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IN THIS ISSUE

NOVEMBER 2003
VOL. 25, NO. 11 • (pages 121-132)

Don't be the fall guy: Investigate every accident and find ways to prevent them

Respond quickly and thoroughly to falls and near misses

You're busy with a dozen other issues when you get a phone call notifying you that a visitor has fallen in the lobby and broken her arm. Do you chalk it up to "just another fall" and get back to work, or do you spring into action?

The answer may depend on how well you've prepared for the moment, and how seriously you take slips and falls in your institution. The experts say that if you're taking the right steps to reduce falls and all the attending liability, you'll probably get up from your desk and make investigating the incident your top priority for the day.

A speedy response and full-scale investigation may not be necessary for every incident. But the more serious the fall, the more you should pull out all the stops in your response. A serious injury such as a broken arm is enough to justify a full response, says **Ronald Miller**, CSP, director of training and consulting services for the occupational safety and health group of the National Safety Council in Itasca, IL.

"Most employers handle this rather poorly," he says. "Most of the companies I've worked with needed extensive training on how to do a good investigation. If a health care provider wants to reduce falls, you need to take a hard look at what happens when someone falls."

There could be a tough decision to make in some circumstances, though — if you document the incident well enough to learn from it, will you create ammunition for a plaintiff's attorney?

Investigate every fall, sometimes with a team

The risk manager should take the lead in ensuring that all falls, and most near misses, are investigated thoroughly, Miller says. Sometimes, the local supervisor can be trusted to conduct the investigation and document the incident, but sometimes the seriousness of the fall can require a multidisciplinary team approach. That team may include the risk manager,

director of safety, the facility's head engineer, the director of housekeeping, and the manager of the unit where the incident happened.

Whether a team or an individual investigates the fall, a quick response is vital, Miller says. Employees, especially managers, should be educated about the need to preserve evidence and investigate after falls. For serious incidents, they should be trained to call the risk management department immediately so that a full-scale investigation can commence.

"Incident investigations should be done immediately because conditions change," he says. "If there is a hazard on the floor like a spilled liquid or bodily fluid, someone is going to clean it up quickly, especially after there is an incident. Unless the investigation is done quickly, you may never find that root cause. The cause could be a motorized equipment cart with an oil leak; and if the spill has been cleaned up and no one remembers leakage from that cart, you may never find it."

Many providers avoid documenting falls

Not only do many health care providers not adequately investigate falls, many willfully avoid documenting the incidents for fear of creating evidence that can be used against them in court, says **Russell J. Kendzior**, CSP, president of the nonprofit National Floor Safety Institute and Traction Plus, a manufacturer of slip-and-fall prevention products, both in Southlake, TX. Kendzior often testifies as an expert witness for slip-and-fall cases, and says health care staff often are conspicuously unable to show documentation of the incidents.

The problem is especially bad in nursing homes, where the risk and potential liability from falls is the greatest, he says.

"One unfortunate reality in health care is that they often have been trained by risk managers, loss-control experts, and third-party claims managers to be very vague in gathering information," he says. "They will say you don't want to collect or track certain information because it can only come back to haunt you in court. I know that sounds crazy, but I see it a lot."

Some health care providers even choose not to have a policy on the prevention of slips and falls, for fear that a plaintiff's attorney will use it to prove that the facility was not following its own policy. Kendzior says is a very poor strategy if you're trying to reduce falls, which he calls "by far the biggest risk your patients face while they're in your care."

Responding properly to a fall is important, but Kendzior says a proactive program is even more effective. The risk manager should work closely with the engineering and housekeeping departments to ensure that floors are maintained in such as way as to minimize the risk of falls, he says. And the proper maintenance of floors is more complicated than you might think; "clean" is not simple to define. **(See p. 123 for more on how proper maintenance can prevent falls.)**

When you investigate a fall, Miller says you should gather as much information as possible about the area and the activity leading to the fall. Document the information and consider photographing pertinent scenes, especially those that

Healthcare Risk Management® (ISSN 1081-6534), including **HRM Legal Review & Commentary**™, is published monthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Healthcare Risk Management**®, P.O. Box 740059, Atlanta, GA 30374.

Healthcare Risk Management is approved for approximately 18 nursing contact hours. This offering is sponsored by Thomson American Health Consultants, which is accredited as a provider of continuing education in nursing by the American Nurses' Credentialing Center's Commission on Accreditation. Provider approved by the California Board of Registered Nursing, Provider Number CEP 10864, for approximately 18 contact hours.

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may mitigate the institution's liability for the fall. Investigators often photograph the area in which the person fell and maybe even the fluid spill that caused it, but they sometimes overlook documenting the precautions that mitigate the damages. For instance, you may wish to photograph the "wet-floor" sign that housekeeping had in place to warn people, or the handrails that helped the person avoid a more serious fall.

Miller suggests that risk managers should draw on a skill they employ for other investigations — the root-cause analysis (RCA). The incident investigation after a serious fall should follow the same methodology and strive for the same goals as a RCA after an adverse medical event, he says. The goal should be to uncover the real cause of the fall, not just the defect that appears most obvious.

Just as with less-than-optimal investigations of medical incidents, a common failing of fall analyses is blaming the employee who fell or who made the fall possible by leaving a hazard on the floor, Miller says. That is rarely the root cause.

"Most reports by a supervisor will conclude that the way to fix the problem is to retrain the employee, but you'll never see one that says retrain the supervisor. Few people condemn themselves," he says. "If you don't focus on the root-cause analysis, you'll stop before you find the real problem."

Punishing employees or laying all the blame on them also will discourage the free reporting that is so important for good fall investigations, he says. If your employees only report the ones they have to report — the falls that leave someone lying on the floor needing medical help — you'll miss the opportunity to learn.

When investigating and analyzing the data, Miller says you should focus on these four areas that lead to most slips and falls:

- **Equipment:** Check to see if any items were defective, such as handrails that did not support the person or anything that could have led to tripping.
- **Environment:** This area includes all types of hazardous conditions, such as the condition of stairs and floors. Was there blood or other fluid on the floor? Why? How long had it been there?
- **Management:** Ascertain whether there was a breakdown in management, such as allowing employees to run through the department. Was management condoning it or even encouraging it?
- **People:** Who fell? Was the person impaired in any way? What was he or she doing at the time of the fall? Also consider the type and condition of the person's shoes.

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Find links to other web sites that are essential references for risk managers. There also is a guide to upcoming conferences and events of interest to risk managers. Click on the User Login icon for instructions on accessing this site. ■

Miller says most falls can be traced to failures in at least three of those categories.

"And remember that you have to do something with the data," he says. "If you don't use it to improve, you're just wasting your time and opening yourself up for more incidents." ■

Floor surface, cleaning agents make a difference

Russell Kendzior, executive director of the National Floor Safety Institute (NFSI), offers this advice on how proper floor maintenance can reduce falls in health care facilities:

- **Consider the choice of floor surfaces, especially when remodeling.**

The particular type of flooring can make a big difference in the risk of falls. Some flooring is more slippery or slip-resistant, and others can react differently when a liquid is spilled. Consult with flooring experts to find the best product for your budget. Insist that floor safety be made as big a priority as aesthetics.

Some problems with floor surfaces are hard to imagine until you do the research. High-gloss floors, for instance, look pretty but can be difficult for older patients. The glossy surface challenges their depth perception, leading to falls, so

many nursing homes have switched to low-gloss flooring. Keep that in mind when choosing how floors are maintained also. The housekeeping department may think they're doing a good job by making floors extra shiny, but not if you're trying to prevent falls.

• **Select cleaning agents very carefully.**

What you put on the floor makes a huge difference in reducing or increasing the risk of falls. Health care facilities usually focus on sanitizing the floors, but sanitizers are not cleaners, Kendzior says. Even worse, they often leave a slippery film behind. **(See article, right, for more on selecting cleaners.)**

Health care providers also focus on odor control, so they choose products that mask offensive smells, he says. The first thing that hits you when you walk in the door is a strong scent such as pine. But the effect on floor safety can be tremendous, he says. Pine oil cleaners can drop slip resistance by 40%.

Work closely with housekeeping and engineering to choose products that actually accomplish what you want — cleaning.

"In the past 50 years, the floor cleaning industry has convinced us that you can tell how clean a floor is by how it smells or how shiny it is. That's an American perception that has been marketed down our throats for many years," he says. "The fact is that the smell of clean is no smell at all. And shiny doesn't mean anything about how clean it is. Many shiny floors actually aren't clean at all."

• **Develop a proactive auditing program for your floors.**

Randomly test walkways and floors for slip resistance. The testing will reveal if certain areas are more prone to being slippery and, if so, you can focus on that area to determine why and how to lower the risk.

Kendzior recommends random auditing of floor surfaces throughout the facility on a monthly or quarterly basis. If someone slips and falls, bring in all the auditing statements to show there was no reason to expect a fall in this location.

"The plaintiff's attorney will go to the nth degree to show that you didn't care and didn't do anything to prevent this injury, and auditing can be a tool to counter that," he says.

Such testing once required an engineering consultant and could be quite expensive, but the NFSI now offers an electronic tool that tests for you. The Universal Walkway Tester operates like a small robot and produces a visual reading on its display and a paper printout. Cost is $4,295, but can be rented for $500 per week. (For more information, see the NFSI web site at www.nfsi.org.)

When analyzing slip resistance, Kendzior says health care risk managers should shoot for a sweet spot of between 0.6 and 0.7 static coefficient of friction. Remember that a higher coefficient isn't necessarily better. Anything above that level, like carpet, can be a tripping hazard.

Anything below can lead to slipping. ■

Floor cleaners can increase slip-and-fall risks

Many cleaning products leave floors more slippery than they were before cleaning, the National Floor Safety Institute (NFSI), reports.

NFSI recently released results of a study that showed 10 out of 19 of the best-selling floor cleaners on the market tested made floors more slippery**. Russell Kendzior**, executive director of NFSI, labels the results "shocking."

"Many of the floor cleaners actually contribute to the floor's slippery condition. More than half of the products left a slippery residue after only one application," he says.

The average product reduced the floor's slip-resistance (amount of traction) by 10%. After a month's worth of applications, 13 out of 19 products left a slippery residue, with an average decrease in slip-resistance of 18%.

"Most of the products tested contained a strong fragrance," he says. "It was like putting perfume on the floor. Although they made the room smell good, such fragrances are most likely the culprit behind the slippery film."

For more information on NFSI's research, see its web site at www.nfsi.org. ■

Disclosure still could be an issue despite new options

New reporting options from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are a good step forward in the effort to prevent the disclosure of sensitive information through the accreditation process, says an attorney who is responding to the concerns of risk managers.

But, she cautions, the two options may not

work for you unless your state laws already provide significant protection for such privileged information.

JCAHO recently announced two options designed to address legal disclosure concerns related to the Periodic Performance Review (PPR), which is an integral component of its new accreditation process that will debut in 2004. The PPR process requires each accredited organization to conduct a midcycle self-assessment against applicable JCAHO standards; develop a "Plan of Action" to address identified areas of noncompliance; and identify "Measures of Success" for validating resolution of the identified problem areas when the organization undergoes its complete on-site survey 18 months later.

Under the usual PPR process, organizations will be expected to share all of this information with the JCAHO at the midcycle point. JCAHO staff will work with the organization to refine its Plan of Action to assure that its corrective efforts are on target.

Risk managers and health care lawyers expressed concerns about the potential discoverability of PPR information, particularly where it is shared with the JCAHO, says **Elizabeth Summy**, executive director of the American Society for Healthcare Risk Management (ASHRM) in Chicago. Along with other health care groups, ASHRM has been communicating with JCAHO about the legal concerns raised by risk managers.

As originally proposed, the plan would have forced health care providers to hand over protected information in a way that would make it available to the public and plaintiff's attorneys, she says.

The new options will help some providers avoid that risk, but they don't solve the problem entirely, she says.

"It depends on what state they reside in what legal protections they have," Summy says. "These changes are a good positive step, but there will still be people who have a hard time using this tool because of their legal situation."

ASHRM plans to provide specific guidance on how to use the PPR process without putting your institution at risk, but Summy says that the best advice in the meantime is for risk managers to study the protections provided under their own state laws.

"It's a very complicated issue," she says. "To really understand it, you need to be an expert in 50 state statutes regarding protection of confidential information."

These are the two options recently offered by JCAHO:

- **Option 1 was designed to address "waiver of confidentiality" concerns that could arise if the organization shares sensitive performance information with the Joint Commission.** Under Option 1, the organization performs the midcycle self-assessment, and develops the Plan of Action and Measures of Success. It then attests that it has completed the foregoing activities but has, for substantive reasons, been advised not to submit its self-assessment or Plan of Action to the Joint Commission. The provider does not submit.

The organization may discuss standards-related issues with JCAHO staff without identifying its specific levels of standards compliance. It also provides its Measures of Success to the Joint Commission for assessment at the time of the complete on-site survey.

- **Option 2 has been designed to address concerns that the very requirement for a self-assessment at a specified point in time may create a vulnerability to discovery of the self-assessment findings and any related Plan of Action.** Under Option 2, the organization need not conduct a midcycle self-assessment and develop a Plan of Action. It will undergo an on-site survey at the midpoint of the organization's accreditation cycle. The survey will be approximately one-third the length of a typical full on-site survey.

The organizations will be charged a fee to cover the costs of the survey. The provider develops and submits to JCAHO a Plan of Action to address any areas of noncompliance found during the on-site survey. JCAHO will work with the organization to refine its Plan of Action. The organization provides its Measures of Success to the Joint Commission for assessment at the time of the complete on-site survey.

Still working on more options

In announcing the new options, JCAHO president **Dennis S. O'Leary**, MD, said he believed most health care organizations will use the PPR process despite concerns about confidentiality. "However, these two constructive options should assuage legal concerns some organizations may have about sharing self-developed performance information with the Joint Commission," he said.

O'Leary also noted that JCAHO staff and legal counsel continue to work with risk managers and with lawyers from the American Hospital Association and state hospital associations to

explore other potential options and to determine whether there are any additional steps that would help in addressing the legal concerns.

The options are welcomed as a sign that JCAHO is trying to address risk manager's concerns, but they don't go far enough, says **Mary Marta**, MSN, JD, attorney with Epstein Becker in Washington, DC. Neither of the two options will alleviate the concerns of all risk managers, she adds.

Some lawyers have concerns about the first option because some state laws have language stating that accreditation-related information can be requested or must go to a state regulatory agency. In those states, the information still might be accessible under Option 1 through state Freedom of Information laws.

"Option 2 allows the surveyors to come in and do a third of the standards at cost, which is still a substantial amount of money, and the issue is that everyone is seeing that as punitive," Marta says. "First, you don't get as much information out of the process because you're only doing a third of the standards. And No. 2, you're paying a hefty fee, and a lot of hospitals can't afford that."

The second option was expected to help a lot of providers, but Marta says many analysts still see substantial risk. Some providers have suggested that they would be better off with something like the Option 4 that is available in JCAHO's sentinel events policy.

That option, developed in response to concerns that the previous requirements for reporting sentinel events risked the disclosure of sensitive information, states that it can be used when "the organization affirms that it meets specified criteria respecting the risk of waiving legal protection for root cause analysis information shared with the Joint Commission," an on-site visit will be used to conduct interviews and review relevant documentation to obtain information about the organization.

Marta says she is optimistic that JCAHO will offer better options soon, but in the meantime, she says risk managers must study their own state laws to see whether either of the current options will suffice. She cautions that understanding the applicable laws is a big task to undertake.

"Because the state laws are so varied, with some states having no protection and some having a lot, it's very important for risk managers to take a look at not only their state regulatory scheme but also what state case law says," she says. "In South Carolina and New Jersey, for example, neither of these options seem like they will work at this time because those states offer so little protection." ■

GUEST COLUMN

Spa services can bring hidden risks if not assessed

By **Marva West Tan**, RN, ARM, FASHRM
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A claimant alleged that she had developed a severely infected finger that required surgical drainage and intravenous antibiotics following a manicure with dirty implements at a beauty salon located on the hospital campus. The plaintiff named the hospital, the salon manager, and the nail technician as defendants. Investigation of the claim revealed that the managing cosmetologist, an independent contractor, had not verified current licensure of the uninsured nail technician and that there was no consistent method for disinfecting nail implements between clients. The hospital risk manager had not conducted a risk assessment of the on-site beauty salon, which was new to the hospital facility, before the salon opened.

An unlikely claim for a hospital? Perhaps not for long, as hospitals seek to expand profitability by adding spa services, such as massage therapy, aromatherapy, reflexology, manicures and pedicures, to their wellness program. Even hospitals that do not undertake a full hospital-based spa program may arrange for a cosmetologist to come on site and provide beauty salon services in a hospital-owned space.

Besides adding another revenue stream to hospital services, spa services have other benefits such as meeting patient demand for a full range of complementary/alternative medicine techniques, supplementing a holistic wellness program, and increasing patient satisfaction through stress reduction and improved self-image.

Hospitals with long-term care services may find that offering full or partial spa services enhances the quality of life for their residents. Spa services not only pamper patients, but also may offer clinical benefit. For example, early research indicates that massage therapy may be useful in treating depression, chronic pain, immune and autoimmune conditions, and improving weight gain in pre-term infants.

As with any new service, the addition of spa services to the hospital setting introduces new risks as well as benefits.

Conduct risk assessments of all new services

Ideally, the risk manager should conduct a risk assessment of every new clinical service so that risks are identified and addressed before the services are implemented. Promote these prospective risk assessments as a valuable service provided by the risk management department. Develop good rapport with senior management, department heads and clinical chairman so that you will be kept informed of any new services that are being contemplated. If you hear about a possible new service, discover who is on the planning group and ask if you can participate in the planning process. Seek advice from your manager on the best way to become involved in new program risk assessment within your environment.

If you achieve access to evaluate risks of a planned new service, do some research about the proposed service to learn the terminology, relevant national associations, major risks and claims history or adverse events in other settings, if possible. Develop an organized approach to assessing risks of new services and programs using risk management principles. Consider professional and general liability factors, operational issues, construction risk, employment liability, compliance issues and financial risks.

The American Society of Healthcare Risk Management's *Self-Assessment Tool for Risk Management Programs & Functions, 2nd Edition,* Appendix D, contains an extensive list of risk factors to consider when evaluating loss potential that could be used as the basis for your own checklist. Be supportive to the planning process by suggesting strategies to address any identified risks rather than only pointing out the possible liabilities of the new service.

Major risks of spa services

Initially, assessing the risks involved in providing massages and manicures may seem very different from the usual world of hospital risk management. But, on reflection, spa risk factors fall into familiar categories, including the few areas discussed below.

• ***Financial risk***

A 2001-2002 Health Forum/American Hospital Association Complementary and Alternative Medicine (CAM) Survey of 502 hospitals with CAM services found that the greatest obstacles to successful implementation of CAM services were physician resistance, budgetary constraints, lack of internal expertise and credentialing. Spa services are likely to face similar obstacles to "breaking even" unless marketing clearly promotes the clinical links that differentiate hospital-based spa services from commercial spas in the community. Physician resistance to spa services may be reduced by education about the growing patient demand for expanded CAM services and the emerging body of research literature addressing the value of selected spa services. Some medical services, such as dermatology, plastic surgery or physical medicine, may be interested in forging closer clinical links with spa services.

• ***Credentialing***

Credential all spa therapists and technicians using a formal system similar to the allied health or CAM practitioner process. At a minimum, verify licensure and conduct a background and reference check. If your state does not license or regulate a specific category of spa worker, national associations, such as the American Massage Therapy Association, can provide guidance on expected levels of training, education, experience, and skills. Some therapists, such as massage therapists, may have completed a national certification such as the one offered by the National Certification Board of Massage Therapists and Bodywork.

Delineate privileges if therapists will offer specific clinical treatments such as manual lymph drainage for post-mastectomy arm edema. Check credentials even if salon staff will be independent contractors working in hospital-owned space. Don't learn from a claim that an independent technician working in your hospital has a felony theft or sexual assault record.

• ***Confidentiality and privacy***

Stress the importance of patient confidentiality and privacy for all spa staff. Gossiping with clients at the beauty salon takes on different implications when the salon or spa is hospital-based. All staff must protect the privacy of the physical person as well as patient/resident clinical information.

Because patients undergoing some services may be partially or completely unclothed, insist on staff maintaining appropriate boundaries to avoid allegations of sexual misconduct. The American Massage Therapy Association has a code of ethics addressing these issues.

• ***Infection control***

Spa services involve considerable direct contact with patients, which increase the risk of hospital-acquired infections. Stress careful hand washing

and maintenance of good infection control practices regarding linens, solutions, equipment and water therapies. Contact your local board of cosmetology regarding sanitation methods. Check out fire safety implications before recommending alcohol-based hand rubs in the spa area. Involve your infection control practitioner in review of the planned spa programs.

• ***Fire safety***

Because flammable liquids, such as nail polish and remover, and electrical equipment, such as hair dryers, will be intensively used in spas or salons, conduct a careful fire safety inspection of planned use and storage of flammable materials and electrical appliances. Involve the safety officer or your local fire department.

• ***Policies and procedures***

Develop appropriate policies and procedures for spa services, such as whether a general physician order or approval is adequate or whether in certain clinical situations, such as pedicures for a diabetic patient, services require a specific physician order. Spell out who will provide supervision and the supervisor's responsibilities.

Supervision may be a foreign concept to therapists or cosmetologists accustomed to working on their own. Orient all staff, including employees and independent contractors, about what to do in case of a patient/resident emergency.

Word marketing materials carefully

• ***Insurance risks***

Identify professional and general liability risks and determine how to address these risks. If the hospital does not provide liability coverage for spa staff and premises, require proof of valid insurance in adequate limits from the salon manager and each therapist or technician.

If there are any contracted spa or salon services, have the hospital attorney review the contract. Assure that any indemnification clauses are favorable to the hospital. Try to reduce the risk of "apparent agency" claims by making it clear to the community and patients that the spa or salon staff are independent contractors. Post appropriate signage in the hospital spa or salon area. Word spa marketing materials carefully to avoid taking on unnecessary liability. For example, avoid use of words such as "the hospital's" skilled spa staff.

To sum up, be sure you follow these four steps if there is a spa service within your organization, or if one is planned:

1. Market the risk management program so that you will be viewed as a valuable resource for the planning process.
2. Don't be intimidated by an unfamiliar clinical service or new technology.
3. Apply risk management fundamentals to developing the assessment plan.
4. Tap into available resources, such as national association web sites, professional literature, other risk managers and practitioners working in the proposed field in another facility. ■

Virtual anticoagulation clinic improves safety

A "virtual anticoagulation clinic" is being credited with dramatic improvements in patient safety at Abington (PA) Memorial Hospital, which recently won the John M. Eisenberg Patient Safety Award from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Any hospital or other health care provider wishing to improve patient safety can emulate the effort, the project's leader says. Morbidity and mortality from less-than-optimal medication administration can be a major contributor to your overall patient safety statistics, he says.

The project reduced morbidity and mortality by addressing a difficult medication issue facing any health care provider, says **Doron Schneider**, MD, associate program director for the internal medicine residency program at Abington and a project leader. Abington tackled the difficult issue of monitoring patients on anticoagulant medications, such as warfarin, that are notoriously difficult to use properly.

"They are inherently risky, because too little can lead to strokes and pulmonary emboli, but too much and they can bleed," Schneider says. "It is very difficult to dose correctly because people metabolize it differently, and there are many food and drug interactions."

Needed to standardize

Because there is no standardized way to provide the medication, hospitals nationwide have come to accept a high degree of morbidity. The team at Abington thought they could reduce the morbidity and mortality by standardizing some of the process involved with delivering the drug.

"We set out to create a process that would work within the construct of an office environment, with no additional staffing," he says. "We restructured the existing staff to systematically deliver that medicine in a more consistent way."

Abington put together a team of three physicians, a representative from the hospital's performance improvement committee, and a pharmacist. A key component of their plan turned out to be a virtual anticoagulation clinic — a web site that provides resources and tools for monitoring patients on anticoagulation medications. Among other things, the web site provides standardized patient education materials.

"Because of the complexities of interactions with warfarin and over-the-counter medications, and food, we needed to educate people in a standardized way to make sure they got the right information," Schneider says. "We developed host of materials for patients explaining interactions and symptoms to watch for. All the materials can be downloaded from the virtual clinic."

A patient education tracking form also was created. The patient signs the form, acknowledging that he or she received the information about the risk of bleeding and signs to watch for.

Coordinator in office has big role

The project also involved recruiting an office-based anticoagulation coordinator in each doctor's office participating in the project. This person is not a physician, but rather a nurse or sometimes even an administrator in the office. The coordinator plays a key role in monitoring the patient's level of anticoagulation medication — perhaps the most important, but sometimes the most challenging, part of treating a patient with these medications.

Patients' blood levels must be monitored frequently, creating a headache for scheduling and a great deal of work for physicians who must check the lab results and adjust the drug dosage if the blood levels are not in the therapeutic range. The amount of work could overwhelm the physician, increasing the chance that an important lab result could be overlooked and the health care provider would be held liable for the oversight.

"There are always lot of lab results coming into the office for monitoring," Schneider says. "Instead of having all those come into the office to each individual physician, we have all of them come to the anticoagulation coordinator in that office, and she uses a protocol based on national guidelines and consensus statements to manage that patient independently of the physician. If the patient's values are within a defined range, she can make a dose adjustment."

The coordinator puts a sticker on the lab slip indicating that he or she reviewed the results and adjusted the dose accordingly. At the same time, the coordinator checks the patient for any signs of bleeding or stroke, and schedules the next lab test.

"If the results are outside the mildly abnormal range, the physician is notified immediately," Schneider says.

System recommends clinical path

The virtual clinic on the web also provides a database in which all the patient's clinical and demographic information is entered. The computer automatically recommends the correct dosage and when the patient should return for another lab test. The physician always has the ability to override the computer's advice.

In addition, the system automatically reminds the physician or anticoagulation coordinator about patients who are late for scheduled testing.

Abington has used the system for more than a year now, so what is the effect on patient safety? Schneider says the hospital was able to increase the percentage of patients with ideal anticoagulation dosing from 55% to about 80%. He calls that a "dramatic improvement."

"We've had 495 patient-years of therapy, and the complication rate was .01 per patient year," Schneider says. "We had one major bleed, and that was in a patient whose physician did not consistently take the recommendations from the computer. Having a greater percentage of patients in the therapeutic range is directly tied to patient safety."

Schneider says the key to making such a project work is finding participants who are not just willing, but eager. The physicians who kick off the project must be enthusiastic enough to bring in more skeptical colleagues. And he adds that the anticoagulation coordinators, not the physicians, are the linchpins of the entire system.

The same sort of system could be implemented for monitoring the use of any medication, Schneider says. Start-up costs were minimal.

"This did not slow the physicians down at all. In fact, they appreciate the ability to off load much of this responsibility to another willing individual in the practice," he says. "There also was very little extra cost associated with this. We estimated the costs at about $3 per year per patient." ■

After tragedy, Duke works to improve patient safety

The Centers for Medicare & Medicaid Services (CMS) has accepted a corrective action plan from Duke University Hospital in Durham, NC, to ensure safety in the hospital's intensive care nursery (ICN). CMS directed Duke to make patient safety changes following an Aug. 31 incident in which a premature infant suffered burns from heated air in an incubator.

The incident followed two other reported cases at the hospital involving children recently, including a heart/lung transplant case in February and an accidental flash fire in the pediatric intensive care unit in June that resulted in burns to a child.

Duke and CMS have agreed that Duke University Hospital will make significant changes that strengthen the hospital's patient safety programs, particularly in pediatric care. For starters, Duke officials said the hospital is establishing a pediatric safety program.

The Duke University Health System (DUHS) also will take several steps that increase safety protections, such as inviting outside experts to serve on its Patient Safety and Quality Assurance Committee. CMS administrator Tom Scully recently announced that Duke's corrective actions helped it avoid a longer bureaucratic process.

"Traditionally, CMS would be issuing notices proposing to revoke Duke's hospital certification, Duke would appeal, and a long, cumbersome process would begin," he said. "Instead, we have avoided that normal bureaucratic dance and engaged in a real workout plan with Duke. This will more quickly improve patient safety — and result in real change at Duke Hospital — which is what this is all about."

CMS initiated a review involving Duke University Hospital on Sept. 4, 2003, after the hospital self-reported an incident in which a premature infant received a burn from heated air in an incubator in its ICN. The infant is no longer at Duke and has a favorable prognosis, Duke officials report.

Following its review, CMS informed hospital officials on Sept. 19 that it would terminate its eligibility for Medicare and Medicaid reimbursement unless Duke University Hospital addressed issues the agency had identified. CMS' review identified several problems in the infant's treatment: Nursing staff were inadequately trained in the proper use of the incubator; the infant was not properly monitored during the crucial time period after the procedure was done; and staff failed to note that sterile covers had fallen over one of the incubator's warm air outlet vents, which channeled the heated air directly onto the infant's right side and caused the burns.

Duke's corrective plan includes the following corrective actions: reviewing and revising various ICN policies such as the monitoring of patients, vital signs monitoring, thermoregulation and documentation guidelines; educating ICN staff on these revised policies prior to their next shift assignment; and re-educating ICN staff on the safe use of incubators, insertion of umbilical artery catheters and endotracheal tubes, and role delineation of ICN staff.

Additionally, Duke will strengthen policies and guidelines on where procedures may be performed in the ICN, actions to be taken should a procedure need to be performed in an incubator in the ICN, insertion of umbilical artery catheters and endotracheal tubes, actions to be taken should a portable X-ray not be performed within the expected time frame, and delineation of the roles of the care nurse and neonatal nurse practitioner while performing a procedure in the ICN. Finally, the ICN will have temperature alarms on monitors used in the unit defaulted to the "on" position. ■

Guidelines show when an issue becomes 'grievance'

The Society for Healthcare Consumer Advocacy, part of the American Health Association, has developed a document outlining when a patient issue should be categorized as a grievance under Center for Medicare & Medicaid Services' (CMS) regulations. It developed the document based on discussions with top CMS staffers, prompted by requests for clarification from risk managers and other health care professionals.

The document identifies differences between a patient complaint and grievance and provides tips for discussing complaint and grievance issues with state surveyors. It can be found at www.shca-aha.org. This is some of the advice:

- An issue is not a grievance if it can be handled on the spot by staff present.
- An issue is not a grievance if the patient (currently in the hospital) calls the patient representative first and has not yet tried to resolve the issue

with the involved department. The patient representative can forward the issue to the involved department(s) for resolution and consider it a complaint. However, if the issue comes back to the patient representative as unresolved to the patient's satisfaction, it escalates to grievance status.

- If other staff must be called in (i.e., the patient representative) after staff present have failed to resolve the issue, then the issue is considered a grievance in most cases.
- Billing issues are not considered grievances unless the patient is disputing charges due to poor care or service.
- All issues from patients who call or write to the hospital after discharge are considered grievances because the issues were not resolved during their stay. ■

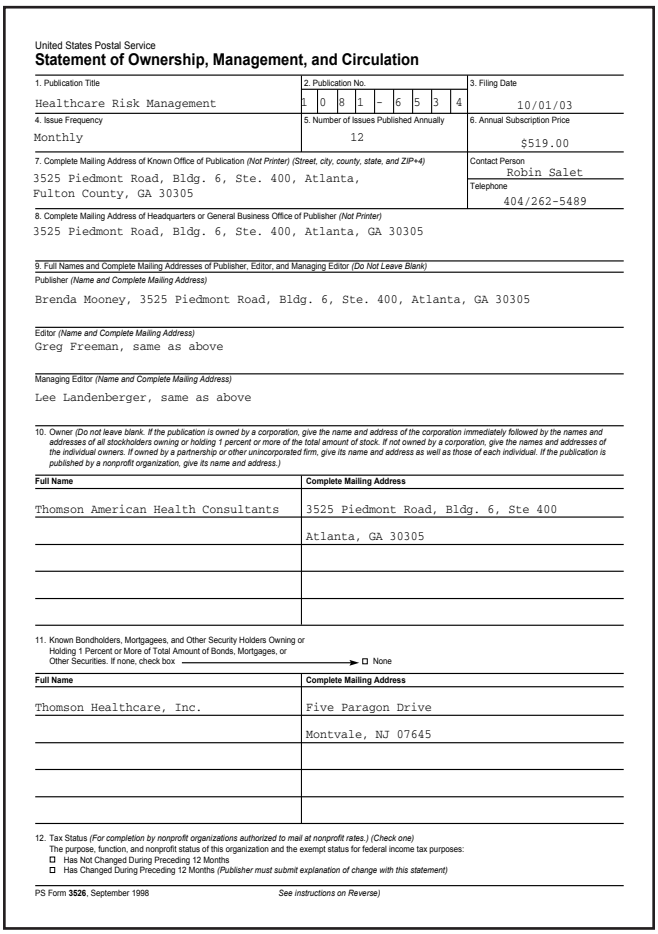
JCAHO revises performance areas for some surveys

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recently announced that it will revise the fixed and variable performance areas evaluated during random unannounced surveys, starting in 2004.

Under the current accreditation process, the identification of fixed and variable performance areas have been at the grid element (performance category) level. However, beginning in 2004, the reporting of standards compliance will be organized by Critical Focus Area — processes, systems, or structures in a health care organization that significantly impact the quality and safety of care — rather than by grid element.

This change is part of a series of significant standards and survey process improvements. The 2004 fixed performance areas approved recently by the Accreditation Committee of JCAHO's Board of Commissioners are staffing, infection control, and medication management, plus National Patient Safety Goals that are relevant to an organization's care and services.

The variable performance areas that are part of the random unannounced surveys will be based on prioritized Critical Focus Areas that are specific to each organization. A sample of 5% of organizations accredited under the ambulatory care, behavioral health care, home care, hospital and long-term care programs are randomly selected for unannounced surveys each year. ■



United States Postal Service
Statement of Ownership, Management, and Circulation

1. Publication Title	2. Publication No.	3. Filing Date
Healthcare Risk Management	1 0 8 1 - 6 5 3 4	10/01/03
4. Issue Frequency: Monthly	5. Number of Issues Published Annually: 12	6. Annual Subscription Price: $519.00

7. Complete Mailing Address of Known Office of Publication *(Not Printer) (Street, city, county, state, and ZIP+4)*: 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, Fulton County, GA 30305 — Contact Person: Robin Salet; Telephone: 404/262-5489

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not Printer)*: 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do Not Leave Blank)*

Publisher *(Name and Complete Mailing Address)*: Brenda Mooney, 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

Editor *(Name and Complete Mailing Address)*: Greg Freeman, same as above

Managing Editor *(Name and Complete Mailing Address)*: Lee Landenberger, same as above

10. Owner *(Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual. If the publication is published by a nonprofit organization, give its name and address.)*

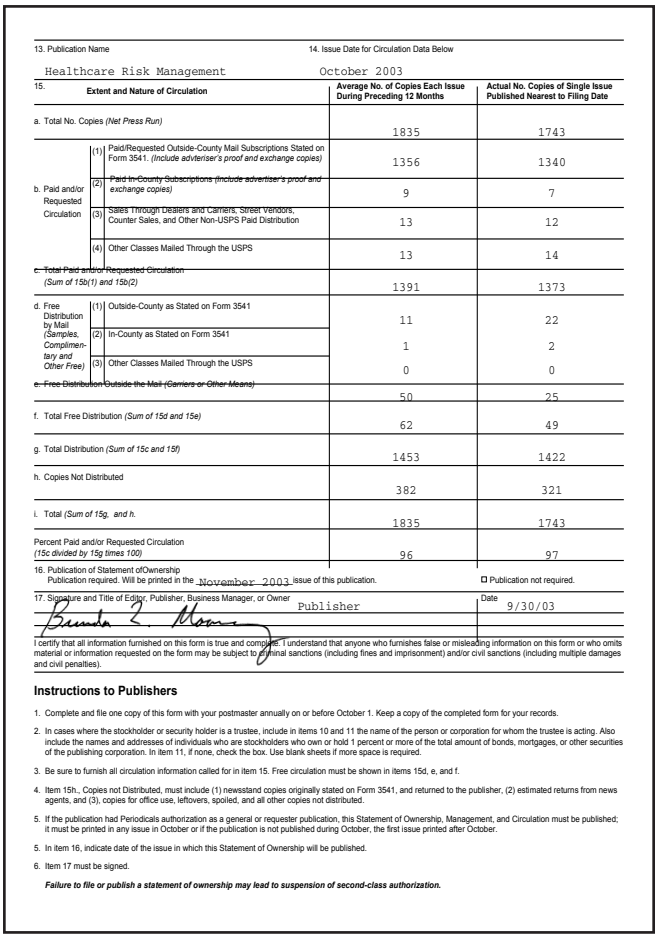
Full Name	Complete Mailing Address
Thomson American Health Consultants	3525 Piedmont Road, Bldg. 6, Ste 400 Atlanta, GA 30305

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☐ None

Full Name	Complete Mailing Address
Thomson Healthcare, Inc.	Five Paragon Drive Montvale, NJ 07645

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates.) (Check one)*
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☐ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months *(Publisher must submit explanation of change with this statement)*

PS Form **3526**, September 1998 *See instructions on Reverse)*



13. Publication Name: Healthcare Risk Management — 14. Issue Date for Circulation Data Below: October 2003

15. Extent and Nature of Circulation		Average No. of Copies Each Issue During Preceding 12 Months	Actual No. Copies of Single Issue Published Nearest to Filing Date
a. Total No. Copies *(Net Press Run)*		1835	1743
b. Paid and/or Requested Circulation	(1) Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. *(Include advertiser's proof and exchange copies)*	1356	1340
	(2) Paid In-County Subscriptions *(Include advertiser's proof and exchange copies)*	9	7
	(3) Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Non-USPS Paid Distribution	13	12
	(4) Other Classes Mailed Through the USPS	13	14
c. Total Paid and/or Requested Circulation *(Sum of 15b(1) and 15b(2)*		1391	1373
d. Free Distribution by Mail *(Samples, Complimentary and Other Free)*	(1) Outside-County as Stated on Form 3541	11	22
	(2) In-County as Stated on Form 3541	1	2
	(3) Other Classes Mailed Through the USPS	0	0
e. Free Distribution Outside the Mail *(Carriers or Other Means)*		50	25
f. Total Free Distribution *(Sum of 15d and 15e)*		62	49
g. Total Distribution *(Sum of 15c and 15f)*		1453	1422
h. Copies Not Distributed		382	321
i. Total *(Sum of 15g, and h.*		1835	1743
Percent Paid and/or Requested Circulation *(15c divided by 15g times 100)*		96	97

16. Publication of Statement of Ownership
Publication required. Will be printed in the November 2003 issue of this publication. ☐ Publication not required.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner: Brenda J. Mooney, Publisher — Date: 9/30/03

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CE objectives

After reading this issue of *Healthcare Risk Management,* the CE participant should be able to:

1. Describe legal, clinical, financial, and managerial issues pertinent to risk managers in health care.
2. Explain how these issues affect nurses, doctors, legal counsel, management, and patients.
3. Identify solutions for hospital personnel to use in overcoming challenges they encounter in daily practice. Challenges include HIPAA and EMTALA compliance, medical errors, malpractice suits, sentinel events, and bioterrorism.
4. Employ programs used by government agencies and other hospitals (such as EMTALA, HIPAA, and medical errors reporting systems) for use in solving day-to-day problems. ■

CE Questions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity each semester, you must complete the evaluation form provided and return it in the reply envelope provided in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

17. Select the answer that agrees with advice from Ronald Miller, CSP, director of training and consulting services for the occupational safety and health group of the National Safety Council.
A. Individual falls do not need a thorough investigation.
B. All falls should be investigated by a full fall investigation team.
C. The local supervisor can handle all fall investigations.
D. Some falls should be investigated by the supervisor, and more serious falls should be investigated by a full team.

18. What is the ideal static coefficient of friction for floors in a health care facility?
A. Between 0.6 and 0.7
B. Between 0.2 and 0.5
C. Anything below 0.6
D. Anything above 0.7

19. Under Option 1 offered by JCAHO in response to confidentiality concerns related to the Periodic Performance Review (PPR), when does the provider submit its self-assessment or Plan of Action?
A. Never
B. Immediately after the self-assessment
C. After a six-month review period
D. One year after the self-assessment

20. How much did the "virtual anticoagulation clinic" at Abington (PA) Memorial Hospital improve the percentage of patients with the correct therapeutic level of anticoagulants reported in laboratory tests?
A. From 55% to about 80%
B. From 30% to 60%
C. From 15% to 45%
D. From 65% to 95%

Answers: 17-D; 18-A; 19-A; 20-A.

Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Dosage mix-up leads to an overdose and $2.25 million in damages

By **Jan Gorrie**, Esq., and **Blake J. Delaney**, Summer Associate
Buchanan, Ingersoll Professional Corp.
Tampa, FL

News: A man was admitted to a hospital after presenting to the emergency department (ED) with chest pain. After an initial cardiac catheterization revealed serious coronary disease, open-heart surgery was performed. During his recovery, an unlicensed nurse administered an overdose of the medication Digoxin. The patient claimed the overdose caused a heart attack, which ultimately lead to the amputation of his leg, partial loss of his intestine, and diminished mental capacity. The patient and his wife brought suit against the hospital for medical negligence and a derivative claim for loss of consortium. The jury found the hospital negligent and awarded $2.25 million in punitive damages to the plaintiff.

Background: The patient presented at the hospital ED complaining of chest pain. Once admitted, he underwent a cardiac catheterization, which showed that he was suffering from serious coronary disease. Two days later, bypass surgery was successfully performed. However, two days post-surgery, the nurse caring for the patient found that he was experiencing arrhythmia or irregular heart rhythm, a common post-bypass symptom.

His primary caregiver in the cardiac unit was a nursing school graduate who had not passed her licensing examination. She failed the test the first time she took it and was under the supervision of a licensed nurse in the unit. In response to the patient's arrhythmia, the unlicensed nurse called the patient's attending physician, who verbally ordered administration of 0.25 mg Digoxin. Digoxin can be effective for the treatment of heart rhythm disorders, but the physician must determine the actual dosage and administration schedule for each patient based on the patient's height and weight. Dosing and its timing is critical for this medication because the difference between toxic blood levels and therapeutic blood levels is small.

The unlicensed nurse thought the doctor ordered 1.25 mg Digoxin. She was unfamiliar with the medication, and it was the first time she administered it. She confirmed the dosage with her supervising nurse, who did not note the incorrect dosage, and administered the overdose. Soon after, the pharmacist called the unit to confirm the validity of the 1.25-mg order, but it was too late. The patient had gone into cardiac arrest. A code was called, but not before the patient suffered serious injuries, which resulted in his losing a leg and part of his intestine. The patient also was left mentally diminished.

The patient sued the facility for the drug error. The plaintiff's expert called the incident a "massive overdose" that resulted from human error and inadequate hospital procedures regarding the use of dangerous drugs. The supervising nurse admitted she was not in the room when the unlicensed nurse administered the overdose.

In addition to the patient's claim for compensatory and punitive damages, his wife filed a derivative claim for the loss of consortium due to the seriousness of the injuries to her husband.

The hospital conceded the overdose was a mistake, but argued that the plaintiff's condition was related to a long history of coronary disease and could not be attributed solely to the medication error. In particular, the defendant claimed that the patient would have lost his leg regardless. The jury returned a verdict for $2.25 million in punitive damages only. The compensatory and consortium claims were rejected.

What this means to you: While nursing practice acts may vary from state to state, this scenario raises various concerns from both a risk management and patient care perspective, including recording and implementing physician orders, nursing education and supervisory practices, and obviously a medications error.

"As this case illustrates, it only takes one such error to cause immeasurable harm, and precautions and safeguards should be in place to mitigate their occurrence," notes **Diane Giraudi Perry**, PhD, LHRM, a health care risk manager at Bon Secours Health System Inc. in Venice, FL.

The recording and implementation of physicians' orders are fertile ground for nursing error and medical malpractice litigation.

"Medication orders are especially problematic and at the forefront of concern as evidenced by the Institute of Medicine's and the Institute for Safe Medical Practice's reports of medication errors in the United States," says Giraudi Perry. "And nurses are at the forefront of the issue of medication errors because they are most often the caregiver administering drugs. Therefore, nurses have a duty to ensure to the best of their ability that physicians' orders are properly transcribed and implemented. Nurses are required to administer medications as properly prescribed by physicians and dispensed by a pharmacy. Medications must be administered in the prescribed manner and dosage to the proper patient at the right time. One common medication-administering problem [wrong dosage] occurred in this situation."

Health care organizations have a responsibility to employ medication administration safeguards, such as unit doses, to prevent overdose errors. In this instance, the pharmacist caught the error, "but the train had left the station, so to speak. Once the overdose had been taken to the cardiac unit, it was just too late. The call from the pharmacy should have been made before dispensing the overdose to the unit, particularly in light of the inherent dosage precautions with Digoxin. The prescribed dose of this drug should have registered with the pharmacist," adds Giraudi Perry.

Educating and training nurses is critical to addressing the national shortage of health care workers and facilities should be involved in the process. However, educational precautions and protocols should not be overlooked. In this case, the unlicensed nurse should not have been allowed to function as an independent care provider with regard to medication administration because the person making the error did not hold a license.

"Initiating a call to the attending physician and taking verbal orders requires a licensed nurse [LPN or RN]. The unlicensed nurse should never have made the call. Medication administration is a nursing care responsibility, and the liability for such remains with the licensed nurse even when delegating the task or activity. The licensed nurse essentially permitted her supervisee to act independently with regard to contacting the physician, taking orders, and independently administering the medication," adds Giraudi Perry.

After appropriately identifying a change in the patient's condition and reporting that change to the physician, an oversight in the process appears to have occurred.

"It seems that the unlicensed nurse did not validate the verbal order with the physician upon taking the order. According to recommendations by the Joint Commission on Accreditation of Healthcare Organizations, orders should always be repeated to the physician for verification to reduce medication errors and increase patient safety. Unfortunately, this did not occur," adds Giraudi Perry. "This oversight was then compounded when the supervising nurse reviewed the orders but did not recognize the dosage as potentially hazardous. It was the first dose given to digitalize the patient. Generally, the initial dosage is no greater than 0.25 mg and is sequentially given until therapeutic level is reached. However, the unusually high initial dosage of 1.25 mg was not recognized as such by either the licensed or unlicensed nurse. Both should have questioned this dosage as it was five times the amount the physician ordered."

There are process and performance issues that should be examined.

"Both the competency of the registered nurse and that of the unlicensed nurse are at issue. The

nurses were in an environment — the coronary care unit/critical care unit— that requires highly skilled and specialized nursing. The expectation is that the nursing staff will have knowledge of the medications used at this level of care and potential adverse effects of these medications. The medication in this instance, Digoxin, is a commonly used drug for heart patients. This leads to questions of appropriateness of unlicensed staff on such a unit and competency. Additionally, staffing issues may be of concern since there is an appearance that the RN was not available to provide adequate supervision to the unlicensed nurse," says Giraudi Perry.

The event merits review of the systems in place so that medications errors can be avoided in the future.

Reference

• *Hodgen v. Mobile Infirmary,* Mobile County (AL) Circuit Court, Case No. 01-0341. ■

Temp worker's mistake costs a life and $800,000

News: Unable to care for herself, a Parkinson's disease patient contracted for services provided in her home, including meal preparation. One day, the home health company was short-staffed and subcontracted with a temporary personnel agency to care for the patient. The temporary employee served the woman a meal that violated her dietary restrictions, and the patient choked to death. The patient's estate brought suit, and the jury returned a verdict of $800,000 against the home health provider; the estate settled confidentially with the temporary personnel agency.

Background: The decedent in this case suffered from Parkinson's disease and was unable to fully care for herself. With no family to assist with her care, she contracted with a home health services company. Parkinson's disease caused her difficulty in swallowing, leading the home health services company to prepare her meals according to specific feeding and dietary restrictions.

One day, the home health care provider was short-staffed and subcontracted with a temporary personnel agency to provide care to the plaintiff. The temporary employee assigned to care for her did not know she had difficulty swallowing and was unaware of her dietary restrictions. The temp, at the patient's request, served the woman menudo, a hearty and spicy Mexican soup made with tripe, calf's feet, chile peppers, hominy, and seasonings. In the middle of her meal, the woman choked to death.

The decedent had no surviving spouse or children, but her estate brought forth an estate claim against the home health provider and the temp agency, claiming negligent hiring, negligent supervision, and improper care. The plaintiff's position was that the meal should never have been served, that the home health provider failed to provide the temp with adequate information regarding the patient's condition and special needs, and that the home health provider's overall care was severely lacking.

The home health care provider raised a variety of defenses. It claimed that it provided only personal assistance services, not true home health services. It also maintained that the decedent demanded menudo, which was served properly, and that the patient's death resulted from a natural condition, not from the food intake. Lastly, the home health company claimed that, if there was negligence, it was the subcontractor that was the negligent and culpable party. The temporary personnel agency failed to make an appearance in court.

The jury returned a verdict for the plaintiff in the amount of $800,000 against the home health company. The case against the temp agency was later settled for an undisclosed sum.

What this means to you: This client contracted with the home health agency for certain services and the agency had a responsibility to obtain and maintain particular information about the client. In the event the home health agency, or any organization, subcontracts with another organization to provide care or services in its stead, the contracting organization has a responsibility to pass on any and all information to the contracted party. In such cases, the contracting party, in this situation the home health agency, still retains the responsibility for the client, says **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, CHt, director, risk management services, of the Miami Jewish Home and Hospital for the Aged.

Even if this client contracted only for activities of daily living and meal services, the home health

agency still should have provided supervisory oversight, especially when the assigned personnel is unfamiliar with a client's needs. Specifically, it was known that this client had difficulty swallowing as a result of Parkinson's disease.

"Special care of diet and feeding is very important when caring for anyone with swallowing difficulties. Serving thickened liquids and complying with other dietary requirements are necessary. This information should have been made available to the temporary staffing agency, which would then have had a responsibility to pass it on the temporary personnel assigned to this client. The temporary staffing agency should have taken this need into consideration when selecting and assigning the personal assistant to this client. Furthermore, the home health agency had a responsibility to outline certain qualifications and responsibilities required of the person assigned," adds Kicklighter.

In this matter, we do not know if the client was capable of understanding the swallowing dangers in certain foods when she demanded a particular meal be prepared.

"The home health agency should have advised the temp agency companion to call for clarification of issues that might arise, such as the client's insistence for a certain meal that proved to be inappropriate. It may have been that the patient client realized that this was not a regular employee and therefore the patient knew that she could try to break the rules, but should not have been allowed to do so," notes Kicklighter. "In view of the fact that the client was known to have a swallowing problem, the home health agency should have made sure there was a suction machine available in the client's home and that any and all staff members who took care of this client were trained in using the suction machine and in the Heimlich maneuver in the event of choking."

Swallowing difficulties are complications in many diseases and conditions and are a recognized potential problem in the elderly, especially those with Parkinson's disease. Health care providers must be aware of these dangers of choking, learn methods to minimize them, and be prepared to intervene when choking occurs, regardless of the setting.

"Risk managers should review the process and content of the communication between the admissions intake personnel and the caregiving staff in the field. Systems should be set up to accomplish this same process in the event temporary staff is utilized. Many organizations develop working relationships with temporary staffing agencies. Risk managers should work with administration to decide whether it would be in the organization's best interest to contract with the temp agency. Such a contract might set out the responsibilities for each party that could address some of the issues described in this scenario," concludes Kicklighter.

Reference

- Bexar County (TX) District Court, Case No. 98-PC-1630. ■

HIPAA Regulatory Alert

Supplement to Healthcare Risk Management and Hospital Access Management

THOMSON
AMERICAN HEALTH CONSULTANTS

IN THIS ISSUE

NOVEMBER/ DECEMBER 2003
VOL. 1, NO. 6 • (pages 41-48)

Privacy regulations complicate communication with patients

Balancing confidentiality and safety is a challenge

The privacy regulations enacted as part of the federal Health Insurance Portability and Accountability Act (HIPAA) have caused some unforeseen complications for hospitals trying to ensure patient safety and improve communication between providers and patients, say health care professionals and legal experts.

And as hospitals continue to develop new policies and procedures to comply, it's important that they carefully examine how their efforts will affect caregiver-patient relationships.

"Some of the good things about HIPAA, obviously, were the enacting of standards to ensure continuity of care and maintenance of insurance coverage while switching jobs and health plans," notes **Arnold Rosenbaum**, MD, a practicing surgeon and president of Seacrest DocSecurity, a HIPAA consulting firm in Middletown, RI. "But some of the regulations are actually going to impede care in some ways by slowing things down. It is impairing simple communication where there really needs to be communication."

Because HIPAA allows patients to request total or limited anonymity while in the hospital and to have a significant amount of control of over the dissemination of information about their health conditions, most hospitals have done things such as removing the patient names from large boards behind the nurses' stations and replacing names and other information on wrist bands with bar codes to prevent unauthorized disclosures of information.

While these measures do improve the patient's confidentiality, they can complicate patient care, Rosenbaum says.

"Hospitals have, in good measure, replaced the patient boards with names in most nursing units with boards that have initials or some other identifier," he explains. "But it can become quite difficult to find your own patient. There are added difficulties to patients requesting anonymity because just finding the patient becomes a significant effort for anyone who has to do it, whether it is a physician, nurse, or technician needing to draw blood. You then have more potential for treating the wrong patient, operating on the wrong patient, etc. You have now this dual purpose in preventing errors and mistakes and in maintaining privacy and confidentiality."

Provider communications with family members — already difficult waters to navigate — are even more complicated now because HIPAA

requires that hospitals get written authorization before disclosing information to a third party.

If a patient has established ahead of time that his or her condition can be discussed with a spouse or a child, no problem. However, providers frequently find themselves in other situations, says **William J. Spratt Jr.**, JD, a former health care administrator now a health care attorney with the Miami law firm Kirkpatrick & Lockhart, and vice chair of the Florida Bar Association's Health Law Certification Committee.

"HIPAA has put some constraints and created some doubt as to what the health care provider can do when they are dealing with a patient who is either incapacitated or in an emergency medical condition," Spratt explains. "They are limited in their disclosure. Basically, they have to make a determination of what is in the best interests of the patient and disclose only the personal health information that is directly related to that person's involvement."

So if an 85-year-old woman in Miami suffers a heart attack and is taken to the hospital, and the woman's son in New York calls to speak to the physician, barring any prior authorization from the woman, the physician can only confirm to the family member that the patient is receiving care at the hospital and basic information about the patient's current condition.

"But they cannot talk about it," Spratt explains. "They can't say, 'Mom had a heart attack and we've taken a look at it, and it appears to have subsided; she has some weakness of the upper wall.' They cannot go into that level of detail."

Such efforts to protect the patient may do more harm than good, says Seacrest's Rosenbaum.

"Open communication — communication with both family and other individuals — frequently is very important in patient care," he notes.

Now, physicians and nurses may feel a dual responsibility — to provide information to worried family members about a patient who may need their support and at the same time to protect their hospital and comply with the privacy protections mandated by federal law.

With no clear guidance, hospital personnel can go overboard with compliance efforts and restrict the flow of information even further than necessary, he adds.

"This issue has not been adequately clarified in the hospitals where I have worked," Rosenbaum says. "There may be a specific form relating to who can be spoken with and who cannot be spoken with, but that is very difficult to work with in the heat of the moment."

The overcompliance problem

In their efforts to comply with the privacy regulations, some facilities have gone overboard and restrict information even when they don't have to and when the patient wants his or her health information transmitted elsewhere, Spratt notes.

HIPAA allows the free flow of information among covered entities for the purposes of treatment, payment, and health care operations, without prior patient authorization. But some facilities, under the gun to develop compliance plans, have blanket policies that require patient authorization in all instances.

"My wife had a procedure done in the outpatient center of a hospital and requested that the results be forwarded to her physician once the radiologist interpreted the study," Spratt says. "She called and asked them to send it, and they said they needed either a written authorization or she needed to

HIPAA Regulatory Alert (ISSN 1542-9830) is published bimonthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **HIPAA Regulatory Alert**, P.O. Box 740059, Atlanta, GA 30374.

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Customer Service: (800) 688-2421 or fax (800) 284-3291. Hours of operation: 8:30-6. Monday-Thursday, 8:30-4:30 Friday EST. World Wide Web: http://www.ahcpub.com. E-mail: customerservice@ahcpub.com.

Subscription rates: Free to subscribers of *Healthcare Risk Management* and *Hospital Access Management*. For nonsubscribers, the price is $149. U.S. possession and Canada, add $30 plus applicable GST. Other international orders, add $30. (GST registration number R128870672.) 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 $48 each.

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come down there and pick up the results herself. That is basically a covered entity to covered entity and a disclosure for treatment purposes between a hospital and treating physician, but they were being a little overly cautious, I guess. I had to speak with them to assure them that HIPAA certainly allows them to share the results of diagnostic tests with the patient's physician."

Spratt finds that he frequently has to correct misunderstandings among hospitals and physicians and other providers about the purpose and intent of HIPAA.

"The purpose of HIPAA is not to interfere with the regular ongoing exchange of health care information that is relevant to the common treatment of patients," he notes. "It is really intended more to protect that information from disclosure outside the scope of the treating people and put some limitations on exchange of information between health care providers and insurers so that insurers can't assemble huge databases on patients that may be used for improper purposes — denying coverage of determining pre-existing conditions, things like that."

HIPAA was enacted because the health care industry was so far behind most other industries in terms of automation and use of electronic data and electronic medical records because of myriad state regulations and an overdependence on paper systems.

"HIPAA was invented to set the stage for facilitating the electronic exchange of information in order to increase efficiency and reduce health care costs by eliminating duplicative testing and things of that sort and to make the information more available to treating physicians and providers so that there may be a reduction in errors because information was not available," Spratt explains.

At the same time, Spratt notes, the federal government was concerned that facilitating the efficient exchange of information would enable the establishment of huge databases of medical information about individuals and that this had a huge potential for abuse.

"This is a recurrent theme in federal regulations," he says. "Any time there is an initiative to aggregate substantial amounts of personal data, this element of Congress raises up and says, 'No, that's not what this country is about.'"

So, though the intention of the privacy regulations was to prevent Big Brother from knowing everything about everyone's medical condition, the real-world impact is that a worried sister might not be able to obtain information about her sick sibling hospitalized across the country.

Further complicating matters, HIPAA allows health care providers to provide information to persons without prior authorization if they are allowed to do so under state laws, but only under the specific provisions under those laws.

The only recourse hospitals have is to ensure that they understand HIPAA and its interaction with the laws in their state and that they develop policies that accurately guide their staff interactions with patients, says **Linda Ross**, JD, a health law attorney with the law firm of Honigman Miller in Detroit.

"There are already differing laws in differing states that deal with things like confidentiality and patient records and disclosures and subpoenas, etc.," she explains. "Rather than have HIPAA just trump everything, the lawmakers created a system where if the state law is contrary to, but more stringent than, federal law, the state law remains in place."

In Michigan, the health law section of the state bar spent months in committee going over the different provisions in HIPAA and any related statutes in their state to determine which requirements held.

"We created this tool for the state that is available and a guideline that goes through our analysis and decides what requirements hospitals and other entities in the state must do to comply," Ross says.

As people become more educated about and comfortable with HIPAA, much of the confusion and conflicts will die down, she notes. But for now, hospitals must look at everything they do for how the privacy regulations may have an effect.

They must not only develop policies that require personnel to obey the law but also ensure that the policies don't encourage staff to become so rigid in protecting information that they harm patient relationships or impede patient care.

"Especially things like patient rights — patients have a right to access their records, request amendments, and say, 'Talk to my husband, but not to my son,' or 'Call me on my cell phone, but don't call me at home," Ross says. "The result is that hospitals need to implement behavioral changes, cultural changes, and administrative changes with how they deal with patient information."

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What to do if you're just getting started

Time to prioritize your responses, expert says

At the Seventh HIPAA Summit held in Baltimore in mid-September, "Doctor HIPAA" — former Centers for Medicare & Medicaid Services (CMS) executive **William Braithwaite** — said that while Transactions and Code Sets (T&CS) testing should have started in April at the latest, vendors should have provided software to all their clients and completed testing, clearinghouses should have finished testing for all customers, and health plans should have finished testing all transactions with providers and clearinghouses, the reality was that much of the testing still was being done and some entities hadn't yet started.

Those who haven't started need to understand the reality of their situation in terms of the law and guidances from CMS, a reasonable definition of "compliance," and the consequences of their failure to comply, he said.

"It's time to prioritize your responses and create and promulgate contingency plans," Braithwaite said. "Establish reasonable compliance targets. Coordinate, cooperate, and push your trading partners to become compliant over time."

He reviewed the provisions for civil and criminal penalties and CMS' initial enforcement approach, noting that the agency intends to focus on obtaining voluntary compliance and will use a complaint-driven approach for enforcement.

If CMS receives a complaint about a covered entity, it will notify the organization that a complaint has been received and provide it an opportunity to demonstrate compliance, document good-faith efforts to comply, and/or submit a corrective action plan.

Braithwaite noted that there is no definition of "compliant" in the CMS guidance and said the agency will consider an organization's good-faith efforts to comply when assessing individual complaints.

"CMS understands that transactions require the participation of two entities," he said, "and CMS will look at both entities' good-faith efforts to determine whether a reasonable cause for noncompliance exists and the time allowed for curing the noncompliance. CMS says it will not impose penalties on entities that deploy contingencies to ensure the smooth flow of payments if they have made reasonable and diligent efforts to become compliant and, for health plans, have taken reasonable steps to facilitate the compliance of their trading partners. As long as a health plan can demonstrate its active outreach and testing efforts, it can continue processing payments to providers."

He said covered entities might be able to demonstrate good faith, he said, by steps such as increased external testing with trading partners; lack of availability of, or refusal by, trading partners to test transactions with the entity whose compliance is at issue; and concerted efforts by a health plan before Oct. 16, 2003, and continuing efforts after that date to conduct outreach and make testing opportunities available to its provider community.

Braithwaite urged organizations to document that they had exercised good-faith efforts to correct problems and implement changes required to comply in case a complaint is filed. He said that CMS will expect noncompliant covered entities to submit plans to achieve compliance and that CMS flexibility will permit health plans to mitigate unintended adverse effects on covered entities' cash flow and business operations during the transition to the standards.

(For more information, e-mail Mr. Braithwaite at Bill@braithwaite.com.) ■

Privacy implementation going well, says HHS

Compliance 'widespread,' says OCR director

Department of Health and Human Services Office of Civil Rights director **Richard Campanelli** says that many covered entities have done a good job of coming into compliance with the HIPAA privacy requirements that took effect in April, although there remain some misunderstandings about the requirements that need to be cleared up.

Campanelli presented his assessment in a Sept.

23 testimony to the Senate Special Committee on Aging.

"The privacy rule establishes the nation's first-ever comprehensive standards for protecting the privacy of Americans' personal health records," he said. "As of April 14, 2003, patients have sweeping federal protections over the privacy of their medical records, right to access and to correct errors in their medical records, right to control how their protected health information is used and disclosed, and a clear avenue of recourse if the rights afforded by the privacy rule are violated."

He told the senators that a number of areas that have received a lot of attention since April were significantly changed through modifications to the rule made last August, but some confusion still needs to be addressed.

One aspect of the privacy rule that had been the subject of much public response during the comment period was the requirement to obtain written consents from patients to use or disclose their protected health information to treat them, obtain payment, or carry out day-to-day operations. "Requiring consent in these contexts," Campanelli said, "would have been unnecessarily burdensome on patients and providers, and interfered with timely access to quality care, without improving privacy. It would have meant, for instance, that a doctor would have needed a patient to sign a privacy consent before he could use health information to treat that patient; that a specialist contacted by the patient's doctor would have needed to obtain the patient's consent to read treatment information; and that a pharmacist would have needed the patient's consent to fill a prescription written by the provider."

He said the modifications to the privacy rule removed the requirements that providers obtain prior consent to use or disclose a patient's health information for treatment, payment, or health care operations purposes. Although obtaining such consent is considered the optimal situation, he said, the change assures providers ready access to health information about their patients and the ability to share that information so that timely access to quality health care is not unduly impeded.

According to Campanelli, the notice requirement was strengthened at the same time by requiring direct treatment providers to make a good-faith effort to obtain a patient's written acknowledgement of receipt of a privacy notice. "This ensures that patients have the opportunity to consider the provider's privacy practices, both to be better informed of how their information may or may not be disclosed, and to be informed of their rights," he said.

The modifications also clarified that with reasonable safeguards, uses and disclosures that are merely incidental to privacy rule uses and disclosures will not be considered a violation. Campanelli said the rule recognizes that communications necessary for quick, effective, and high-quality health care might unavoidably lead to overheard communications. For instance, a physician may discuss a patient's condition or treatment regimen in the patient's semiprivate hospital room, or a pharmacist may discuss a prescription with a patient over the pharmacy counter, so long as they take reasonable precautions, such as lowered voices or stepping away from other people.

Misconceptions, not rule, cause confusion

According to Campanelli, "since April 14, 2003, there has been widespread compliance by health plans, health care clearinghouses, and those providers covered by the privacy rule. For example, physicians, hospitals, clinics, pharmacies, health insurance carriers, employer group health plans, and others have distributed notices, required by the privacy rule, that tell consumers about how their health information can and cannot be disclosed, and their rights. . . . Given the extensive scope of the protections established in the privacy rule, implementation has gone smoothly, without the disruption of the health care system that had been predicted in some quarters."

When confusion has arisen, he said, it appears to be not because of problems with the privacy rule itself, but rather because of misconceptions about the rule. In addition, he said, it appears that providers and other covered entities are educating other covered entities where overly restrictive practices were initially adopted and incorrectly blaming them on the privacy rule.

"For example," Campanelli said, "we have heard reports that some covered entities are reluctant to share health information with other providers, for the purpose of treating their patients, claiming that the privacy rule requires that patients execute written consents for these disclosures to occur." Providers who attribute this practice to the rule apparently are unaware that it was modified specifically to permit treatment disclosures among providers without a need for patient consent, he said.

He also mentioned receiving reports of providers saying they cannot share information

with family members or loved ones. The reality, he said, is that rather than foreclosing such communications, the privacy rule provides a number of common-sense methods that appropriately permit such disclosures while respecting and protecting individuals' right to control their health information. In a similar vein, incorrect reports that clergy can't get information they need about congregation members who are hospitalized have circulated. Campanelli reported that hospitals may continue to maintain patient directories with information including a patient's religious affiliation if the patient shares it. He said clergy can always ask for individuals by name and get the information they need, but also can refer to hospital directories if the hospital maintains one.

"It appears that confusion on these issues is dissipating as covered entities and consumers become more familiar with the rule's requirements," he told the committee. "The problems do not arise because of the privacy rule, but rather seem to arise either because providers have elected to take a more restrictive approach than the privacy rule requires, or because of a misconception about the requirements of the privacy rule." He said the Office of Civil Rights has conducted and is continuing to use an extensive public education effort so providers and consumers know what is and is not in the rule.

(Additional information is available from www.hhs.gov.) ■

CMS implements contingency plan

Legacy claims accepted for undetermined period

With surveys indicating that the required Oct. 16 compliance with transaction and code sets (T&CS) HIPAA requirements would be spotty at best, the Centers for Medicare & Medicaid Services (CMS) has drawn industry support for deciding to implement its contingency plan and accept legacy claims for an undetermined period of time while efforts toward full compliance continue.

The announcement from the federal agency was followed by one from the Blue Cross and Blue Shield plans saying that they, too, would accept noncompliant claims for a while, as long as good-faith efforts toward compliance continue.

Representatives of all elements in the HIPAA process praised the decision to avoid a major train wreck of claims not being processed by accepting noncompliant claims, but also stressed the need for all parties to make good use of this grace period by taking the steps necessary to come into full compliance.

As the Oct. 16 T&CS deadline loomed closer, CMS first announced on Sept. 11 its contingency plan for temporarily accepting noncompliant claims. "As the largest HIPAA-covered entity," agency acting deputy secretary **Leslie Walker** said in an announcement, "we at Medicare do understand the difficulties in becoming compliant first-hand. That's why we've been working hard to help our HIPAA partners become compliant. . . . Now we are working on the possibility of Medicare implementing a contingency plan, and I urge other health plans to announce their contingency plans as soon as possible to allow their trading partners enough time to make any needed changes to their business operations to make sure any disruptions in their health care operations are minimal."

Contingency plans will help meet agency goals

CMS administrator Tom Scully later said that implementing the contingency plan moves the agency toward the dual goals of achieving HIPAA compliance while not disrupting provider cash flow and operations. And CMS director of Medicare management **Tom Grissom** said, "Medicare is able to process HIPAA-compliant transactions, but we need to work with our trading partners to increase the percentage of claims in production."

During the contingency period, CMS regularly will reassess the readiness of its trading partners to determine how long the plan will remain in effect. With the contingency plan in effect, there was no chance that the implementation date would be delayed.

American Association of Health Plans vice president for private market regulation **Tom Wilder** tells *HIPAA Regulatory Alert* that stakeholders accepted the CMS announcement because it's in line with what most health plans will do — accept legacy claims for some period of time from clearinghouses or providers that aren't ready for the Oct. 16 deadline, so long as the submitter is making a good-faith effort to transition to the new standard.

American Medical Association trustee **Joseph Heyman** said his organization had a three-step

plan for a smooth transition to the T&CS standard — 1) physicians finalize plans to become HIPAA-compliant as quickly as possible; 2) CMS implements its contingency plan; and 3) private sector payers also develop contingency plans to allow legacy claims while the transition to full compliance continues.

American Hospital Association officials had called for implementation of contingency plans before the announcement was made and praised CMS for its decision.

Testifying before the U.S. Senate Special Committee on Aging just after CMS said it would implement its contingency plan, CMS Office of HIPAA Standards director **Jared Adai**r said experiences in other industries have shown the need for health care to standardize transaction information. "Because the banking industry has agreed upon transaction standards," he said, "customers enjoy the safe use of their bankcards at ATMs around the world. Likewise, standards in the shipping industry make it possible to track and deliver parcels worldwide. Such standards and interoperability will benefit the entire health care industry."

There will be cost savings over time

Adair added that while many entities, including CMS, have revised upward their estimated costs for implementation of the T&CS requirements, because of unexpected complications encountered during the assessment and implementation process, "it is clear that HIPAA is going to improve the administrative costs for everyone in the long term. For example, HIPAA is expected to create significant savings for the health care industry and the taxpayer over the first 10 years of implementation. It also is important to note that HIPAA carries significant cost-reduction capabilities over time, when taking into account the start-up costs currently being incurred. Health care providers will be able to submit bills in the same format to all payers and be assured the bills will be accepted. Providers also will have the ability to query claim status and eligibility by computer rather than over the phone. Plans will not have to keep or store paper claims. This will reduce overhead as well as improve turnaround time for transactions, both of which should have a positive impact on cash flow."

Adair said that despite the significant challenges involved, substantial progress has been made toward T&CS implementation, although the progress was not enough to ensure that all health care providers and payers are 100% ready to support the uninterrupted continuation of the nation's $1.4 trillion in health care payments.

He said as the industry moves toward full implementation, three areas of the process need to be reviewed: 1) use of companion guides that describe situational elements but could be misused to exceed HIPAA standardization requirements; 2) required data elements not necessarily needed to adjudicate a claim; and 3) clarification of implementation guidance that is open to interpretation.

"While difficulties exist in achieving compliance," Adair said, "this is not the time to waver in our commitment to offer order and consistency in health care administrative transactions. Rather, it is a time to work with covered entities as they strive to cross the finish line."

(CMS contingency plan information is available at www.hhs.gov.) ■

Survey shines light on HIPAA compliance efforts

Nonprovider compliance improves

The summer 2003 Industry HIPAA survey conducted by HIMSS (Healthcare Information and Management Systems Society) and Phoenix Health Systems found that "not enough time" was seen as the major roadblock to meeting the Oct. 16 implementation deadline for transactions and code sets (T&CS). And that report helped set the stage for CMS and others to apply their contingency plans and continue to accept noncompliant claims.

In online surveys completed in early July, 81% of providers said they had either completed or expected to have completed their T&CS gap analysis before October. But only 74% said they would have implemented all T&CS changes by October.

The researchers said, "lack of cooperation/communication among industry segments remains an ongoing impediment."

Provider readiness for October for various types of transactions ranged from 1% for "None" and 6% for the 820 transaction form to 76% for the 837. For payers, readiness ranged from 3% "None" and 45% for the 820 to 84% for the 837.

Obstacles cited by providers included payer not ready to test (48%), payer not ready for the transaction type (37%), noncompliant software (29%), and internal data collection (27%).

Nonprovider privacy compliance better

In another aspect of HIPAA, the surveyors said that nonprovider privacy compliance had improved dramatically since the group's spring report. Reporting compliance were 88% of clearinghouses (up from 47%), 81% of vendors (up from 39%), and 85% of payers (up from 68%). At 77% (down from 78% in April), providers were the least privacy-compliant segment of the health care community.

HIMSS and Phoenix said that hospital budgets for HIPAA compliance in 2003 generally are higher than they were in 2002, but spending seems to be leveling off.

Survey information is available at www.HIPAAAdvisory.com or contact Phoenix Health Systems at (301) 869-7300 or e-mail info@phoenixhealth.com. ■

Labs seek HHS transaction guidance and relief

ACLA president testifies before Senate

In testimony before the U.S. Senate Special Committee on Aging, the president of the American Clinical Laboratory Association (ACLA) said that although labs are committed to compliance with the transaction standards, the Department of Health and Human Services (HHS) needs to provide more specific guidance to assist providers struggling with implementation and also must streamline the mechanisms for development and maintenance of the transaction standards.

ACLA president **Alan Mertz** said that clinical laboratories are in a unique position with respect to implementation of the transaction standards because they typically have no direct patient contact and thus little opportunity to obtain much of the information that now is required to be submitted in compliant claims. "Clinical laboratories generally perform testing at the request of a physician, on a specimen they pick up from the physician, and they report test results back to the same physician," he said. "As a result, clinical laboratories must rely on physicians to provide patient information." But, he said, because of other demands on the time of physicians and their staffs, they often fail to provide the information initially and also may not be responsive when laboratories make a point of requesting it.

Mertz made particular reference to the problem of providing patient demographic information and also diagnosis coding, noting that physicians have little incentive to provide a laboratory with diagnosis codes because there is virtually no legal or financial consequences to them for transmitting incomplete information to a laboratory. While the laboratory has no ability to force physicians to give them the information, he said, they have to expend precious resources trying to do so.

"As a practical matter," according to Mertz, "a laboratory cannot refuse to perform testing ordered by a physician. Laboratory testing is a critical, and often time-sensitive, health care service. Most laboratories feel they are obligated to perform the testing that is ordered once they receive a specimen, and the laws of several states specifically require testing on all specimens that are submitted to a laboratory. Further, a laboratory could be held liable if a patient later suffers harm as a result of the laboratory's failure to perform testing ordered by a physician. Thus, the practical reality is that if diagnosis information is required to electronically submit a claim, laboratories will be faced with filing paper claims or will end up doing testing for free when they cannot obtain the required information from a physician."

Mertz also raised questions about the HIPAA regulatory process, noting that the law generally requires the department to adopt a standard that has been developed, adopted, or modified by a standard-setting organization. But the law also requires that any standard adopted be consistent with the objective of reducing the administrative costs of providing and paying for health care and accommodate the needs of different types of health care providers.

Mertz said in addition to comprehensively evaluating the relevant regulatory processes, HHS should provide covered entities with additional guidance on compliance with the transaction standards, including a definition on what constitutes a compliant claim and recognition that less-than-perfect claims may be considered compliant initially.

(Contact Mertz at (202) 637-9466 or go to www.acla.org.) ■