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Patient safety the VA way: One hospital can point the way for others to follow

Its focus is prevention, not punishment

The efforts by the U.S. Department of Veterans Affairs (VA) to improve patient safety are paying huge dividends for the hundreds of hospitals participating in its system of adverse-event reporting and analysis, suggesting that other health care providers could benefit from adopting the same techniques.

As all health care providers focus more on patient safety, the VA's National Center for Patient Safety (NCPS) is being hailed as a proven way to make health care safer. The NCPS recently received the John E. Eisenberg Award in Patient Safety for System Innovation, awarded by the Joint Commission on the Accreditation of Healthcare Organizations and the National Forum for Healthcare Quality and Reporting. The VA's patient safety program relies on a method that combines voluntary and mandatory reporting systems, root-cause analysis, and corrective actions to improve patient safety. The NCPS represents a unified and cohesive patient safety program, with active participation by all 172 VA hospitals supported by dedicated patient safety managers, says **Caryl Lee**, RN, MSN, the NCPS program manager in Ann Arbor, MI. Lee says the program is unique in health care because it focuses on prevention rather than punishment, applying human factor analysis and the safety research of "high-reliability organizations" such as aviation and nuclear power to identify and eliminate system vulnerabilities.

The program began in 1999 and relies on a multidisciplinary staff of nurses, biomedical engineers, safety engineers, pharmacists, attorneys, and others. The goal of the NCPS is to improve patient safety throughout the VA medical system, so the staff concentrate on collecting information about adverse events or close calls. Those events are carefully analyzed to determine how they might be avoided in the future, and the results are applied throughout the VA medical system.

"One benefit is that all of the VA hospitals can learn from a single experience instead of waiting for it to happen to them. We're learning from one hospital's experience so that we can improve care at 171 other facilities,"

Lee says. "The same idea can be applied to other health care organizations just as well. If you have five hospitals, a system like we have with the NCPS can help all five learn from each other. If you have five departments, a smaller system can help you bring all of your experience together."

Two reporting systems make up the backbone of the NCPS. One is internal, essentially a root-cause analysis system with VA software designed to support it. Hospitals are encouraged to conduct team-based analyses of adverse events or close calls. The findings of the root-cause analyses are forwarded to the NCPS headquarters, where Lee and the rest of the patient safety experts can watch for system-level vulnerabilities. A patient safety risk at one VA hospital could represent a risk present in all the VA hospitals, so the NCPS team can act to eliminate that risk across the board.

The second reporting system is called the Patient Safety Reporting System (PSRS) and is patterned after the aviation industry's safety reporting system. In that industry, anyone working with aircraft is encouraged to report observations about accidents or close calls so that the Federal Aviation Administration or the National Transportation Safety Board can spot systemwide problems. In the VA system, all employees are encouraged to report their patient safety concerns to the PSRS database, which is managed by the National Aeronautics and Space Administration (NASA). Employees are encouraged to report in narrative form explaining what happened, why they think it happened, and what solution might keep it from happening again. The analysts at NASA act as impartial middlemen, stripping the patient safety reports of any identifying information before determining what lessons might be gleaned from them. NASA then reports to the NCPS about lessons that might be applied throughout the VA system.

"The anonymity is a big factor in getting good information through the PSRS," Lee says. "We think of this system as sort of a safety valve to get people to report their concerns. Reporting has increased astronomically, particularly with close calls, which is something people didn't used to talk about."

NCPS also provides training and news updates to the VA hospitals, sending alerts that notify providers of recurrent problems with a particular medical device, for instance. Much of the training focuses on human engineering, trying to design systems so that they take the burden of memory and vigilance off of the individual provider and allow it to focus on decision making. In addition, the NCPS offers specific tools such as its "Triage Cards," a set of small laminated cards that one can use to prompt questions after an adverse event or close call. In the "Human Factors — Fatigue / Scheduling" section, the questions include these: Were the levels of vibration, noise, or other environmental conditions appropriate? Did scheduling allow personnel to have adequate sleep? Was the environment free of distractions? **(See p. 3 for more categories of the triage questions.)**

Many of the tools used by the NCPS can be found on the group's web site at www.patientsafety.gov.

"We have had lots of non-VA folks take our training. Health care providers are more than welcome to look at our tools and techniques,

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much of which is available on our web site," Lee says. "Many things like the health care modes effects analysis are completely transferable to your own organization. Just like we've borrowed from other fields like aviation, we're totally happy if people look at our work and adapt it for themselves."

That offer is echoed by **James Bagian**, MD, PE, director of the National Center for Patient Safety. Bagian works extensively with non-VA health care providers interested in adopting the NCPS systems, and he says the private sector can adopt the tools with little difficulty. Health care providers in Australia, Sweden, Denmark, and Japan have adopted the NCPS systems with success, he says. **(A related VA program focusing on surgical quality improvement might be available to the private sector within a year. See the story on p. 4 for details.)**

"The NCPS puts a lot of good patient safety ideas into a framework," he says. "Rather than just the theoretical, saying it would be nice if we could do this, it leads you through a system that helps you put those ideas into action. You can have lots of bells and whistles, but if you don't show people how to actually use something like the root-cause analysis to get useful information, you're just wasting everyone's time."

A major component of the NCPS philosophy is the focus on close calls, Bagian says. It used to be that no one ever reported or analyzed close calls, and only in the past few years has that changed somewhat. But even now, he says, providers do not study close calls thoroughly enough.

"When I ask if you do a root-cause analysis for a close call just the same as if you had killed someone, almost nobody says yes," Bagian says. "If you're just reporting that close call and not acting on it, you're not doing any good. You have to go after it and study it carefully if you want to learn anything from it." ■

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There also are links to every article published in *Healthcare Risk Management*'s *Patient Safety Quarterly* and *Patient Safety Alert* supplements from January 1999 to present.

HRM's 2001 salary survey also is available in its entirety.

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. ■

These tools show cause of close calls, adverse events

These are the categories of triage questions used by the Veterans Affairs' National Center for Patient Safety (NCPS) to help health care providers determine what really led to an adverse event or close call. The NCPS training tools provide specific questions you can ask in each category. For more information on this tool and others used by the NCPS, see the NCPS web site at www.patientsafety.gov.

- **Human Factors/Communication:** Questions that help assess issues related to communication, flow of information, and availability of information as needed. These questions also reveal the importance of communication in use of equipment and application of policy and procedure, unintended barriers to communication, and the organization's culture with regard to sharing information.

For example: A patient without an identification bracelet is administered medication based on the nurse's memory of the patient's identity. The hospital has a policy requiring that wrist bracelets be checked before every dose of medicine, but because the dose is overdue, the nurse delivers the medicine without confirming the patient's identity.

- **Human Factors/Training:** Questions that help assess issues related to routine job training, special training, and continuing education; including the timing of that training. Training issues may concern application of approved procedures, correct use of equipment, or appropriate manipulation of protective barriers. These questions also focus attention on the interfaces between people, workspace, and equipment.

For example: A new group of physicians in residency training arrived this week to start a rotation

at your facility. A lab error occurs when the wrong form is submitted with a blood vial.

• **Human Factors Fatigue/Scheduling:** Questions that weigh the influence of stress and fatigue that may result from change, scheduling and staffing issues, sleep deprivation, or environmental distractions such as noise. These questions also evaluate relationships to training issues, equipment use, management concern and involvement.

For example: Renovation is taking place in adjoining space, making it difficult for staff to converse and to hear patient call alarms.

• **Environment/Equipment:** Questions to help evaluate factors related to use and location of equipment; fire protection and disaster drills; codes, specifications, and regulations; the general suitability of the environment; and the possibility of recovery after an error has occurred. These questions show that what appears to be equipment failure may relate to human factors issues, policy and procedure questions, and training needs.

For example: Housekeeping staff are thorough in their care of bedding material. While the patient is in physical therapy, they flip a patient's air-filled anti-decubitis mattress inadvertently, reversing the correct alignment of the air chambers.

• **Rules/Policies/Procedures:** Questions that help assess the existence and ready accessibility of directives including technical information for assessing risk, mechanisms for feedback on key processes, effective interventions developed after previous events, compliance with national policies, the usefulness of and incentives for compliance with codes, standards, and regulations. The qualifications of the facility and employees for the level of care provided; orientation and training for compliance with safety and security measures including handling of hazardous material and emergency preparedness; and the availability of information to all part-time, temporary, or voluntary workers and students also are considered.

For example: A nurse hired for the day through the local registry is not familiar with your facility's policy against unlocking the door to the balcony in order to smoke while taking a break.

• **Barriers:** Barriers protect people and property from adverse events. Questions assess barrier strength, fault tolerance, function and interaction / relationship to Rules / Policies / Procedures and Environment / Equipment.

For example: A negative pressure room for an infectious patient is a barrier to the spread of the disease. If the ventilation in the room stops working, a critical barrier has been compromised. ■

VA program for surgical quality called a success

The Department of Veterans Affairs' (VA) patient safety system can be mined for strategies that could work well in your own organization, but another successful program from the VA could be directly available to all hospitals within a year. The VA's National Surgical Quality Improvement Program (NSQIP) is an outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care, and its leaders say it has been a tremendous success. The NSQIP incorporates 128 Veterans Affairs Medical Centers (VAMCs) and 14 beta sites in the private sector, but the VA is trying to set up a system in which NSQIP could include any health care provider in the United States.

The VA is working with the American College of Surgeons (ACS) to turn the NSQIP into a nonprofit agency under the oversight of the VA and ACS, says **Shukri Khuri**, MD, chief of surgical service at the VA Boston Healthcare System and professor of surgery at Harvard Medical School. The groups must first obtain Congressional authority to make the VA program available to others, but Khuri says he is confident that the plan will come to fruition. "This could all happen within a year if things go well. We fully expect to see NSQIP made available to everyone very soon," he says.

Research for the system began in 1991 as a way to comparatively measure the quality of surgical care in 133 VA hospitals. A two-year study developed and validated models for risk adjustment of 30-day morbidity and 30-day mortality after major surgery in eight noncardiac surgical specialties, and then similar models were developed for cardiac surgery by the VA's Continuous Improvement in Cardiac Surgery Program (CICSP). The NSQIP was established in 1994 in all medical centers performing major surgery. An NSQIP nurse at each center oversees the prospective collection of data and their electronic transmission for analysis at one of two data-coordinating centers, says **Jonathan Perlin**, MD, PhD, deputy undersecretary of health at the VA.

Feedback to the providers and managers is aimed at achieving continuous quality improvement. It consists of comparative, site-specific, and outcome-based annual reports; periodic assessment of performance; self-assessment tools; structured site visits; and dissemination of best practices. The

NSQIP also provides an infrastructure for the VA investigators to query the database and produce scientific presentations and publications. Since the inception of the NSQIP data collection process, the 30-day postoperative mortality after major surgery in the VA has decreased by 27%, and the 30-day morbidity by 45%.

An executive committee reviews the information quarterly and then each year generates the annual NSQIP report. This report is a gold mine of quality improvement data, Khuri says. Each VA medical center receives a copy of the report, showing the surgical outcomes data for each hospital in the system. All of the data are blinded, except for the recipient hospital's own data. That way, the chief of surgery and the quality improvement director can compare the hospital's performance to the overall quality measures in the VA system.

Site visits may result from NSQIP data, either to help a hospital determine why its surgical outcomes are unusually high or to see how an especially good program achieved such good results. The annual report in January includes lists of problems that were identified in the high outliers and best practices that were found in the low outliers. All VA hospitals can benefit from the list of potential problems and best practices, even if their own hospitals' quality ratings are average, Perlin says.

In addition to the annual reports, the NSQIP is amassing a large database on surgical outcomes. The database now has information on more than 1 million surgical cases from the past 10 years. Initial efforts at expanding the NSQIP beyond the VA have been encouraging, Khuri and Perlin say. Three medical centers initially tried the system, with good results, and now the trial has been extended to a total of 14 hospitals across the country. ■

Reader Question

Crash carts must be locked; beware of delays involved

Question: I understand that the Joint Commission on Accreditation of Healthcare Organizations requires that crash carts be locked when not in use during an emergency, but how must they be locked? It seems that some obvious solutions wouldn't be practical because they might delay access to the crash cart. Is it OK to just use some sort of safety seal that reveals tampering?

Answer: The Joint Commission does require that crash carts be locked when not in use, but the accrediting body also acknowledges that a typical lock could delay access in an emergency. Other types of locks can suffice, according to Joint Commission spokeswoman **Charlene Hill**. For more information, she directs *Healthcare Risk Management* readers to the Joint Commission's web site at www.jcaho.org, where you will find the following information.

In short, the Joint Commission has recently changed its attitude about how to lock crash carts, allowing breakaway plastic locks that many providers have found are the easiest way to secure the carts. Standard TX.3.5.5 requires that any emergency medication, including those kept on crash carts, be made "secure" between emergencies. Though providers always should strive to keep dangerous medications locked away, the standard actually is intended to ensure that life-saving medications are on the crash cart whenever it is needed. The standard is directed at crash carts ready for emergency use; the Joint Commission specifically states that it is not concerned about the security of used crash carts on their way to the pharmacy for medication refills, as long as that crash cart is considered out of commission and not to be used for emergencies until refilled. As soon as it is refilled, it must be secured. All schedule II drugs (narcotics) must be secured under lock and key, so if you have narcotics on your crash cart, that obligates you to use a lock and key. But the Joint Commission advises against keeping narcotics on the crash cart, partly for that reason.

The Joint Commission specifies that the cart can be secured by using at least one of three methods:

- Use a breakaway plastic lock or a heat-sealed plastic wrap. The Joint Commission had previously said those methods were not acceptable, but the interpretation was changed in 2002 to state clearly that these methods may be used.
- Store the crash cart in a locked room.
- Store the crash cart in an area that is under *constant* surveillance or supervision, such as behind the nursing station.

In addition to ensuring that the crash cart medications have not been tampered with, the breakaway plastic locks or plastic wrap can be used to indicate that the contents are not past their expiration date. If a seal is used and the expiration date is

noted, the Joint Commission does not require you to check the contents of the cart until that seal is broken or the marked expiration date is reached. Some providers use a system in which they use different color breakaway locks, such as one to indicate the crash cart is complete and ready to use, and another to indicate that it is in need of restocking. The Joint Commission approves such systems. ■

Ten steps can improve a risk manager's image

Health care risk managers have suffered from an image problem for too long, and 10 simple steps can greatly improve the way everyone else in your organization thinks of you, says **Geri Amori**, PhD, ARM, FASHRM, president of Communicating HealthCare, a risk management consulting firm in Shelby, VT, and past president of the American Society for Healthcare Risk Management (ASHRM). She says a risk manager's image is about much more than just your self-esteem; your image can greatly affect how well you are able to do your job.

Amori presented her advice at the recent ASHRM conference in Seattle. She tells *Healthcare Risk Management* that her presentation sprung from an experience she had in which she was speaking at another gathering of health care professionals, and three of the speakers before her made disparaging comments about risk managers. Amori sat quietly as they slammed risk managers for playing little or no role in patient safety, urging providers not to talk to the patient, and being more worried about discovery than learning from mistakes.

"When it was my turn to speak, I got up and said, 'My name is Geri Amori, and I am a risk manager,'" she says. "It was like I had to admit this terrible thing. I made light of it at the time, but I realized there really is an image problem, and it's not new."

Amori researched the issue and found that much of the negative image is based on misconceptions about risk management, and some is based at least loosely in fact. In the past, risk managers often were taught that their main role was to protect the assets of the organization, and one of the main cautions passed on from insurers was, "Don't admit anything."

"The insurer actually meant that we shouldn't admit any liability for the insurer; but over time, we became sort of paranoid about being truthful and honest," she says. "We have to admit this. We developed a tarnished image, and we became low on the food chain, considered the people who deal with bad things after they happen."

That image can cripple a risk manager's ability to be proactive and to work at a high level within the health care organization, Amori says. If you carry that negative image with you everywhere you go, it will color every interaction with others even when you actually try to act counter to that image. She points out that once people have a certain image of you, they will look for anything in your words and actions to confirm that image.

"If they think risk managers are just naysayers, they'll look for information that confirms that and they'll find it even if you're trying your best to be positive and helpful," she says. "You've got to deal with the negative image and get it out of the way so you can get on with your real work."

Amori summarizes the image problem by suggesting that many risk managers are seen as secretive, focused on data and not useful information, and not important in improving patient safety. The good news, she says, is that a health care risk manager can improve his or her image in 10 steps without spending an extra nickel. These are the 10 steps she recommends:

1. Don't hide behind the "legal" excuses. Too many risk managers get used to saying "It's not legal. You can't do that." Amori says it is better to know the law but respect that it is an imperfect reflection of societal mores and responsibilities. Flexibility is always needed.

"Don't be known as someone who comes out first with, 'We can't do that because of the law,'" she says. "Seek to do what is effective and ethical and right. Be known for doing that."

2. Use numbers effectively. Data are important for a risk manager, but avoid being known as someone who just spouts numbers as an excuse for saying no or demanding better performance. Remember that data can lie. Use numbers carefully as part of your narrative rather than the whole explanation.

3. Be informed. Others in the organization need to see you as a resource. That means you must be very well informed. Reading professional publications and participating in on-line discussion groups can be excellent methods for staying current.

4. Become an indispensable resource to others. Once you are well informed, offer that information to others. Be the person whom everyone

comes to for anything risk-related. Send information to people when you find it might be useful, and offer to speak, teach, and facilitate.

5. Be willing to unlearn. Unlearn the old way of doing things when necessary. Unlearn how you think of assets. Assets can be money, as in the old definition, but they also can be patients and staff.

6. Develop your power. A certain amount of power comes from your title, but your "referent power" is more important. That refers to the power that draws people to you and makes them want to be like you. Model nonpunitive attitudes, systems thinking, ethical mindsets, customer service, and the belief that you protect the organization best when you protect patients, staff, and visitors. If you become a leader that others admire because you have the right attitude and actually model the right behaviors, you develop a power within the organization that will be useful in many ways.

7. Be proactive. Always start with what you *can* do, not what you can't. Whenever a colleague comes to ask you about the risk management implications of an idea or a goal, resist the urge to say "it can't be done because . . ." If a clinician says he wants to obtain a drug that is useful in England, don't say, "We can't import drugs from foreign countries." It is much more productive to start out with the ideal goal and work backwards: "So you want to use this drug because it is effective in England. OK, let's see how we can make that happen."

You might still run into roadblocks, but the way you approach the idea can greatly influence how the other person sees you. They can walk away thinking you were a partner in trying to make it happen, or you can be seen as the person who killed their idea. However, don't be surprised if this helpful, collegial approach sometimes backfires.

"People often *want* us to be the naysayers," Amori says. "They want us to quash the whole idea so they don't have to work on it anymore but they can blame it on us. Sometimes you'll offer a helpful way to make their idea happen, and they'll suddenly turn the tables and find reasons to say no. It's still the right thing to do, because you don't want to be the company bad guy even if that would make some people more comfortable."

8. Teach and coach. Don't keep your thoughts to yourself. Think out loud, weigh the pros and cons, and ask others what they think might work. Every time you discuss a risk management issue with another person, you're training a junior risk manager. The biggest sign of success is when someone calls you just to confirm that they've made the right decision. Make sure that person is rewarded for taking the right approach.

9. Articulate your value and your values. Speak up at every opportunity to make sure people know your attitude and your approach to risk management. Don't let them assume you're like every other risk manager. Write articles for your in-house newsletter, and write articles for your local newspaper explaining how your policies help patients. Advertise your success in patient safety.

10. Take responsibility for how you present yourself. Ultimately, your image is your own responsibility, Amori says. Consider actually marketing your risk management department with a new logo or motto. Do something fun to promote yourself or your department throughout the organization.

To start, Amori suggests you do an assessment of your risk management department. Look at how others see yourself, your office, and your staff. Find out what people are saying about your services.

"This is so important to determining where we will be as risk managers in five years or 10 years," she says. "If we don't lose the negative image, we'll be pushed aside to a lesser position, and a patient safety leader will take over." ■

ECRI issues alert on some thoracic catheters

An independent health care safety watchdog has issued a critical alert to hospitals regarding a potential threat to patient safety caused by some thoracic catheters in Pharmaseal Thoracentesis Trays distributed by McGaw Park, IL-based Allegiance Healthcare Corp.

The catheters, which are used to aspirate fluid from the lungs, may be brittle and can fragment in the patient's pleural space, according to ECRI, a medical device research organization in Plymouth Meeting, PA. Because the catheter is exposed only after it is inserted into the patient, the health care provider cannot examine the flexibility or strength of the catheter before insertion, complicating efforts to spot the defective products, says **Mark E. Bruley**, vice president for accident and forensic investigation at ECRI.

Possible complications resulting from fragmented catheters are foreign-body reactions,

infection, and the need for surgery to remove the fragments. ECRI's Accident and Forensic Investigation Group discovered the problem when a member hospital requested an investigation following the surgical removal of a catheter fragment after aspiration of a patient's parietal cavity. ECRI's team of investigators determined that three more catheters from trays with the same lot number L1N094, were found to be broken or brittle. Bruley says another instance has been reported to the U.S. Food and Drug Administration with the same Pharmaseal thoracentesis catheters but with lot number L1K058.

"The problem may be more extensive than those particular lots," he says. "We'll know more once Allegiance Healthcare has conducted a wider investigation of the catheters." ■

Bar codes help reduce some medication errors

A study at the University of Wisconsin (UW) Hospital and Clinics in Madison shows the hospital has reduced medication administration errors by 87% with the use of a hand-held wireless bar code scanner.

By employing a hand-held bar code scanner at the bedside, the hospital strives to ensure that the five key aspects of medication administration are correct, thereby reducing medication errors. The results of a recent study show dramatic improvements in medication administration and documentation accuracy, based on a direct observational study of caregivers by trained observers, says **Steve Rough**, PharmD, UW Hospital's director of pharmacy service organization. Of the errors observed in the pre-bar code phase of the study, 44% involved medications given at the wrong time; 21% involved the wrong dose of a medication; 15% resulted from omission of a medication; 15% used the wrong dosage form (for example, injection vs. medication taken by mouth); and 5% involved use of an incorrect drug.

Although the vast majority of these errors don't result in negative consequences, hospital proponents say the value of hand-held bar code scanners is in eliminating the small number of errors that can cause serious patient harm. Following implementation of the new technology, the prevalence of wrong dose, wrong dosage form, and omission errors were observed to decrease by more than 90%, while medications given at the wrong time dropped by more than 75%. UW chose a hand-held bar code scanner called Admin-Rx, manufactured by McKesson Automation Inc.

"Nurses have come to appreciate Admin-Rx's ability to avert errors," Rough says. "We know that approximately 3.2% of doses scanned generate some sort of warning message to help nurses avert potential errors."

The device is currently used on 11 of the hospital's 22 inpatient units. Based on the immediate benefits observed in the study, Rough says implementation is being accelerated with the goal of having it operational hospitalwide by April 2003. **Tom Thielke**, PharmD, UW Hospital director of pharmacy, says the initial results suggest that the hand-held scanners are a good way to reduce common types of medication errors.

"These results are very enlightening, and not just for our hospital," Thielke says. "The system virtually eliminates human errors in administering and documenting medications. When you see how many medication errors are averted by the system, you realize how crucial point-of-care bar code technology is for enhancing the medication administration process."

The Admin-Rx product is a hand-held computer that displays, receives, and charts real-time patient and medication information. Before giving a patient medication, nurses scan a bar code on their identification badge, a second bar code on the medication and a third on the patient's wristband. If there are any discrepancies regarding patient, dose, method, or time, the device alerts the nurse. If everything is verified, the nurse gives the patient the medication and documents it via the unit, which logs a historical record of all medications given to the patient.

The McKesson product is part of a larger system of hospital pharmacy automation products**. Sue Lehnherr**, RN, UW Hospital's nursing director, says the reduction in errors isn't the only benefit from the bar code system. The hand-held units produce dramatic improvements in medication administration record documentation accuracy, with post-implementation accuracy exceeding 99%. Additionally, pre- and post-use satisfaction surveys have demonstrated a 42% overall improvement in nurse satisfaction with the medication administration and documentation process, and a 64% improvement in nurse perception of system efficiency and safety.

"These results can be attributed to the nurses having clear, real-time patient information at

their fingertips, a reliable system that alerts the caregiver to late doses or medication omissions, and consolidation of medication verification, administration and documentation into a single step at the point of care," Rough says.

Nurses welcome the technology after some initial trepidation, she says, and patients also can feel more secure about receiving the right medication when they see the nurse check all the bar codes with the scanner. ■

Pennsylvania hospitals still fighting insurance crisis

Pennsylvania's hospitals continue to struggle with the medical professional liability insurance crisis, according to a new member survey conducted by The Hospital & Healthsystem Association of Pennsylvania (HAP).

The survey found that insurance costs are continuing to rise, critical services are being closed, medical residents are fleeing Pennsylvania, and hospitals are having increasing difficulty filling physician openings, says **Carolyn F. Scanlan**, president and chief executive officer of HAP.

"This survey is a snapshot of the crisis as it existed in October," she says. "A look at the headlines over the past month tells us that the situation continues to deteriorate."

The HAP survey collected data from 150 hospitals and health systems in Pennsylvania. Among the survey's findings, nearly two-thirds of hospitals report that some physicians are retiring early, curtailing practices, or relocating as a result of increasing liability costs. One-third of hospitals report closing, temporarily closing, or otherwise limiting the volume of services available due to physicians leaving or because of rising liability insurance costs. More than 75 hospital services have been closed over the past 12 months. The most severely impacted specialty services are obstetrics, orthopedics, general surgery, and neurosurgery. More than half of hospitals report having difficulty recruiting physicians to fill vacant positions because of rising liability insurance costs.

Nearly two-thirds of medical teaching programs report that their medical residents are choosing to continue their practices outside Pennsylvania. Half of hospitals report that members of their active medical staffs were denied coverage by commercial insurers and were forced to find alternative coverage in the past 12 months. The total cost of medical liability insurance coverage for Pennsylvania's hospitals has increased 215% over the past 12 months, and 25% of hospitals reported premium increases exceeding 300%.

"We have made significant progress this year with the enactment of three laws that provide structural changes to the state's insurance and tort systems," Scanlan says. "But the job is not finished. Our hospitals and physicians still need short-term financial relief, and we will continue to advocate for reforms that fully protect injured patients' rights to be fully compensated for their economic losses while placing reasonable limits on the excessive noneconomic damage awards that threaten to cripple our health care delivery system."

Steps to short-term relief

Pennsylvania Gov. Mark Schweiker recently took steps to provide short-term, medical malpractice insurance relief for health care providers. Schweiker directed insurance commissioner Diane Koken to request that private medical-malpractice insurers postpone the collection of the Medical Care Availability and Reduction of Error fund assessment from health care providers until April 30, 2003. The insurance department has also been directed by Schweiker to ask the Pennsylvania Professional Liability Joint Underwriting Association, commonly known as the insurer of last resort, or JUA, to investigate whether it can accept monthly premium payments for medical malpractice insurance coverage. Premiums are currently paid every six months.

Pennsylvania health secretary Robert S. Zimmerman Jr. also announced that the Health Department has contracted with The Hospital and Healthsystems Association of Pennsylvania to distribute $3.3 million of federal funds to Pennsylvania's acute-care general hospitals with emergency departments to assist in emergency preparedness planning and response. A total of 200 hospitals will receive a $5,000 base amount plus 50 cents for every emergency department visit that was reported to the Department of Health in each hospital's most recent annual survey. A recent assessment by the state found that in 2002, Pennsylvania hospitals spent $8.3 million on emergency preparedness activities. In 2003, hospitals plan to spend $24.6 million. ■

Tenet: When is a physician an independent contractor?

Tenet Healthcare Corporation's claim that it considers Redding, CA, physicians as independent contractors, as opposed to hospital employees, will do nothing to lessen the company's exposure from a rapidly growing list of lawsuits filed by former cardiac surgery patients at Tenet's two Redding-area hospitals, according to one of the nation's leading mass torts attorneys.

Michael Hackard, JD, who recently filed suit on behalf of a former patient of Chae Moon, MD, says California law holds hospitals accountable for the conduct of physicians practicing in their facilities, regardless of whether those physicians bill patients on their own, or through the hospital. He made his comments in light of Tenet Chairman and Chief Executive Jeffery C. Barbakow's efforts to reassure Tenet shareholders while confirming that the Securities and Exchange Commission had launched an informal investigation. The investigation will focus on allegations that two Tenet hospitals in Redding where Moon and Fidel Realyvasquez, MD, performed surgeries allowed the physicians to push patients into unnecessary cardiac bypass operations, resulting in excessive charges to the Medicare system.

"If Mr. Barbakow truly wants to promptly resolve issues, he might start with the current state of California law. California law is clear and settled — a hospital owes a general duty to insure the competency of its medical staff and to evaluate the quality of medical treatment rendered on its premises," Hackard says. "If Tenet had been providing the same kind of oversight to its medical staff and quality of medical treatment that it paid to its bottom line, a lot of Tenet patients wouldn't have had unnecessary surgery and all the potentially lethal complications that go with it."

He says it is not relevant that Moon and Realyvasquez billed for their own services and weren't designated employees of the hospital. What is relevant is that the two doctors practiced in Tenet hospitals, where according to an FBI affidavit, as many as half of the heart surgeries and tests performed by the pair were "unnecessary by commonly held medical standards." The same affidavit also contains allegations that an estimated 25% of these procedures were performed on patients who had no serious heart problems. Hackard filed the case on behalf of Carl L. Roberts, a 75-year old northern California man treated by Moon. Despite the results of a stress test that showed Roberts was healthy, Hackard says, Moon informed him that he needed a four-way bypass, which he performed the same day at Tenet's Redding Medical Center.

"Tenet's woes won't be overcome by an independent contractor theory," Hackard says. "California law, patients' expectations, and ethical practice demand a more reasoned approach. Tenet is liable for negligent conduct of independent physicians and surgeons who, as members of the hospital staff, avail themselves of the hospital facilities, but who are neither employees nor agents of the hospital." ■

Most hospitals ill-prepared to deal with bioterrorism

In spite of heightened awareness of bioterrorism, and the recent terrorist threat to hospitals in key U.S. cities, 70% of hospital emergency department (ED) managers polled at a recent conference revealed that their hospitals are not prepared to deal with bioterrorist-related medical emergencies. More than 90% of poll respondents cited patient violence as the greatest threat to ED personnel, says **Jeanne McGrayne**, RN, MSN, director of VHA's sonsulting services.

"This is the second consecutive year that conference attendees have reported patient violence as the No. 1 threat to personal safety in the emergency departments, even after the Sept. 11 terrorist attacks and recent threats against hospitals," McGrayne says. "It's clear that despite concerns about bioterrorism, the major threat to personnel continues to be violence in the emergency department."

Leaders in emergency medicine from 73 health care organizations nationwide gathered recently for VHA Inc.'s Emergency Department Conference in Chicago. Attendees at the fourth annual event explored trends in emergency department care and learned how to improve patient care and customer service in their organizations. Of the more than 100 professionals in attendance, 74 responded to the poll. The results of the poll revealed that 66% of respondents saw the risk of contracting hepatitis C as the second-biggest threat to ED personnel. Thirty-two percent of those polled said the lack of acute and critical care beds to which ED patients can be transferred is the primary factor for

overcrowding in EDs. Other reasons for overcrowding included work force and staffing issues (the primary factor for 24% of respondents) and uninsured patients using the ED for primary care (19%).

"Issues that other areas of the hospital are wrestling with are having tremendous impact on the ability to deliver care efficiently in the emergency department," McGrayne says. "Health care organizations need to address these issues before current ED problems can ultimately be resolved. The longer hospitals wait to identify resolutions, the worse hospital and ED conditions may get." ■

Study: 10% of children get wrong dosages in the ED

Ten percent of children treated in the emergency department (ED) may get the wrong dose of medicine or be administered medication at the incorrect frequency, according to a new study.

The highest risk was for children seen between 4 a.m. and 8 a.m., children with severe disease, and kids seen on weekends. Children in those groups were between 1.5 and 2.5 times more likely to experience a medication prescribing error, according to the study led by **Eran Kozer**, MD, at the Hospital for Sick Children in Toronto. Errors also were more likely when a medical resident or intern had ordered the medication (*Pediatrics* 2002; 110:737-742).

Kozer and colleagues report that between 44,000 and 98,000 people die each year in the United States as a result of medical errors. And prescribing errors, they note, occur most frequently in pediatric and EDs. The researchers evaluated medical records for 1,532 children treated in the ED of a pediatric hospital.

Two pediatricians independently decided whether a medication error had occurred and gave errors a numerical severity score.

Prescribing errors were identified in 10.1% of the charts. The most common types of prescribing errors were dosing errors, followed by drugs given with incorrect frequency. Kids seen between 4 a.m. and 8 a.m., and kids with severe disease were roughly 2.5 times more likely to have a prescribing error, the authors report. Those who went to the ED on a weekend were nearly 1.5 times likely to have a prescribing error.

Another study indicates that physicians sometimes make mistakes when noting the physical form a prescription medication should take — such as a tablet, liquid, or cream. However, these types of errors, known as dosage form errors, occur relatively often for hospitalized patients, and the rate at which they take place appears to have increased during the past five years (*J Gen Int Med* 2002; 17:579-587).

Inside the study

The results are based on a review of dosage form errors at one hospital during that five-year period. Timothy S. Lesar, MD, of the Albany Medical Center in Albany, NY, was the lead author of a study that found the rate of these errors increased from slightly higher than 0.6 for each 100 patients in 1996 to 1.3 per 100 patients in 2000. The findings are based on a review of all prescription errors stemming from mistakes in how the medication should be given.

During the study period at the 631-bed hospital, a total of 1,115 errors involving dosage form took place, 52 of which were considered to be potentially fatal or have serious effects. The most common types of errors involved those in which the prescriber did not specify that the drug needed to be given to the patient in a controlled release form, which ensures that the medication will exert its effects in the body over a protracted period.

Three of the instances of medication order errors, if not corrected, were considered to be potentially fatal or severe, while another 49 errors were classified as serious. More than half of the errors involved cardiovascular drugs. ■

Nursing shortage affects patient postsurgery survival

The ongoing nursing shortage can have a direct effect on a patient's survival after surgery, according to a new study.

Linda H. Aiken, MD, from the University of Pennsylvania in Philadelphia, surveyed more than 10,000 staff nurses and reviewed medical data on more than 230,000 general, orthopedic, and vascular surgery patients, all discharged from one of 168 Pennsylvania hospitals over nearly two years (*JAMA* 2002; 288:1,987-1,993).

Aiken reports that the patient-to-nurse ratio ranged from less than 4-to-1 to more than 8-to-1, and the research revealed a correlation between a higher patient-to-nurse ratio and an increased risk of patient death. Each additional patient per nurse was associated with a 7% increase in the risk of dying within 30 days of surgery, she says. ■

CE Questions

For more information about the continuing education program, contact customer service at (800) 688-2421 or by e-mail, customerservice@ahcpub.com.

1. Veterans Affairs employees are encouraged to report observations about accidents or close calls in a narrative form explaining:
A. what happened
B. why they think it happened
C. a possible solution
D. all of the above

2. Identify one of the methods that the Joint Commission on Accreditation of Healthcare Organizations accepts for securing crash carts:
A. a typical lock
B. plastic breakaway locks
C. cotter pins
D. chock blocks

3. In a recent study of dosage problems with children in the ED, which was not found to be one of the highest risk factors:
A. children seen between 4 a.m. and 8 a.m.
B. children with a severe disease
C. children seen in the late evening
D. children seen on weekends

4. Select the reason given in a recent study for the high level of nurse burnout:
A. the highest number of patients per nurse
B. the lowest number of patients per nurse
C. low pay
D. turnover

Answers: 1. D; 2. B; 3. C; 4. A.

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. ■

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

Hot water for tea burns a patient, costing a hospital $100,000

By **Jan. J. Gorrie**, Esq.
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Tampa, FL

News: An elderly man was admitted to a hospital for observation. The following morning, the patient spilled hot tea in his lap during breakfast, resulting in burns severe enough to require surgical repair. The patient brought suit against the provider, which was settled for $100,000 prior to trial.

Background: In August 1999, the 87-year-old plaintiff had coronary artery bypass surgery, followed by a complicated and lengthy recovery. His treating physician noted that "his mental faculties were definitely declining, and as his progress was monitored, it was also noted that he was taking numerous medications that were 'probably excessive.'"

On Oct. 1, 2000, he developed constant minimal substernal chest pain that radiated to his left arm, and his son transported him to the hospital in the early morning hours. He was examined in the emergency department and found to be essentially pain-free. His private physician admitted him to the hospital for observation and further testing. Further tests failed to show any evidence of an acute injury.

The next morning, a nurse brought him a breakfast tray with very hot water for tea. He claimed that, while unattended, he inadvertently spilled the tea onto his lap scalding his left thigh, perineum (the space between the anus and the scrotum), and his right posterior thigh.

The patient's burns were managed conservatively at the hospital with antibacterial dressings. A plastic surgeon's examination revealed deep and partial thickness burns to the left thigh, measuring 22 cm by 18 cm; to the right posterior thigh, which were 12 cm by 6 cm; and to the shaft of the penis and scrotal area and perineum, measuring 4 cm by 4 cm. He underwent whirlpool treatments, but the wounds failed to respond. On Oct. 13, 2000, the plastic surgeon performed a tangential excision of full-thickness skin burn of the left anterior thigh, right posterior thigh, and perineum with split thickness graft under general anesthesia.

The plaintiff maintained that his treating physician failed to inform the hospital of his need to be carefully observed due to his compromised mental faculties and that the hospital was negligent in failing to monitor him and serving him hot liquid while by himself. Both hospital and physician claimed they were unaware of any condition of limitation that precluded serving him hot liquid.

Prior to trial, the action was settled for $100,000.

What this means to you: We learned from a famous fast-food hot coffee spill just how much of a potential risk hot water can be. The facts in that case are somewhat different than in this scenario — in the fast-food incident, the person was fully clothed and apparently had no limitations of movement.

"This was an elderly gentleman, 87 years old, which brings with it some of the physical changes that come with the natural process of aging, such as the loss of adipose tissue and the fragility of the skin. With the altered mental state and advanced age, it is probable that he had slower reactions as well. With this patient's current physical and mental status, the nurse's admission intake assessment should have provoked nursing interventions to address appropriate care and preventive nursing measures focused on those observations," notes **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, CHt, director of risk management services at the Miami Jewish Home and Hospital for the Aged.

Hospital and other licensing regulations govern the temperature of the potable water coming out of the facets in these facilities to prevent the potential for inadvertent or accidental burning/scalding patients. Regulations also cover the temperatures considered satisfactory for the safe and sanitary storage, preparation, and distribution of food. Generally, storage of food is recommended to be below 41° F or above 140° F to reduce the risk of foodborne pathogens — except during periods of preparation and service.

"By regulation, the temperature of potable water should be no greater than 120° F, and most facilities keep water in the 108°-118° F range. And the water for the gentleman's tea could have just as easily been soup," Kicklighter says. "At this point, we don't know if this patient was capable of feeding himself or if he needed assistance. Neither do we know if the nurse prepared the tray for the patient or just delivered it and left the patient to fend for himself. At the time of admission or at least in conjunction with the first meal, time should be taken to assess the patient abilities and to at least assist by setting up their meal tray, which would include pouring coffee or tea, if served in a teapot. Similarly, milk is usually served in a carton, and many patients cannot open them easily by themselves.

"In this instance, the water for the tea was obviously TOO hot, as evidenced by the location and severity of the burns sustained by this patient. It seems that the severity of the burn was also aggravated by the fact that the hot water fell on both sides of the right thigh and between the patient's legs and pooled there, causing more of a burn than if the patient had more agility and mobility to be able to move and get out to the pool of hot water," Kicklighter says.

"What this means to the risk manager is that steps should be taken to work with the dietary department and the nursing unit directors/managers to determine where the water and coffee furnished with the meals is generated. If it is put on the meal trays by the dietary personnel when preparing the trays, that is one issue. If it is placed on the trays when they are served, then the process on the unit needs to be evaluated. Each alternative then calls for a set of preventive interventions, but in any case a threshold temperature for hot coffee, tea water, soup, and other hot liquids for consumption should be established. Food thermometers should be located on each unit and staff shown how to use them to assure the liquid isn't too hot," recommends Kicklighter.

"Unfortunately for this patient, it was not simply a matter of serving him hot liquids — it was the serving of liquids that were much too hot. And both he and the facility were burned," concludes Kicklighter.

Reference

• *Anonymous Burn Patient v. Anonymous Hospital and Physicians,* Los Angeles County (CA) Superior Court. Abram C. Zukor, Zukor & Nelson, Beverly Hills, CA, for the plaintiff. ■

Scalding hot water enema leads to $1.65M verdict

News: An elderly woman with end-stage Alzheimer's disease was admitted to the hospital for pneumonia. On the third day of her stay, she was given an enema containing scalding hot water, which caused first- and second-degree burns. The burns were not discovered until nine hours after the incident, and 20 hours had passed before she was given any pain medication. Over the next few weeks, her health deteriorated and she died. After several failed attempts to mediate the case, a $1.65 million settlement was reached with the hospital. The settlement also included a public apology by the hospital in the local newspaper.

Background: The decedent, an elderly woman in her 80s and a mother of nine children, was admitted to a hospital for pneumonia. On her third night at the hospital a newly hired nurse's aide who still was in training, and a certified nurse assistant (CNA), came to her room to

administer a soapsuds enema. The CNA drew water from a hot water spigot in the patient's room. Neither the CNA nor the nurse's aide tested the water before administering the enema to the patient. Even though the patient was not completely coherent, upon administration of the enema, she cried out in pain. The CNA told the nurse's aide that all patients reacted that way and continued to administer the enema. The patient then sat up in bed and shouted, "You're burning me up! You're burning me up!"

This, too, did not prevent the CNA from continuing to administer the full course of the enema.

The patient was lying on a rubberized sheet, which allowed the hot water to pool around her. The patient suffered first- and second-degree burns that extended from her back to her knees. She had blisters on her thighs, buttocks, legs, and perianal region. The extent of internal burns was unknown.

Despite their severity, the patient's burns were not discovered until the next morning. The order for pain medication was not given until nine hours after the incident, and another 11 hours passed before the pain medication was administered by nursing personnel. Twenty hours passed from the time the enema was administered to when the patient received pain medication.

After the incident, the patient's health deteriorated steadily. She was noncommunicative and eventually transferred to a tertiary medical center. She remained there for approximately two weeks and was then taken home under hospice care and died a few days later.

The plaintiff alleged a wrongful death cause of action and alternatively pre-death pain and suffering. The defendant hospital admitted medical negligence in connection with the enema administration, but denied negligence with respect to the pain medication regimen. Defendant also denied a causal relationship between the burns and the patients death; however, there was significant evidence showing that the burns hastened her death.

The case was mediated twice and ultimately settled for $1.65 million. The hospital also agreed to issue a public apology in the local newspaper.

Although hospital risk management tried to get out of the public apology, in the end, the decedent's eight surviving children and family insisted that the public apology was more important than any monetary settlement.

What this means to you: This incident certainly falls within the parameters of a sentinel event and should be handled accordingly.

"In reviewing this case, it is difficult to say which is worse — the use of scalding hot water or the disregard for the patient's pain afterward. Conducting a root-cause analysis should certainly be considered in light of the severity of the outcome of this incident. In addition, the family and the patient should be told of the incident in keeping with the Joint Commission on Accreditation of Healthcare Organizations [JCAHO] disclosure standard and the risk manager should coordinate the meeting," notes **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, CHt, director of risk management services at the Miami Jewish Home and Hospital for the Aged.

After addressing the immediate need to meet with the patient's family, at a minimum, the risk manager should thoroughly review and assess staff training policies and procedures and determine staff competency to perform work functions.

"In this case, we have a nurse's aide in training with a certified nurse assistant apparently instructing. The first issue to assess is whether or not it was standard practice for CNAs to train nurse's aides. Second, if CNAs routinely train aides, the practice should be revisited in order to examine if and how the trainers' competency to provide such instruction is determined," says Kicklighter.

Additional training and competency issues for consideration by risk management are, according to Kicklighter:

Whether or not review of policies and procedures is part of the nurse's aide training because assuming that such policies and procedures existed if first reviewed by the trainee, she might have posed the question regarding the need to test the water temperature prior to administration.

Whether or not water temperature was included in the policy or procedure. As for staff competency generally, given that JCAHO uses competency evaluations as a part of their evaluation process, this case raises the issue of whether or not the proper procedure for administration of an enema was (or is) a part of that evaluation?

As for the existence or not of a policy or procedure on enema administration, "even though the administration of an enema is very commonplace and can even done at home without the assistance of a health care professional, when given in a hospital or other health care setting it carries risks, albeit rare, if not done properly. Therefore, nursing and risk management should review all policies and procedures for these types of seemingly low risk treatments and procedures to verify that all steps — including

testing of the water temperature — to prevent injury are included," notes Kicklighter.

"Any procedure that includes the use liquids [even water] should include strong cautionary language and the use of thermometers to check that the temperature of the liquid is within published parameters. Patient care units should be stocked with thermometers to easily check the liquid temperature. In addition, all patient care staff should be required to attend an inservice program on proper administration of an enema and a review of the pain management program. Another principle that should be revisited with staff is that when a patient cries out or questions something the staff should give it due consideration and evaluate the patient and the issue before proceeding, even in instances where the patient suffers from dementia," notes Kicklighter.

"Burns are very painful. This patient sustained severe burns over a large part of her outer body. If the outside of her body was burned so extensively and severely, one can only imagine how badly the inside of her bowel was burned. We must remember that the hot water pooled in the bowel and that the closed space did not allow for heat evaporation and more rapid cooling down. Further, pain has been added to the list of vital signs, and the severity of pain levels is to be evaluated along with other vital signs. In light of the incident, the entire pain management program should be revisited and all staff re-educated. The wait of nine hours after the enema to obtain an order for pain is unreasonable. If the patient had no orders for pain meds, the nurse can call for orders. The wait for another 11 hours to finally administer pain medication after an order was received is unconscionable. The occurrence of the burns in the first place followed by the delay in appropriate treatment is why a root-cause analysis is recommended — basically to address and assess all of the whys raised by this case," says Kicklighter.

"The Alzheimer's disease process deteriorates a patient's memory and ability to speak, but it does not dull their pain sensations. The bodies of patients with Alzheimer's still swell, bleed, and feel pain due to injury. This raises the question of how could the burns on this patient not be discovered until the next morning? From the information we are provided here we can only surmise that the CNA and nurse's aide did not report the patient's reaction to the enema or how hot the water was. When the patient was cleaned up and the rubber mat removed after the enema did the CNA and nurse's aid not notice the reddened skin? We have no indication when the physician was made aware of the incident and the severity of the outcome. When did the physician come in to examine the patient? We must remember that the skin of an elderly person, as a natural part of the aging process loses its adipose tissue and becomes very thin and fragile and therefore is much more vulnerable to bruising, tears and extreme changes in temperature," says Kicklighter.

"One can only imagine the damage done to the vulnerable bowel lining. As a part of the alimentary track [the food digestion track], one can only wonder how this injury affected the dietary intake and elimination of this patient. Was this a contributory component to the patient's health deterioration and death? This case is a risk manager's nightmare! It would be hard to look only at process and not at the competence of the staff involved in the various aspects of this tragic event," concludes Kicklighter.

Reference

• *Anonymous Deceased Alzheimer's Patient v. Anonymous Hospital,* Robeson County (NC) Superior Court. Jim Billings and Jeanne Washburn, Raleigh, NC, attorneys for the plaintiff. ■

HIPAA Regulatory Alert

INSIDE

JANUARY/ FEBRUARY 2003

VOL. 1, NO. 1 (pages 1-8)

HIPAA privacy guidance seeks to maximize voluntary enforcement

Enforcement rule is in drafting stage

In December 2002, the Department of Health and Human Services (HHS) Office of Civil Rights (OCR) released an extensive guidance outlining various aspects of the privacy portion of the Health Insurance Portability and Accountability Act (HIPAA). That follows a recent decision by HHS to place OCR in charge of enforcing HIPAA's privacy mandates.

OCR now is in the process of drafting the enforcement rule, says **Richard Campanelli**, director of OCR. He says that rule will answer questions such as whether it is the company, the chief executive officer, the chief privacy officer, or the person who commits a specific privacy violation who will be fined.

The HHS guidance is not technically binding. "The guidance is not a regulation," says Campanelli. "It is an indication of how we view this and an attempt to clarify and expand on [the rule]," he explains. "It is not a binding document because it has not been published as a regulation."

Paula Stannard, counsel to the general counsel at HHS, points out that the Administrative Procedures Act requires that anything that can impose binding obligations on the public must go through the rule-making process.

According to Campanelli, while the privacy rule implements the foundation of federal protections for protected health information, the modifications released last summer attempt to do that in a way that avoids erecting undue barriers to health care. In short, he says it is the agency's goal to help covered entities understand the rule and maximize voluntary compliance. "The bottom line is that we are looking to maximize voluntary enforcement," he says.

The final modifications were adopted to improve "workability" of the rule and eliminate unintended consequences that may have arisen from the December 2000 version of the rule, he explains. For example, Campanelli notes that the modifications make advance consent voluntary for treatment, payment, and health care operations while strengthening the notice requirements to patients.

The modifications also make it explicit that incidental uses and disclosures of protected health information are permitted as long as reasonable safeguards are in place and the minimum necessary requirements were observed. In addition, they facilitate research

activities and make it clear that public health disclosures are permitted. **(See related story, p. 3.)**

'Voluntary compliance' urged

Since the modifications were released last summer, Campanelli says OCR and its sister agencies have emphasized "voluntary compliance" through expanded education. He says HHS now is in the process of developing technical assistance for targeted audiences for various segments. Those guidance documents will be released on a rolling basis over the next few months, he says.

Campanelli encourages providers to review the new guidance, published Dec. 4, which is posted on the OCR web site along with the complete text of the privacy rule. "That is a very helpful tool so you do not have to keep referring back and forth from the modifications to the prior regulation," he says. Fact sheets on the modification and sample business associate contract provisions also are posted, he adds.

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Editorial Questions

For questions or comments, call **Russ Underwood** at (404) 262-5521.

According to Campanelli, HHS continues to field thousands of questions regarding privacy. However, many of these questions can be answered by information that already has been released. For example, he says OCR has a covered entities decision tool that is posted on both the HHS web site, which answers many questions about who is a covered entity and how that applies. "We are not saying that will answer all questions," he says, "But it is quite helpful."

Sue McAndrew, senior advisor for HIPAA privacy policy in OCR, says that tool likely will be supplemented to answer additional questions about the definitions of covered entities and how they apply in various situations.

McAndrew says the agency continues to receive numerous questions regarding the status of covered entities and the definitions of health plans and health plan providers. She points out that the primary aim of the guidance is not to address particular scenarios so much as it is to help people learn how to approach those circumstances, understand what they need to think about, and learn how to find the information they require to come to reasonable and correct answers.

According to Campanelli, HHS will continue to provide technical assistance efforts well after the April 14 compliance deadline. Meanwhile, OCR is developing its enforcement program. "At the outset, our enforcement will be compliance driven," he asserts. While OCR has the authority to engage in compliance reviews, that will not be the driving factor at the outset.

Campanelli notes that the privacy rule requires that when OCR investigates complaints, it also provides for notice and an attempt at informal resolution where indication of noncompliance is found. "We certainly intend to do that," he says, "because that is the way we can most efficiently bring about voluntary compliance and the protection of individual's health information."

He also points out that the vast majority of all complaints at OCR are resolved with informal rulings. "That is certainly our goal here," he says. "We anticipate that many issues will just be a question of education and compliance."

While OCR is not yet authorized to pursue investigations, Campanelli says the agency already is receiving many letters on issues such as access to records, which will be required under the rule. "We believe many of these issues can be resolved just by quickly getting in touch and informally resolving it with the organization," he says. "It will be a matter of education."

Campanelli notes that covered entities will have 30 days to cure a violation if it knew or should have known about a violation. "That 30-day period may be extended by the department," he adds, "so there is plenty of opportunity for voluntary compliance."

In the event permission is not granted, the agency may impose civil monetary penalties (CMPs). Penalties amount to $100 per violation or a maximum of $25,000 in a calendar year for repetitions of the same violation. However, CMPs will not be imposed if the penalty is punishable as a criminal offense. "There is no overlapping jurisdiction there," he adds.

Likewise, CMPs may not be imposed if HHS determines that the person did not know and by exercising reasonable diligence would not have known it was a violation. Also, they cannot be imposed if failure to comply was due to reasonable cause rather than willful neglect and if the problem was corrected in the 30-day period.

McAndrew says the agency is using guidance to answer "burning questions" that had been addressed in previous guidance. The agency also added some new topic areas that were not included in earlier guidance. "This is the start of an ongoing process where we will be expanding the guidance material," she says. When OCR is unable to publish guidance, it will continue to answer specifics through its "Frequently Asked Questions," she adds. ■

HHS outlines major changes in privacy

The Department of Health and Human Services (HHS) has said for months that HIPAA would continue to be a work in progress. The agency proved that again last month when it added a new section to the guidance on public health disclosures and another on workers' compensation disclosures. In addition, HHS updated and expanded the guidance with regard to research. These areas shared a common theme, namely that disclosures are permissible in these areas, says **Sue McAndrew**, senior advisor for HIPAA privacy policy in HHS' Office of Civil Rights.

According to McAndrew, HHS heard from many varied sources that the final rule threatened the flow of information. She says the agency wanted to use the guidance to assure people that it is permissible to disclose information for public health purposes as well as workers' compensation purposes.

According to McAndrew, it also is important to cooperate with researchers to keep those activities moving forward. She says there were a number of questions regarding research, and some of them have been addressed in the guidance. For example, the guidance addresses recruitment policies and how the privacy rule may affect recruitment for these studies.

The guidance also addresses questions about ongoing research where consent had been obtained prior to the implementation date. "Those types of research projects will be grandfathered in based on the consent that was received prior to the compliance date," she reports.

HHS makes more changes

Here are several other areas where HHS recently has made significant changes:

• **Marketing.** The definition of marketing is one of the areas that was changed substantially in the modifications, according to McAndrew. If a third party is paying to obtain a list of patients for its own marketing efforts, that clearly is marketing, she says. With limited exceptions, all marketing will require an authorization, she adds.

In addition, CMS has tried to clarify both in the rule and in the guidance material what kind of communications do not constitute marketing. For example, McAndrew says that communications with individuals regarding their own health-related products and services have been expressly carved out. "It is not marketing when they are communicating about their own health-related products or services," she says.

Other carve-outs pertain to communications related to the individual's treatment or care coordination, case management, or alternative therapy recommended to the individual. "All these types of communications can go on freely," she says. "That is not marketing."

• **Incidental uses and disclosures.** Another area that was modified is incidental uses and disclosures. "Clearly, these are permissible provided that they are incidental to another permitted use or disclosure," says McAndrew. This issue arises in many treatment settings where the patient may be in a semiprivate room and the conversation between a patient and a physician may be overheard by other patients or visitors. Likewise, physicians and nurses might confer at areas of the hospital where others

could potentially overhear the conversation.

• **Business associates.** Another area that was the focus of many questions that resulted in the guidance being expanded is business associates. HHS expanded the guidance to try to address more situations where a business associate contract would be required, says McAndrew. The agency also provided some examples of instances where a business associate arrangement would not be necessary. ■

How to deal with family members under HIPAA

Facilitywide culture change may be necessary

One of the many challenges facing providers under the Health Insurance Portability and Accountability Act (HIPAA), particularly in the context of oncology, cardiac surgery, and OB-GYN services, involves health care services provided to a family member. The final HIPAA regulations say that if the patient is present, providers can infer from specific circumstances that the patient wants you to share certain information with the spouse or family member. The more difficult question arises when the patient is diagnosed and a family calls the provider, says health care attorney **Susan Bonfield** of Fox Rothschild in Philadelphia.

Moreover, she says this is a common occurrence. "The problem is that the regulatory allowance that allows a provider to share that kind of information does not apply in the same way if the patient is not physically present in front of the provider," she explains. For example, a verbal authorization by a spouse over the phone generally is not HIPAA-compliant, she notes.

Bonfield says one way to deal with this problem is through some type of "registration authorization." For example, she says providers might give patients an authorization with checkboxes about what information they are allowed to share with specific family members. Patients then would fill in the rest of the HIPAA-mandated authorization, which would indicate the type of information along with an expiration date or event.

Changing the culture

When using this approach, she says providers should include an expiration date or event. "Oftentimes, there is a term of treatment such as six months for chemotherapy," she points out. "You can also do it on a month-to-month basis to be more specific, but I think it is reasonable to use a course of treatment as an expiration event."

Beyond the simple mechanics involved in questions such as this is the process of changing the culture of an organization. For example, physicians typically walk the patient out and to the front desk, often to schedule the next procedure or appointment, with a waiting room full of patients. Since the physician assumes everyone is there for a similar reason, he or she may not be mindful about what is said. Or the receptionist may be designated to call to confirm appointments. Depending on the amount of information communicated to those patients, this practice may need to be reviewed.

"The point is that everybody is entitled to privacy," she warns. As a result, she says physicians and other providers must learn to conclude the visit in the office. That may mean handing the patient a piece of paper with instructions for the front desk and letting the patient take it to the registration person without the physician verbalizing the information in front of others.

Many organizations maintain they will never get the physicians to change, says Bonfield. However, it is vitally important to get buy-in from management and leadership beforehand so the rest of the staff will follow suit. It will be difficult to impress upon staff that they must embrace HIPAA if the leadership fails to do so.

According to Bonfield, another issue involves the facility's patient directory. Under HIPAA, she says patients have the right to opt in or out of having their name and their identity included in the facility directory. This largely applies to hospitals, nursing homes, and other entities, she adds.

According to Bonfield, the first operational issue in this regard is how to document when patients say they do not want to be in the facility directory. She says providers can either remove the name from the list of the patients or simply flag it. However, there are some problems associated with the latter approach.

Bonfield suggests that providers script this process out for the person who is at the switchboard. "These are people who until now may not have had a lot of responsibility for decision making and following particular policies or procedures," she explains.

For example, she says providers must know what to do if somebody calls and asks for a

How to deal with minors under HIPAA

One of the problems facing providers under the Health Insurance Portability and Accountability Act (HIPAA) will be how to deal with minors, including newborns.

Health care attorney **Susan Bonfield** of Fox Rothschild in Philadelphia, notes that the final privacy regulations eliminated the requirement that there be a specific consent to use or disclose protected health information.

Now providers can obtain a written acknowledgement in whatever fashion they like and, in an emergency, document good-faith efforts if they are unable to obtain a written acknowledgement. "They still need to provide a notice," she says. "It made it easier in that it eliminated one mandated document, but the spirit of the requirement is still there."

According to Bonfield, one problem area for providers is newborns, who are people entitled to their own notice. The mother always will be the personal representative, she points out. "You might have a case where a mother is deemed not competent," she explains. "Likewise, the mother might be a minor." In those cases, Bonfield says providers must look to the state law. For example, it may be reasonable to have some sort of waiting period as long as the notice explains what is going to happen.

When it comes to minors covered by their parents' health plans, she says a different set of questions must be addressed. If a minor turns 18 and is covered by the parents' health plan, one of the issues that will arise is whether the minor must be informed about the existence of a notice. "The HIPAA regulations say you don't, but there is a sense among some health plans that you should," she says.

Another issue that providers will confront dealing with minors involves states where the majority age is at variance. For example, the majority age in New Jersey is 18, while it is 21 in Pennsylvania. "This raises the question of what to do when a New Jersey provider receives a Pennsylvania resident for services who is 20 years old," says Bonfield. "There is going to have to be some close scrutiny regarding the different state laws."

She says these are just some of the areas providers should consider when they are drafting procedures on minors and notices. "Once you understand HIPAA, and you start drafting procedures, you suddenly realize that you are going to have to think through some of these real-life situations," she explains.

Bonfield says that if health plans opt to provide only one notice to the person who is listed as the policyholder and it is his or her responsibility to pass it on to everybody else, that is their right under the law. However, she says, plans must provide notice every three years that the notice is available. "The question is whether that should go to all enrollees as opposed to just the enrolled individual," she says. ■

patient's room and a flag shows that the patient wanted to opt out of the directory. "If the name is flagged, and you have them say, 'I am sorry, I show no record of anyone by that name,' that is untrue," she points out. "I am not sure you want to put people in that position."

On the other hand, if the operators are vague about in their response, that may only lead to more questions. Since that will place the person at the switchboard in an awkward position, Bonfield says it is probably better to simply remove the names completely from the list of patients. Then the switchboard operator will not be in a compromising position, she explains.

Ultimately, Bonfield says it depends on what kind of computer system the facility is using and what specific information is accessed. She says that it's essential to train front desk personnel and switchboard personnel, regardless. "They are going to require some specific training," she emphasizes. "You do not want to put them in a position of having to make policy decisions for that facility on an ad hoc basis."

According to Bonfield, this question highlights the broader decision about whether it is easier to take an existing procedure and overlay HIPAA requirements or to take a HIPAA requirement and place existing procedures on top of that. "There are pros and cons to each approach," she says. " One may require more work while the other may require more of a cultural change. I have organizations do it both ways." ■

Survey finds major progress toward HIPAA compliance

HHCA compares old, new responses

According to a survey just released by the Minneapolis-based Health Care Compliance Association (HCCA), the health care industry is continuing to take the necessary steps to ensure compliance with sweeping changes required by the Health Insurance Portability and Accountability Act (HIPAA). The deadline set by the government for the health care industry to comply with new regulation is April 14, 2003. Here are some of the major findings included in the study:

HIPAA Education

Survey respondents indicate that most organizations have held one or two hours of HIPAA privacy training for the majority of the stakeholders such as medical staff, nursing staff, executives, and board members. According to the HIPAA Readiness Survey results, 33% of executive staff received three to five hours of HIPAA training. In all cases, those indicating that no training had been conducted decreased from the previous surveys.

	Survey	
Organizational Steps	11-02	11-01
• HIPAA Task Force has been established	96%	87%
• Indicate that a privacy officer has been designated	93%	73%
• Have designated a security officer	70%	57%
• Have developed organization structure delineating responsibilities for privacy and security	75%	37%
• Privacy and security responsibilities have been assigned to one individual	43%	54%

Fifty-seven percent of respondents have developed cost estimates for the privacy, security, and transaction requirements, according to the survey.

Policies and Procedures

According to the survey, 68% of respondents have developed policies and procedures related to discipline for breach of privacy principles and security. Progress on other policies developed include the following:

	Survey	
	11-02	11-01
• Developed grievance policy for complaints/breaches of confidentiality	66%	40%
• Developed policies related to patient access to records	74%	47%
• Developed disposal of PHI policies	65%	34%

Forty-eight percent of respondents have developed policies addressing the potential exposure of protected health information (PHI) through viewing, paging, or other operational activities, and 55% report having developed policies related to verbal discussions of PHI by authorized persons.

Security

According to the survey, 38% of respondents reporting on Security aspects of HIPAA indicate they have performed a "penetration analysis" to determine where and how security breaches may occur; 52% have assessed the physical location and the type of storage media to be used of all PHI; 36% have addressed how to authenticate users and receivers of health information.

Transaction and Code Sets Preparation

Seventy-eight percent of respondents have identified all transaction standards and code sets. Other survey results related to transaction and code sets preparation include:

	Survey	
	11-02	11-01
• Determined preparedness of trading partners	54%	28%
• Developed a system for maintenance of standards transaction and code sets	46%	25%
• Educated business office on standards and code sets	49%	26%

The rule requires that transaction and code sets be in place by October 2002, but the deadline was pushed back one year to October 2003.

HCCA's Third HIPAA Readiness Survey, released Dec. 11, was conducted in fall 2002 and compares the results to a similar survey

conducted in fall 2001. The association developed the survey to track the industry's progress in preparing for HIPAA privacy and security. It is meant to be a snapshot of the health care industry's progress rather than a statistically valid study.

Complete results available

The association mailed 3,273 surveys, and 289 surveys are completed and returned. According to the respondents, 96 (33%) came from hospitals, 76 (26%) from health care systems, 26 (9%) from physician/clinics, 21 (7%) from nursing homes, 19 (7%) from academic medical centers, 17 (6%) from health plan, and 34 (12%) indicated "other." Seventy-two percent indicated their organizations were not-for-profit, while 18% were designated as for-profit.

Thirty-seven percent of the respondents indicated their facilities are located in urban areas, 29% are in suburban areas, and 18% are in rural areas. The complete results of this survey are available on the HCCA web site, www.hcca-info.org. ■

How to draft documents for HIPAA implementation

Know requirements for consent, covered entities

The first task in drafting and negotiating Health Insurance Portability and Accountability Act (HIPAA) documents is to understand the requirements for consent, business associates, and covered entities.

By now, most providers know that under HIPAA's privacy requirements, a provider with a direct-treatment relationship must have patient consent in order to use or disclose protected health information (PHI) for treatment, payment, or their own health care operations.

It also is important to remember that consent is a one-time event, says **Thomas Bixby** of Michael Best law firm in Madison, WI. Once you get it, you have it until the patient revokes it. "You may condition treatment on obtaining consent," he adds. "If the patient refuses to provide consent, you may refuse to provide treatment."

Under HIPAA's consent requirements, providers must inform the individuals that their data may be used for treatment, payment, or their own health care operations, and must refer to the notice of privacy practices. They cannot, however, combine the consent with a privacy notice, Bixby says.

In addition, the consent must be visually and organizationally separate from an authorization or any other written legal permission and separately signed and dated. It must describe the individual's right to request a restriction and state that it may be revoked at any time. If the covered entity is going to reserve the right to change its privacy practices, providers must indicate that in the consent, he adds.

Business associate agreements are required when two basic conditions are met, Bixby says. First, when a business performs a function or activity on behalf of the covered entity; and second, when that function or activity involves the use or disclosure of PHI.

Business associate functions

Claims, data processing, administration, and utilization review all are examples of functions or activities a business associate might engage in. A business associate also is any person who provides services on behalf of a covered entity that involve the use or disclosure of PHI, such as attorneys, actuaries, accountants, and auditors.

On the other hand, network providers of a health plan are not business associates. Nor are physicians automatically considered business associates simply by virtue of the fact that they provide services in a hospital, he says.

Bixby maintains that simply inserting a provision in the contract that says that the vendor shall comply with the HIPAA privacy rules is not sufficient to meet the needs of the business associate contract provisions in the privacy rules.

Monitoring compliance

Under the rule, a business associate contract must establish the permitted and required uses and disclosures of PHI by the business associate. "A simple phrase that the vendor shall comply with the HIPAA privacy rules obviously does not do that," he explains.

Also, the privacy rules provide that the business associate must not use or disclose PHI in violation of the contract or the privacy rules, must implement the safeguards to protect individually identifiable health information, require

subcontractors to comply with the privacy rules, provide all of the rights that individuals are entitled to under the privacy rules, report improper use or disclosure to the covered entity, and authorize contract termination to material breach in addition to allowing the Department of Health and Human Services (HHS) access to its books and records.

"You may condition treatment on obtaining consent. If the patient refuses to provide consent, you may refuse to provide treatment."

Bixby notes that a covered entity has some responsibility for monitoring the compliance of its business associates with the business associate contract. It does not have to actively monitor, he adds. But if it becomes aware of a pattern or practice that the business associate engages in that is a breach of their privacy obligations under the contract or the rules, then the covered entity is responsible for making sure that the business associate starts to comply or, if necessary, terminate the contract or report the violation to HHS.

Bixby says there are several specific challenges in terms of dealing with business associate contracts. First, you must develop standard terms for business associate contracts, and then identify third parties that collect PHI on your behalf and third parties to whom you disclose PHI, and determine whether those third parties are business associates. "Not everybody to whom you disclose PHI is going to be a business associate," he adds.

Audit existing contracts

In addition, providers must audit existing contracts with business associates and add data privacy provisions to those contracts as warranted. "Obviously, when you reopen longstanding contracts, you are opening the contracts to renegotiation of all of their terms, including the cost of HIPAA compliance," Bixby says.

Providers must terminate noncompliant business associate arrangements before the compliance date of the HIPAA privacy rule, he adds.

Bixby says most covered entities must have and distribute a written notice of privacy practices, and each covered entity will have to implement written privacy policies and procedures. "You cannot implement a change in your privacy practices without first amending your privacy policies and issuing a revised notice," he says. ■

Feds offer database for record disclosures

The Centers for Medicare & Medicaid Services (CMS) has created a Privacy Accountability Database to aid in tracking, reporting, and accounting the disclosures made from all CMS systems of records permitted by the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act.

Information retrieved from the system will be used to support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; support constituent requests made to a congressional representative; and support litigation involving the agency.

The announcement appeared in the Oct. 7, 2002, issue of the *Federal Register*, accessible at www.access.gpo.gov/su_docs/fedreg/a021007c.html. ■

Web site answers FAQs about HIPAA

A "Frequently Asked Questions" document about the Health Insurance Portability and Accountability Act (HIPAA) privacy rule is posted on the Department of Health and Human Services' web site.

The document answers questions ranging from privacy rights to compliance dates. "Does the rule create a government database with all individuals' personal health information?" and "If patients request copies of their medical records, are they required to pay for them?" are examples of the subjects covered. The document also reminds health care providers that the compliance date for the privacy rule is April 14, 2003, or April 14, 2004, for small health plans. To see the questions, go to www.hhs.gov/ocr/faqs1001.doc. ■