the order, or use a different color on the screen, it forces your eye to verify information. Putting it where they're less likely to miss it — like the center of the screen — is as effective as you can be short of forcing someone to do it."

You could enter into your system the requirement to do this step before you can sign an order, but that requirement could add several minutes to each physician's day, he says. "You need balance, so it takes experimentation," says Radecki. Highlights, color changes, or italics may be used to bring attention to important data such as sound-alike names, patient's initials, and date of birth, he says.

Alert fatigue

While the authors note that EHRs can enhance test result communication with automatic notifications of the responsible clinicians about abnormal test values, they added that "this alone does not constitute a fail-safe system."

"One of the problems with putting alert mechanisms into a computer system is you have so many of them, and clinical relevance is hard to distinguish," Radecki says, noting that "between 90% and 95% are dismissed and ignored by doctors because they are not well designed or are deemed irrelevant."

For example, he says, there are many medication interactions, but in some the benefits might outweigh the risks. "When you get so many irrelevant alerts, you can develop alert fatigue," he

cautions, "so if you have a system, it really has to be cautiously defined."

While this constitutes a major area of research, Radecki notes that no solution has yet been found. However, the authors stated, "a fail-safe strategy might be requiring that clinicians acknowledge abnormal test values within a certain time frame (i.e., depending on severity), after which laboratory staff use direct notification." Since there is no way to verify that the information has been received if it is not acknowledged, says Radecki, "you might have to fall back on direct communication between providers."

Using meds safely

The authors noted that EHRs with CDS (clinical decision support) and BCMA (bar code medical administration) capabilities can significantly improve patient safety. However, they warned, "care must be taken to ensure that all of these interventions fit within clinicians' workflow."

In addition, they said, BCMA systems need to be implemented in the pharmacy and at the point of care.

"When fully integrated into the system, a barcode is printed in the pharmacy, affixed to the vial or container that is transported to the bedside, and the nurse has a scanner at the bedside to see if there's a match," Radecki explains. "If there is, the patient gets the drugs. Another barcode is on the patient to ensure that the correct patient receives the correct medication or blood product."

One potential challenge here is "workarounds." How do they occur? "Clever nurses, instead of scanning at the patient's wrist, will print out second labels to have at the nurses' station rather than having one on each patient, which defeats the whole purpose," says Radecki. Hospitals have addressed this problem, he adds, by "making it really hard to get second bar codes printed out."

Monitoring compliance

EHRs can also be useful in making sure that staff members are complying with

infection control protocols. For example, the authors wrote, "when appropriately configured with easy-to-use targeted checklists, [EHRs] may provide an electronic delivery mechanism."

In addition, they explained, nearly any device can be fitted with software and radio frequency identification (RFID) transmission capabilities so that checklist monitoring can take place in real time via the EHR. "For example, if you want 100% compliance in hand-washing, you can put a transmitter on the dispenser, and if a staff member's RFID tag goes near it without registering, you can tell that staff member isn't washing their hands," says Radecki. Also, some providers are using RFID technology to track where items are moved, by whom, and to whom (the right patient). Additionally, some equipment can set be set up to sound an alarm when a piece of equipment is touched that has not yet been cleaned from the last patient.

The authors concluded, "As with all computer-based interventions, incorporation of EHRs into routine clinical workflow is critical; their effectiveness depends on appropriate maintenance, effective user training, periodic institutional self-assessment of EHR safety and effectiveness, and clinically focused policies to support their use."

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1. Radecki RP, Sittig DF. Application of electronic health records to the Joint Commission's 2011 National Patient Safety Goals. *JAMA* 2011; 306:92-93.

SOURCE

For additional information, contact:

* **Ryan P. Radecki,** MD, Department of Emergency Medicine, East Carolina University/Brody School of Medicine, 2100 Stantonsburg Road, Greenville, NC 27834. E-mail: radecki@gmail.com. ■

Compliance issue: clinical privileges

One of the accreditation standards causing the most headaches for ambulatory organizations is the one on credentialing. In fact, statistics gathered by The Joint Commission indicated that for the first half of 2011, 48% of ambulatory organizations and 56% of office-based facilities were noncompliant with standard HR 02.01.03: The organization grants initial, renewed, or revised clinical privileges to individuals who are permitted by law and the organization to practice independently.

The process is difficult, acknowledges **Virginia McCollum**, MSN, RN, associate director of standards interpretation at The Joint Commission. In fact, the introduction to the standards manuals describes the process as "one of the most important and difficult responsibilities of an organization."

"The organization needs to have a process,

ongoing, with a two-year cycle [three-year cycle in Illinois] for data collection and assessment," McCollum says. Credentialing and privileging require staff time to meet the time requirements. "Someone always needs to be doing that."

Managers at smaller organizations might not realize how much work the process entails, she says.

One of the biggest stumbling blocks for managers at accredited organizations is follow up, says **Marsha Wallander**, RN, assistant director of accreditation services at the Accreditation Association for Ambulatory Health Care (AAAHC). However, there are software programs that can help, Wallander says. "You can enter providers and dates of their different documents, licenses, board certification, and you get an automatic reminder when that is coming due," she says.

Additional help is available through credentials verification organization (CVOs) that can provide information on individuals in terms of their professional credentials, says McCollum. Some find it's more cost-effective to have someone do the credentials for you. Your organization makes the privileging decisions, after reviewing the credentialing information provided by the CVO, she says. The glossary in the *Comprehensive Accreditation Manual for Ambulatory Care (CAMAC) — 2011* lists 10 principles that CVOs must follow for healthcare programs to use them.

AAAHC provides organizations with a sample medical staff application, Wallander says. "It's perfectly OK to develop their own, but they can use the template we provide as a sample," she says. "If they did that, they'd cover everything."

Another challenge is collecting documents, Wallander says. "If you want a new photocopy of an existing applicant's new license, you sometimes have to rely on someone to produce that piece of paper, but it is an important aspect," she says.

Do you know the difference?

Part of the difficulty with compliance might come from the fact that providers confuse credentialing and privileging, say leaders in accreditation groups.

Credentialing is "the process of obtaining, verifying, and assessing the qualifications of a practitioner to provide care or services in or for a healthcare organization," says McCollum, again quoting *CAMAC — 2011*. Credentialing includes relevant training, current license, current competence, and the ability (health) to perform requested privileges. In comparison, privileging is "the process whereby a specific scope and content of patient care services — that is clinical privileges — are authorized for a healthcare practitioner by a healthcare organization, based on an evaluation of the individual's credentials and performance," says McCollum, again quoting the handbook.

In summary, it is the process to "make sure someone who is who they say they are, and they have what they need to do what you want them to do," she says. ■

The Joint Commission wants you to go for gold

In an era when controversial mandatory flu vaccine policies threaten to end up in some high court as a *cause célèbre*, The Joint Commission is urging healthcare organizations to go for the proverbial gold.

Joint Commission Resources recently launched the fourth annual Flu Vaccination Challenge, which is a nationwide charge to healthcare managers to raise their flu vaccination rate among staff.

"Flu vaccination of healthcare workers [HCWs] is important not only to help protect themselves, but also to reduce the risk of flu infection for patients," the JCR states. "Studies have shown that HCWs can be a potential source of flu infection in healthcare settings."

For the 2011-2012 flu season, Joint Commission Resources challenges organizations to reach a 75%, 85%, or 95% staff vaccination rate (bronze, silver, or gold, respectively). Last year, the average flu vaccination rate among participating healthcare organizations was 80%, which was 16% higher than the national flu vaccination average estimated by the Centers for Disease Control and Prevention for healthcare workers (63.5%).

More than 1,200 health care organizations participated in the 2010-2011 Flu Vaccination Challenge. Of the organizations that submitted data (n = 826), 60% increased their flu vaccination coverage among staff from the previous season. As part of the Flu Vaccination Challenge, approximately 780,000 health care workers were vaccinated against the flu during the 2010-2011 flu season, Joint Commission Resources reports.

In the last flu season for facilities that submitted data, 17% (142) claimed a Gold Recognition Award, while 22% (177) achieved Silver, and 27% (255) were awarded Bronze. *(Editor's note: For more information on the challenge, go to http://www.jcrinc.com/FLUChallenge.)* ■

Anesthesia Medication Reconciliation 2011 template									
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SOURCE: OA Center for Orthopaedics, Portland, MN.

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2011 Index

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