AMERICAN HEALTH CONSULTANTS®

HIPAA Regulatory Alert — a free supplement for navigating the world of HIPAA — inside

Celebrating our 25th year as a source of risk management information

Healthcare Risk Management™

INSIDE

Earn 18 hours of continuing education credit. See page 36.

MARCH 2003

VOL. 25, NO. 3 (pages 25-36)

Speak my language: Lax interpreting may be a root cause of medical errors

Dangerous to rely on family, ad hoc translators to relay medical information

Translating medical information for patients who don't speak English has always been a difficult issue for health care providers, but evidence is mounting to suggest that health care providers risk major lawsuits from medical errors traced to inadequate translation. Translators commonly make important errors, according to new research, and most providers need to formalize their translation services instead of relying on whoever you can find to speak the language.

If risk managers had any doubt about the risk posed by translators, new research from the Medical College of Wisconsin in Milwaukee makes the danger crystal clear. **Glenn Flores**, MD, director of community outcomes in the department of pediatrics and an associate professor of pediatrics, epidemiology, and health policy, recently studied the accuracy of translators in health care situations and found that errors were common and significant.[1]

"Interpreter errors could be a previously unrecognized root cause of medical errors," Flores tells *Healthcare Risk Management*.

The resulting medical errors could lead directly to lawsuits, says **Grena Porto**, RN, ARM, DFASHRM, senior director of clinical operations at VHA Inc. in Berwyn, PA, and past president of the American Society for Healthcare Risk Management. A plaintiff recently was awarded $71 million when paramedics misinterpreted the word "intoxicado" to mean that the unconscious man was drunk.[2] They reported that the patient was intoxicated and he was treated accordingly. In actuality, his girlfriend was trying to tell them that he had been nauseated before collapsing, Flores says. The patient's true condition was not diagnosed for two days, and he was left a quadriplegic.

Two New York hospitals were sued in 2002 for failing to provide translation services to non-English-speaking patients. Advocates for the Hispanic community filed suit against Wyckoff Heights Hospital and Woodhull Hospital, both located in Bushwick, a heavily Hispanic section of northern Brooklyn. A Woodhull Hospital spokeswoman tells *HRM* that the suit has

not been settled yet. The hospital has a volunteer translation pool of 625 staff members who collectively speak 50 languages.

In addition to the risk of lawsuits from medical errors, the 1964 Civil Rights Act requires that language barriers not prevent patients from receiving adequate medical care. The Department of Health and Human Services has indicated in past years that it would stiffen requirements for translation services, but the Bush administration more recently softened its stance. That doesn't lessen the liability risk or the risk to patients, Porto says.

"We've known this is a problem for years," she says. "Too many health care providers have gotten by with translation services that aren't as sophisticated as they need to be, taking the convenient way just to get by. It's time for us to start tightening up and making this more of a formal, organized approach."

Family members not good translators

In other words, Porto says, the days are long gone when you could depend on a family member to translate or informally pull in a staff member from housekeeping who happens to speak the language. Those methods always were fraught with danger, she says, but few risk managers were motivated to institute a more formal system. Now that the connection to patient safety and lawsuits is so clear, Porto says you must evaluate your translation services.

Flores agrees, saying his research removes any doubt about how dangerous translation errors can be. His recent study shows an average of 31 medical interpretation errors per patient visit. Mistakes by ad hoc interpreters — family members or staff not specifically designated as translators — were more likely to have potential clinical consequences than those made by professional hospital interpreters — 77% vs. 53%. Errors are more likely in an emergency. The results come from tape-recorded encounters between pediatricians and Spanish-speaking mothers in a Boston hospital outpatient clinic. The ad hoc interpreters included nurses, social workers, and an 11-year-old sibling. The errors fell into these categories:

- **Omission:** The interpreter left out a word or phrase (52%).
- **Addition:** The interpreter added a word or phrase (8%).
- **Substitution:** The interpreter substituted a word or phrase different from what the doctor said (13%).
- **Editorialization:** The interpreter provided his own personal viewpoint about what the doctor said (10%).
- **False fluency:** The interpreter used a word or phrase that doesn't exist in that particular language (16%).

Examples included an interpreter telling a mother to put oral amoxicillin in the child's ear to treat infection. Another interpreter told the mother to start using a topical steroid on the baby in four days, when the doctor actually said to start it immediately and use it for four days. Sixty-three percent of the errors were found to have potential medical consequences. Designated interpreters and ad hoc interpreters made errors at about the same rate, Flores says, but the ad hoc interpreters were much

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

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

Subscriber Information

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

Subscription rates: U.S.A., one year (12 issues), $499. Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $399 per year; 10 to 20 additional copies, $299 per year; for more than 20, call (800) 688-2421. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. **Back issues**, when available, are $83 each. (GST registration number R128870672.)

Editor: **Greg Freeman**, (770) 998-8455.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Lee Landenberger**, (404) 262-5483, (lee.landenberger@ahcpub.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

For questions or comments, call **Greg Freeman**, (770) 998-8455.

more likely to make errors that could jeopardize patient safety.

"When you rely on people like family members, we see that the family member sometimes isn't as honest or as capable as you think," Porto says. "You're asking them to translate complicated things about CAT scans and surgery, things that may even be beyond the abilities of someone who speaks English. And then if you're asking a child to translate for his parents, it gets worse."

Translation always carries a risk of distorting the original message, Porto says, so it is important to minimize that possibility by using trained translators. And she points out that family members are not always completely honest in translating, particularly with sensitive matters such as family violence, sexual assault, drug abuse, and terminal illnesses. The doctor may never know what information the patient actually received or what the patient actually was trying to tell the doctor.

"Our duty as health care providers is to make the patient understand, not just to utter the words," Porto says. "Often I hear people say, 'Well, I told them.' But if you didn't tell them in a way they understand, you didn't really tell them. You didn't fulfill your duty."

A good option — if you can afford it

Flores and Porto agree that the research indicates a need to improve translation services. Flores says health care providers should employ and train professional interpreters, while Porto says that is not necessarily the only way to improve translation services. Fewer than a quarter of hospitals nationwide employ professional translators, Flores says.

"One of the most important messages from our work is that you need to avoid using ad hoc interpreters — friends, people pulled from the waiting room, maintenance workers," Flores says. "They don't have any formal training, don't know medical terminology, and they can't provide confidentiality."

But also be cautious of health care providers who speak the second language. They may not be any better as translators, Porto says. Without properly screening health care workers to gauge their abilities and emphasize the proper technique of translation, you can't be sure whether a physician, nurse, or X-ray technician is translating properly. "False fluency" often trips up well-meaning health care workers, Flores says. They think they can speak German because they studied it for two semesters in college. Then they either mistranslate and never know they made a mistake or they realize they are in over their heads but do their best with the words they know.

Only 14% of hospitals provide training for volunteer interpreters, and training is not mandatory in half, Flores says. Only 23% provide training for clinicians on how to work with interpreters, and in many of those hospitals, the training only amounts to how to request a translator.

Flores acknowledges that most health care providers cannot afford to hire a permanent staff of translators specially trained for medical situations, but he says that is the ideal solution if you have the resources. Some states — Hawaii, Maine, Minnesota, Utah, and Washington — have eased the burden by providing reimbursement for medical translation services.

Providing proper translation services actually can reduce some other costs for the health care provider, he says. When the doctor is not confident about communicating with the patient or family, he or she is much more likely to practice defensive medicine and order more tests.

"The physician has to be safe, so if an adult is admitted with chest pain and there's no interpreter, the patient is much more likely to be admitted," Flores says. "You spend a lot more in resources when you have a language barrier."

Most providers cannot afford a full-time translation staff, Porto says, and for some locations, that would not be justified even if they could afford it. Another solution is to certify staff members as designated translators and obtain trustworthy outside translation, she says.

Some health care providers make a stab at that solution by sending out a survey among staff asking for volunteers who can speak another language, but Porto cautions that simply asking is not enough. People can be overconfident of their skills. Such a survey might be a good first step in looking for translators, but then you should organize those people and conduct testing to determine their fluency. Language programs at local universities may be able to assist with testing. Even those who are fluent in the language probably will need further education in medical terminology. **(See article, right, for more tips on improving your translation services.)**

How much you need to formalize your translation services will depend a great deal on your local community, Porto says. If your health care facility is in an urban area with lots of different ethnic groups, you may need to put a lot more effort and resources into improving your program. If you are in a rural community with little exposure to language difficulties, the risk of problems is much less. But even in that situation, Porto says you must have a contingency plan for the day an Armenian immigrant shows up in your emergency department. One option is subscribing to a commercial service offering telephone or computer links to professional translators 24 hours a day. **(See p. 29 for more on how one hospital is using such a service.)**

The costs are unavoidable, Porto and Flores say. If you want to improve your translation services, it is practically impossible to do it without spending money. How much depends on your own situation and resources. But they say the cost is justified.

"Given that so many people in our country speak another language, you can either pay a little up front or you can pay a lot after you have medical errors," Flores says.

References

1. Flores G, Laws MB, Mayo SJ, et al. Errors in medical interpretation and their potential clinical consequences in pediatric encounters. *Pediatrics* 2003; 111:6-14.

2. Harsham P. A misinterpreted word worth $71 million. *Med Econ* 1984; 61:289-292. ■

Checklist: These tips may help reduce your liability

These tips on improving your translation services are offered by **Glenn Flores**, MD, director of community outcomes in the department of pediatrics at the Medical College of Wisconsin in Milwaukee, and **Grena Porto**, RN, ARM, DFASHRM, senior director of clinical operations at VHA Inc. in Berwyn, PA, and past president of the American Society for Healthcare Risk Management:

• **Omissions are by far the most common error, accounting for about half, so translators should be trained to focus principally on faithfully translating every word the doctor says.** Emphasize that the translator is not there to explain the doctor's words, necessarily, but to accurately translate them. A well-intentioned translator may try to help the patient understand the words beyond just accurately translating them, but that is a slippery slope, Flores says. It is better for the translator to strictly translate and let the patient indicate to the doctor whether he or she understands or needs clarification.

• **All translators, even those who already work in the medical field, should be trained on medical terminology.** An English-speaking doctor who speaks Spanish fluently still may not know the equivalent medical terms in Spanish. Errors can result when the translator tries to compensate by using words he or she does know instead of the proper terms.

• **Flores' research indicates that many translation errors occurred when the interpreter was distracted or out of the room — the doctor continues to speak and thinks the patient understands because the information is simple or the patient is nodding.** Policy should require that the interaction stop when the interpreter is distracted or out of the room.

• **Teach clinicians to plan the interaction with the translator and patient.** People tend to just go ahead and start talking once the translator is present, but Porto says you will get better results if you brief the translator on the situation, generally what you need to convey to the patient, and allow the translator to ask questions about specific facts or terminology. But be careful not to let this preparation veer off course so that the translator thinks you want that information conveyed to the patient in the translator's own words. The preparation is only to help the translator understand the situation; you

still want the translator to wait and convey the doctor's words precisely as the doctor speaks them.

• **Identify which languages for which you may have adequate resources, and which represent more of a challenge.** For instance, you may find that you have plenty of Spanish-speaking health care workers who have demonstrated that they truly are fluent. After providing specific training in medical translation, you can consider Spanish to be a low-risk translation situation, Porto says.

"Then you can decide that you don't have the resources for others, like Russian, and that makes them a high-risk situation," she says. "Decide how you will handle these high-risk translation situations and it can't be the same way you handle the low risk. Organizations must have radar these are high-risk situations, outside the norm, and pay more attention to them. I don't think we do enough of that now." ■

Computer link helps with an immediate translation

High technology can be a solution to improving your translation services. One example is Advocate Christ Medical Center in Oak Lawn, IL, which recently implemented a system providing audiovisual interpreting services on demand for non-English-speaking or hearing-impaired patients.

At Christ Medical Center, instant interpreting services already have been available via phone and in-person translators are on call, says **Meg Adorno**, manager of special services at Christ Medical Center. This new service, however, provides interpreters immediately and in person. Using real-time audio and video, the service links patients to interpreters within minutes for translation in certified American Sign Language or one of approximately 22 different spoken languages.

It is available 24 hours per day, seven days per week. Provided by Deaf-Talk, the system includes a video monitor, speakerphone, and flexible mini camera. The unit can be wheeled into the patient's room, hooked to an ISDN computer line, and, within five minutes an interpreter appears on the screen to begin translating or signing for the patient. Unlike a phone translator, the interpreter can see and hear everything that the patient, doctors, and other medical staff are doing or saying in the room. The flexible camera also can be extended over the patient's bed so that the patient can sign while lying down. The Deaf-Talk system already has been installed in Christ Medical Center's emergency department, and the medical center may consider expanding the system's use to additional areas of the hospital later this year.

Other hospitals within the Advocate Health Care system also are planning to implement Deaf-Talk in 2003. Adorno says the benefits justified the expense, which the hospital won't specify.

"All of our patients deserve equal service," she says. "This new system raises the bar for what's possible in making the hospital experience more comfortable for hearing-impaired patients or for those who speak little or no English." ■

Bush pushes for CA-style reform as doctors rebel

Doctors went on strike recently in several states to protest the malpractice crisis, as President Bush called for significant malpractice reform that would cap damages and rein in the trial attorneys blamed for much of the problem. California's Medical Injury Compensation Reform Act of 1975 (MICRA) could be the solution, some say.

For several days, about 70% of doctors in New Jersey recently stayed away from their offices and hospitals, refusing all but emergency care and delivering babies, according to **Robert Rigolosi**, president of the Medical Society of New Jersey. The action was intended to dramatize the severity of the malpractice crisis and the doctors' call for a $250,000 cap on pain and suffering. No cap was urged on actual damages from a doctor's actions.

Similar walkouts occurred in West Virginia, Florida, and Nevada. The efforts at malpractice reform got a major boost from President Bush, who recently said, "We must have a limit on what they call noneconomic damages. I propose a cap of $250,000." Without such a limit, Bush predicted that "excessive jury awards will continue to drive up insurance costs, will put good doctors out of business, will run them out of your community." Bush also urged Congress to pass caps on punitive damages.

Announcing his reform plan to an audience of health care workers in Scranton, PA, Bush also called for limits on who can be sued.

"A lot of times, these lawyers will sue everybody in sight in order to try to get something," he said. "In cases where more than one person is responsible for a patient's injuries, we need to assign blame fairly."

Lawsuits also have forced doctors to practice "defensive medicine," Bush said, adding that such practices raise the federal government's health care costs by at least $28 billion a year.

Bush urged lawmakers to follow in the steps of California, which capped damages from malpractice lawsuits more than 25 years ago. The American Medical Association (AMA) hailed President Bush's call for meaningful medical liability reform, saying his visit to Pennsylvania underscores the need for elected officials at the state and federal levels to pass reforms aimed at ending "jackpot justice." Something must be done to stem the tide of doctors who are forced to retire early, move to another state, or stop performing certain procedures such as trauma surgery and obstetrics, says AMA president-elect **Donald J. Palmisano**, MD.

According to the AMA, 12 states are facing a medical liability insurance crisis: Florida, Georgia, Mississippi, Nevada, New Jersey, New York, Ohio, Oregon, Pennsylvania, Texas, Washington, and West Virginia. Thirty-one additional states are showing problem signs. In these states, liability insurance premiums are rising at a high rate and insurance companies are not writing new policies.

"Pennsylvania already has lost more than 600 physicians and two maternity wards, and trauma care in Scranton and throughout the state is in jeopardy," Palmisano says. "While lawmakers debate the merits of medical liability reform, their delays are putting patient care at serious risk."

California-style MICRA could be solution

Like Bush, Palmisano points to California's MICRA, saying it protects patients' access to the courts while reining in excessive jury awards and merit less lawsuits. He says MICRA is the reason physicians' insurance premiums in California have risen by 167% since 1975, while physicians in the rest of the country have seen their premiums increase by 505%.

"The solution is plain and simple. We need reforms patterned after California's law, including a cap on noneconomic damages," Palmisano says. "Now is the time to put an end to a broken legal system that has caused crisis conditions in a dozen states, including Pennsylvania. California's law works, and we have the facts that prove it."

Other important provisions of MICRA include ensuring patients receive 100% compensation for their economic losses, including medical expenses, rehabilitation costs and lost wages, if harmed by a physician's negligence. The law also maximizes the amount of money juries award for patients, not trial lawyers, and places a $250,000 cap on noneconomic damages.

Orthopedic surgeons have been hit especially hard, says **Michael Daubs**, MD, an orthopedic surgeon in Las Vegas on staff at the University Medical Center's trauma center. Millions of people in Nevada and three bordering states were unable to use the trauma center for 10 days last summer after surgeons resigned over the escalating cost of protecting themselves in lawsuits.

Daubs says an American Academy of Orthopedic Surgeons (AAOS) study found that premiums for orthopedic surgeons increased by 35% from 2000 to 2002. A recent survey of orthopedic surgeons conducted by the AAOS found that rising liability insurance premiums have caused 55% of orthopedic surgeons to avoid at least some procedures due to liability concerns. Thirty-nine percent report they avoid performing spine surgery, 21% eliminate emergency room call, 6% eliminate all surgery, and 5% retired early.

New Jersey sees 50% increase

A new survey by the nonprofit New Jersey Hospital Association (NJHA) in Princeton shows that the average hospital in that state experienced a 50% increase in medical malpractice insurance costs in 2002, bringing the average hospital annual premium to $1.4 million. The multiyear trend shows that the average hospital's premium has skyrocketed by 207% since 1999. NJHA president and CEO **Gary Carter** says a full 100% of the hospitals responding said their rates had increased in 2002, despite the fact that 14% had reduced their coverage levels in an effort to rein in costs. The findings were based on a survey of all of New Jersey's 119 hospitals conducted in December 2002. The survey yielded a response rate of 46% of the state's acute care hospitals.

"This survey confirms our worries that the crisis is not only deepening but also reaching into every corner of the state," Carter says. "Each and every hospital in New Jersey is struggling with this problem."

Carter cites one finding that he found particularly troubling: a growing reluctance by physicians to treat charity care patients. One-third of

the hospitals said the medical malpractice crisis has made physicians think twice about treating charity care patients because it could make them more vulnerable to medical malpractice claims and rising rates. Hospitals also report that the growing premiums are cutting into their operating budgets and threatening to drain money away from other areas of the hospital. The survey shows that hospital medical malpractice insurance premiums, as a portion of total hospital operating budgets, have nearly doubled in the last four years.

"We've already seen the impact of this crisis in the physician community, with doctors closing their practices or dropping high-risk services," Carter says. "Now it's clear that hospitals are facing tough choices, including the possibility of eliminating services or cutting staff to cover the growing costs of insurance."

In fact, the survey revealed that one out of every 10 hospitals has been forced to lay off staff because of rising malpractice insurance rates. The survey also found that one out of every four hospitals, nearly 27%, has been forced to increase payments to find physicians willing to cover the emergency department. Physicians are increasingly reluctant to take on such assignments because of the greater liability exposure, Carter says.

Hospitals report that more and more physician specialties are being hit by the crisis. While a previous NJHA survey in March 2002 found that OB/GYNs and surgeons were primarily affected, the new survey finds a deepening impact for neurologists/neurosurgeons, radiologists, orthopedists, general practitioners, and emergency physicians. ■

Uterus branding shows risk and benefits of a videotape

In a recent lawsuit, a woman accused her doctor of "branding" his alma mater's initials on her uterus during surgery. A legal expert says the crux for risk managers is how the videotape of the surgery both caused the lawsuit and might end it in the doctor's favor.

If not for the videotape sent home as a keepsake for the patient, the lawsuit might never have been filed, according to **Richard Boone**, JD, an attorney in Vienna, VA, who specializes in defending medical malpractice lawsuits, But once the lawsuit was filed, the videotape became the doctor's very best defense, he says. That conundrum illustrates the pros and cons of sending patients home with a videotape, Boone says.

Sending videotapes home with the patient is a very controversial practice, with some risk managers and attorneys saying they are just lawsuits waiting to happen. The practice is most common in laparoscopic surgery, since a videotape is easily and sometimes routinely made from the video image used by the surgeon. The biggest risk, some critics say, is that patients will wildly misinterpret what they see on the tape and then a lay jury can be equally swayed by a tape that might actually depict standard, high-quality care.

Marking a uterus — on videotape

That appears to be what happened with the lawsuit making headlines in Kentucky, Boone says. J. Michael Guiler, MD, of the Women's Care Center in Louisville, is being sued by former patient Stephanie Means. According to statements made publicly by Means, Guiler performed a hysterectomy on her on Aug. 14, 2002, and gave her a videotape of the surgery to take home. Her attorney, Michael Dean, JD, says the tape clearly shows the 2-inch letters UK being inscribed on Means' uterus shortly before it was removed. The UK stands for University of Kentucky, where the doctor studied.

The lawsuit also names the Women's Care Center where Guiler works. The suit claims that the "branding" was done for no medical reason and that it was "intentional, degrading, reckless, outrageous, and intolerable." It seeks unspecified actual and punitive damages. When the lawsuit received widespread media attention, at least two other women came forward with tapes depicting Guiler marking the uterus in similar ways.

Means filed the lawsuit after watching the videotape at home, months after the surgery. In addition to her own claims, her husband, David, claims he has suffered a loss of companionship with his wife because of the incident. The couple seeks a trial by jury and punitive damages.

In a statement, Guiler said that patients are informed about the procedure before surgery, including the need to mark the uterus. He says he did not specify to Dean how the uterus would be marked. Laparoscopic surgeons report that they commonly rely on stitches or burn marks from cautery, laser, or harmonic scalpel to mark tissue and organs.

The surgeon defended his actions by calling them a routine part of performing a hysterectomy. Others in the surgical community confirmed that it is common to mark the uterus during a laparoscopic procedure to aid the surgeon in orienting left/right and up/down.

Guiler said that marking the uterus gives doctors a point of reference before it is removed, an important concern for laparoscopic procedures with limited visibility and viewed on a video monitor. The doctor acknowledged that he inscribed the letters UK as a tribute to his alma mater, explaining that it doesn't matter what letters or symbols are used to orient the surgeon.

"Not only am I always able to remain oriented for the patient's safety, I felt this was honorable since it made reference to the college of medicine where I received my medical degree," he said.

"In any case where there can be real concern about the technical execution of a procedure and you give away your only copy of the best evidence showing how it was done, that's not a good idea."

Don't give away only copy of best evidence

Boone says it is of no importance that the doctor chose to mark the uterus with his alma mater's initials.

"I don't think it legally makes a difference whether he puts a smiley face or the initials of his alma mater or his wife's birthday," Boone says. "I viewed the videotape on television, and it showed how he used the monogram to make it really clear which was the right side and which was the left side. Listening to the guy explain it on TV, I think a jury is going to believe him."

While it may seem that it was a huge mistake to send the patient home with a videotape of the surgery, since that prompted the lawsuit, Boone says the issue is not that simple. The patient might never have sued, he says, but what if the patient found out about the uterus marking some other way?

"If there had been some inadvertent disclosure, then the case would look much worse for the physician just because of the weird facts," Boone says. "But he voluntarily sent the video home with the patient, so it's clear that he wasn't trying to hide anything. He can make a strong case to the jury that he wasn't doing something funny without the patient's knowledge and then laughing about it with his buddies in the OR. It was routine, nothing to be ashamed of, and so he sent her home with the tape."

That argument should resonate with a jury, if the case gets that far, he says. Boone predicts the doctor will prevail, but he still finds lessons for risk managers in the Kentucky case. For one thing, Boone says, the doctor erred by not keeping a copy of the tape.

"In any case where there can be real concern about the technical execution of a procedure and you give away your only copy of the best evidence showing how it was done, that's not a good idea," according to Boone, who says the same advice applies to other types of medical evidence as well. "I've preached to clients for 20 years that they cannot give up their only copy of an X-ray, but they continue to do it. If the X-ray you're handing to the patient absolutely saves your bacon, it's going to disappear from the face of the earth and you'll never see it again. If it proves you're at fault, you'll see it blown up 8-feet tall and 4-feet wide and projected on the courtroom wall." ■

Safe practices approved to help reduce medical errors

The National Quality Forum (NQF) announced recently that it had approved 26 "safe practices" that should be universally utilized in health care to reduce the risk of adverse events. Four additional practices will continue to be evaluated and may be approved in the coming months.

The report identifies 26 safe practices in five specific categories: promoting a culture of safety; matching health care needs with service delivery capabilities; facilitating information transfer and clear communication; adopting safe practices in specific clinical settings or for specific processes of care; and increasing safe medication use. The report also identifies 27 practices that have great promise for reducing adverse events and should have high priority for further research.

The big 26

These are the National Quality Forum's 26 safe practices:

1. Create a health care culture of safety.

2. Specify an explicit protocol to be used to ensure an adequate level of nursing based on the institution's usual patient mix and the experience and training of its nursing staff.

3. Verbal orders should be recorded whenever possible and immediately read back to the prescriber — i.e., a health care provider receiving a verbal order should read or repeat back the information that the prescriber conveys to verify the accuracy of what was heard.

4. Use only standardized abbreviations and dose designations.

5. Patient care summaries or other similar records should not be prepared from memory.

6. Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion.

7. Ensure that written documentation of the patient's preference for life-sustaining treatments is prominently displayed in his or her chart.

8. Implement a computerized prescriber order entry system.

9. Implement a standardized protocol to prevent the mislabeling of radiographs.

10. Implement standardized protocols to prevent the occurrence of wrong-site procedures or wrong-patient procedures.

11. Evaluate each patient undergoing elective surgery for risk of an acute ischemic cardiac event during surgery, and provide prophylactic treatment with beta-blockers to high-risk patients.

12. Evaluate each patient, upon admission, and regularly thereafter, for the risk of developing pressure ulcers. This evaluation should be repeated at regular intervals during care. Clinically appropriate preventive methods should be implemented consequent to the evaluation.

13. Evaluate each patient, upon admission, and periodically thereafter, for the risk of developing deep-vein thrombosis (DVT)/venous thromboembolism (VTE). Utilize clinically appropriate methods to prevent DVT/VTE.

14. Utilize dedicated antithrombotic (anticoagulation) services that facilitate coordinated care management.

15. Upon admission, and periodically thereafter, evaluate each patient for the risk of aspiration.

16. Rigorously adhere to effective methods of preventing central venous catheter-associated bloodstream infections.

17. Evaluate each pre-operative patient in light of his or her planned surgical procedure for the risk of surgical site infection, and implement appropriate antibiotic prophylaxis and other preventive measures based on that evaluation.

18. Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure, and utilize a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.

19. Evaluate each patient upon admission, and periodically thereafter, for risk of malnutrition. Employ clinically appropriate strategies to prevent malnutrition.

20. Whenever a pneumatic tourniquet is used, evaluate the patient for the risk of an ischemic and/or thrombotic complication, and utilize appropriate prophylactic measures.

21. Decontaminate hands with either a hygienic hand rub or by washing with a disinfectant soap prior to and after direct contact with the patient or objects immediately around the patient.

22. Vaccinate health care workers against influenza to protect both them and patients.

23. Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise.

24. Standardize the methods for labeling, packaging, and storing medications.

25. Identify all "high-alert" drugs (e.g., intravenous adrenergic agonists and antagonists, chemotherapy, anticoagulants and antithrombotics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, narcotics, and opiates).

26. Dispense medications in unit dose or, when appropriate, unit-of-use form, whenever possible. ■

Critically ill kids most likely to suffer from drug errors

The most seriously ill children are more likely than other youngsters in the hospital to experience drug mistakes, according to new research released at the same time as new guidelines on how to avoid such errors with children.

Very sick children also more likely to be involved in "near misses" with medication administration, the research says in a recent

article in the *Archives of Pediatric and Adolescent Medicine* (2003; 157:60-65). The research suggests that the errors may occur because ill children receive more medications, and are not the reason why the children are the sickest in the hospital, as some studies have suggested.

Contrary to some previous reports, researchers led by Mark T. Holdsworth, MD, from the University of New Mexico in Albuquerque, concluded that adverse events related to medications are not the reason seriously ill children are so sick. Previous studies suggesting that medication errors kept children in the hospital were designed poorly, the researchers said.

Why the risk increases

After analyzing data from 992 children admitted to a large metropolitan hospital one or more times between Sept. 15, 2000, and May 10, 2001, the researchers found that adverse drug events occurred in 6% of hospital admissions and potential adverse drug events occurred in 8% of admissions. Seventy-six adverse drug events that occurred, and 18 were considered to be serious or life-threatening. Four of the cases resulted in major or permanent disability.

The risk of adverse drug events increased as the child's disease severity and medication exposure increased. To reduce the likelihood of drug errors in young patients, the United States Pharmacopeia (USP) recently offered a set of recommendations. USP's Center for the Advancement of Patient Safety (CAPS) created the recommendations after analyzing medication error data from its databases.

Pediatric care vs. adult care

Many of the errors relate to specifics of pediatric care vs. adult patient care, says **Diane Cousins**, RPh, vice president of CAPS at USP. Pediatric medication errors often can occur, for example, when a decimal point is misplaced in a medication dose or an incorrect weight conversion from pounds to kilograms is made. Health care practitioners must consider a child's age, weight, medication dosing frequencies, and a number of other factors to help ensure the safety of young patients.

In December 2002, USP released an analysis of medication errors captured in 2001 by MEDMARX, the anonymous national reporting database operated by USP. Of the 105,603 errors documented by MEDMARX, 3,361 errors, or 3.2% of total errors, involved pediatric populations (birth to 16 years). Although the vast majority of errors were corrected before causing harm to the patient, 190 errors, or 5.7% of total errors, resulted in patient injury. Of this number, 156 resulted in temporary harm to the patient and required intervention, 31 required initial or prolonged hospitalizations, one required intervention to sustain life, and two errors resulted in a patient's death.

"The risk to the patient can be minimized when using technology to help calculate a dose," Cousins says. "In fact, human factors engineering approaches suggest that accurate, repeated calculations involving multiple steps are better performed using computer-based algorithms. Pre-printed and pre-calculated dosing guidelines can and should be readily available for staff use and verification."

Here are the USP's recommendations:

- Dosage forms and/or preparations that are compounded, prepared in serial dilutions, and/or extensively manipulated should be prepared in the pharmacy and verified by a pharmacist. Where possible, a second health care professional familiar with dilutions and compounding should verify the product preparation and labeling.
- Policies and procedures should be developed and implemented when automated dispensing machines are being used for pediatric medications, including double independent verification of medications loaded into the machines and the inability to override system safeguards.
- When possible, medications should be prepared and dispensed as "unit-dose" containers for all pediatric medications in all health care facilities.
- Liquid medications dispensed in the outpatient setting should be dispensed with appropriate measuring devices and instructions for use. When possible, use of the measuring device should be demonstrated to the patient/caregiver.
- The prescription order should be reviewed by a health care professional for appropriateness and dosage accuracy using the patient's weight, age, and other appropriate dose indicator(s) before dispensing and administering each dose and/or refill for pediatric patients.
- The patient's weight, age, and other appropriate dose indicator(s) should be available and clearly identified on all prescriptions and orders before the dose is dispensed and administered.
- Wherever possible, pediatric dosages should be calculated by a validated computer algorithm as part of an integrated medication order-entry

system. Calculations, whether computerized or manual, should be independently double-checked by a pharmacist and signed off by at least one other licensed health care professional to confirm accuracy.

• Abbreviations, acronyms, and symbols used throughout an organization should be standardized and readily available. A list of abbreviations, acronyms, and symbols that should not be used should also be available.

• To prevent tenfold overdoses, a terminal or trailing zero should never be used after a decimal. A leading zero should always precede a decimal expression of less than one.

• In all health care settings, patients, parents, and/or caregivers should be provided verbal and written information about the pediatric patient's medication, the common side effects, and the adverse events that should be reported to a health care professional. ■

OR nurse group urges reporting of surgical errors

Recent news reports of patients who lived for months with surgical items mistakenly left in them has spurred the Association of periOperative Registered Nurses (AORN) to urge that such incidents be reported to the national system it has set up to record such errors.

"The articles reported that surgical teams accidentally leave clamps, sponges, and other instruments inside about 1,500 patients nationwide each year," according to a statement issued by the group. "While the number of these errors is very small compared to the number of surgical procedures performed, it is, nevertheless, a critical safety issue."

Research suggests that some of the errors involving retained objects occurred because the appropriate guidelines were not followed, AORN says. AORN urges its members to put these patient safety guidelines into practice and to make sure that surgical facilities are following AORN guidelines. To track such errors and aid in the development of future guidelines, AORN recently developed Safety Net, a voluntary reporting system to capture data about close calls and near misses in the surgical arena. The data collected from nurses and other health care providers will be analyzed to serve as a basis for the development of new guidelines and educational programs to improve patient safety.

Information about surgical close calls initially will be collected only via the Internet at www.patientsafetyfirst.org/safetynet.htm. For more information about this resource, contact the AORN Patient Safety First Hotline at (866) 285-5209. ■

CE instructions

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

COMING IN FUTURE MONTHS

- Hospital's high-tech defense against medical errors
- Certificate of merit could curb lawsuits
- Underinsured docs put hospital at risk
- Bar coding on medications to reduce errors
- Choosing the right counsel

CE objectives

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

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

CE Questions

Please review the text, answer the following questions, check your answers against the key below, and then review the materials again regarding any questions answered incorrectly. To receive credit for this activity, you must return the enclosed CE evaluation in the enclosed envelope at the end of each semester. For further information, refer to the "CE Instructions."

This testing procedure has proven to be an effective learning tool for adults. If you have any questions about the new testing method, please contact customer service at (800) 688-2421.

9. According to research by Glenn Flores, MD, most translation errors occur in which category?
A. Addition
B. Substitution
C. Editorialization
D. Fabrication
E. Omission

10. Errors made by ad hoc interpreters were more likely to have potential clinical consequences.
A. True
B. False

11. California's Medical Injury Compensation Reform Act of 1975 (MICRA) is said to be the reason physicians' insurance premiums in California have risen by only 167% since 1975, while physicians in the rest of the country have seen their premiums increase by ____.
A. 214%
B. 360%
C. 480%
D. 505%
E. 712%

12. MICRA caps noneconomic damages for mal practice lawsuits in California. Identify the cap.
A. $100,000
B. $250,000
C. $400,000
D. $550,000
E. $1 million

Answers: 9-E; 10-A; 11-D; 12. B.

HIPAA Regulatory Alert

INSIDE

MARCH/APRIL 2003

VOL. 1, NO. 2
(pages 9-16)

Fear, anxiety, frustration, and anger on the HIPAA road

OCR should improve HIPAA responses, report says

There is "an extremely high level of confusion, misunderstanding, frustration, anxiety, fear, and anger" in a broad range of people and organizations as the April 14 compliance date for the Health Insurance Portability and Accountability Act (HIPAA) privacy rule nears.

That's the finding of the National Committee on Vital and Health Statistics, a statutory public advisory body to the secretary of Health and Human Services (HHS) in the area of health data and statistics.

The 18 private-sector individuals on the committee have, according to HHS, distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based health research, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services.

In a letter to HHS Secretary Tommy Thompson after three public hearings sponsored by the committee to learn about implementation activities of entities covered by HIPAA, the group said that despite widespread support for the goals of HIPAA and the privacy rule, there are many problems still to be resolved and not much time in which to address them.

The letter suggests that the HHS Office of Civil Rights (OCR) and the Centers for Medicare & Medicaid Services (CMS) improve their coordination of education, outreach, and technical assistance by working more closely with different industries, states, and federal health care programs.

In particular, it said, OCR should improve its responses to HIPAA-related questions and enhance its web site to help explain the compliance process. And, it said, HHS should recommend that Congress provide financial assistance, through grants, increased reimbursements, and incentives for providers struggling to comply with HIPAA.

OCR guidance faulted

The committee reported that many witnesses at the hearings said they viewed OCR as not providing adequate guidance and technical

assistance. In particular, they "lamented the lack of model notices of privacy practices, acknowledgments, authorizations, and other forms.

"Many witnesses also complained that general guidance was of limited value because of their special industry or professional circumstances. Witnesses conveyed a great sense of frustration that they could not obtain any clarifications from OCR or answers to the questions they submitted via OCR's web site."

Pre-emption issues made compliance difficult

Many witnesses indicated to the committee that issues of pre-emption made compliance much more difficult, costly, and complicated. To determine whether state privacy laws or the HIPAA privacy rule applies to many health privacy issues, covered entities have to obtain a comprehensive pre-emption analysis detailing whether state or federal laws apply.

The committee said the analyses often are lengthy documents that are expensive to research, highly technical, and not binding on any enforcement agency or the courts. Large, multistate covered entities need to have an analysis for every jurisdiction in which they do business, and there is no national coordination on the issue of pre-emption, and state and local efforts vary widely in their degree of completion and the cost to obtain copies. A related issue, the committee said, involves conflicts and overlaps between HIPAA and other federal laws dealing with privacy.

Based on testimony at the hearings, the committee declared that "the lack of clarity on compliance responsibilities, the unavailability of free and authoritative model forms, and the absence of widely available training materials have left many covered entities lacking the wherewithal to come into compliance."

Small providers giving up

Several witnesses told the committee that less than half of all small providers had made any effort to comply with the privacy rule and that some have no intention of trying to comply.

"One witness reported that some rural providers have given up on compliance and adopted the position that 'I can't do this; let them catch me,'" the letter says. "Even more troubling are the potential adverse effects on the health care system. Some witnesses said that some Medicaid and other safety net providers may drop out of the system of providing care to indigent patients because they cannot afford to absorb the costs of complying with the privacy rule, and there is no way to pass along the costs."

The committee also cited witnesses' fears surrounding HIPAA. Many expressed concern about the possibility of overzealous enforcement by OCR and private lawsuits, both of which were expected to be costly to defend.

Other witnesses said that fear of violating HIPAA has resulted in negative health outcomes, including providers refusing to share patient medical information that would be helpful in treating another patient, and a decline in mandatory or permissive reporting of essential health data to public health agencies, tumor registries, and other entities.

Another key area in the remaining months will be training, the committee said. "Millions of health care workers will need to be trained in

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

Subscriber Information

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

Subscription rates: Free to subscribers of *Healthcare Risk Management* and *Hospital Access Management*. For nonsubscribers, the price is $149. U.S. possession and Canada, add $30 plus applicable GST. Other international orders, add $30. (GST registration number R128870672.) Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. **Back issues**, when available, are $48 each.

Managing Editor: **Russ Underwood**, (404) 262-5521.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Coles McKagen**, (404) 262-5420, (coles.mckagen@ahcpub.com).
Production Editor: **Nancy McCreary.**

THOMSON
AMERICAN HEALTH CONSULTANTS

Editorial Questions

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

the next few months, but there is a shortage of expertise, materials, and funding. Overwhelmingly, witnesses said that generic training will not work; to be successful it must be customized by industry, entity, and job description.

In addition, consumers have received virtually no information about HIPAA, and it will be difficult for them to understand the basis or context for the myriad notifications, authorizations, and other forms with which they will soon be presented. Public education is complicated by consumers' varying levels of education, cognition, and language proficiency."

The committee said it is aware of the limited resources available to the department, and urged that as much as possible be given to OCR so it can accomplish the massive technical assistance, outreach, and education efforts needed in the coming months to ensure successful privacy rule compliance efforts.

(Editor's note: Download hearing testimony and other materials from the committee's web site at www.ncvhs.hhs.gov.) ■

HIPAA deadline looms: Is your facility ready?

If you're not moving, start

On April 14, covered entities under HIPAA are expected to be in compliance with the new Standards for Privacy of Individually Identifiable Health Information.

"This implies that you have to have trained people in what the policies are," explains **Larri Short**, Esq., of Washington, DC-based Arent Fox, which serves as counsel to the Atlanta-based American Association of Occupational Health Nurses (AAOHN) on HIPAA matters. "Also, you have to begin giving all defined [privacy] rights by April. As an example, AHA's [American Hospital Association's] model notice is 12 pages long — and you have to actually say what you as an organization intend to do."

That being the case, by this time, it would have been prudent to have thought through the regulations, taken a good first stab at appropriate new policies and procedures, and thought of framing what you need to do to make all of this really happen. "If not, you need to move forward as fast as you can to assess the situation and develop policies," Short advises.

Not all-encompassing

The new requirements are not entirely as broad as some might fear. "You only have to apply these requirements to data that can reasonably be linked back to a person," Short explains. "If the information is aggregated, you don't have to worry about it."

In the occupational health context there will be some providers — be they nurses or physicians — who will not be subject to the new regulations, depending on where they work. The three categories of covered entities are health care clearinghouses, health plans, and health care providers. Commercial health insurers, HMOs, and government-funded health care programs such as Medicare, Medicaid, and Tricare are health plans under HIPAA, says Short.

"More occupational health physicians are likely to work in an environment where the rule will apply to them than nurses, but the construct is the same for both," says Short. "Plus, if you don't engage in standard transactions, i.e., filing health claims, coordinating benefits, checking claim status, electronically, the rule doesn't apply to you."

In essence, Short explains, the new regs break down into three major pieces:

- **How providers handle information.** Covered entities are required to have permission to use or disclose individual patient information. It can come in the form of written permission from the patient or, in some cases, it can come in the form of regulatory provisions that allow you to use and disclose information for a designated list of pubic policy issues. Examples would be a response to judicial demands, or to law enforcement.
- **Patient privacy rights.** The use of information will be restricted to the "minimum necessary" to accomplish the purpose at hand, which maximizes patient privacy. "For the first time at the federal level, we have a set of privacy rights for the patient," says Short. "Every patient has the right to access his or her own medical information. You have the right to have your health care provider give you a notice to explain how they are going to use your information."

Some of the rights outlined in the new standards are only a right to *ask;* for example, if an

employee is not happy with what the employer says it will do with the information, the provider can say they can't accommodate the request. If the employer agrees, however, it is then bound to do so.

• **Privacy compliance program.** Covered organizations must appoint an individual who will be responsible for making sure it deals with the first two pieces of the new standards. There are to be written policies and procedures that can be surveyed and, where feasible, technical safeguards and access controls are to be put in place. [The Centers for Medicare & Medicaid Services (CMS) sends surveyors for institutional Medicare providers.]

Outside help available

If you do not have the in-house expertise necessary to bring your facility into compliance, there are a wide variety of resources available, says Short. "You can look to the Office of Civil Rights web site, retain attorneys or consultants, or attend workshops," she suggests.

For example, AAOHN's web site (www.aaohn.org) offers a series of workshops on the topic. There are a number of sources on the Internet as well. "The HHS [Department of Health and Human Services] site [www.hhs.gov/ocr] provides lots of links," Short adds.

The good news is that enforcement will be "kinder and gentler" than it is for some other government regulations, she adds.

"The government will 'seek to achieve voluntary compliance,' with punishment as a last resort," Short explains.

In other words, if all of your preparation is not completed by April 14, you should simply attempt to get it done as soon as possible. "As long as you are cooperative and have made a sincere effort, I don't expect you to get really slammed unless you work in an organization that was certified to participate in Medicare," she adds.

Such organizations are subject to some risk outside of HIPAA through CMS; if they do not meet certain quality standards, reimbursements could be threatened.

[For more information, contact:

*• **Larri Short**, Esq., Arent, Fox, Kitner, Plotkin & Kahn, PLLC , 1050 Connecticut Ave. N.W., Washington, DC 20036. Telephone: (202) 775-5786. E-mail: short.larri@arentfox.com. Web: www.arentfox.com.]* ■

HIPAA Q & A

[Editor's note: This is the first in a series of periodic columns that will address specific questions related to implementation of HIPAA. If you have questions regarding these areas or others, please send them to Russ Underwood, HIPAA Regulatory Alert, *American Health Consultants, P.O. Box 740056, Atlanta, GA 30374. Fax: (404) 262-5447. E-mail: russ.underwood @ahcpub.com.]*

Question: What are the deadlines for compliance with the HIPAA rules?

Answer: There are three sections of HIPAA, each with its own deadline, says **Michael R. Callahan**, partner and head of the HIPAA section for Katten Muchin, a Chicago-based law firm. "April 14, 2003, is the deadline for complying with the privacy rule, and Oct. 15, 2003, is the date to be in full compliance with the transaction code sets," he says. The security rules still are up in the air; and at press time, they had not received final approval. Once approved, providers have two years to comply with the security rules, he adds.

"The difficulty with the unapproved security rules is that many of the security requirements overlap with privacy requirements, such as development of passwords to protect electronic patient information," Callahan points out. This overlap means that an organization must implement some security measures along with privacy measures, he explains. Many organizations are basing their policies and implementing new activities based upon the proposed security rules and hoping they don't change significantly, he adds.

Question: Who must comply with HIPAA?

Answer: "Any health care provider, billing clearinghouse, or other vendor that submits claims electronically must comply with HIPAA," Callahan says. Even if you don't handle everything electronically, if any part of your process is electronic, such as verifying coverage, you must implement measures to meet HIPAA requirements, he adds. For example, if your program

submits claims information on paper to a billing company that subsequently files claims electronically, your program must comply with the standards.

Question: How do I assess my readiness for the privacy requirements?

Answer: Start by looking at all of your policies and procedures to see which already comply with HIPAA, says Callahan. Depending on your organization's resources, this step can be accomplished externally with a consultant or internally, he says.

"Many state associations and trade associations have posted information on the Internet to help hospitals and other providers review their HIPAA readiness," he says.

Compare your state regulations to the HIPAA requirements, he suggests. Many state trade associations have undertaken this task to help their members, he says. "In Illinois, we had to go line by line through 324 state statutes and regulations and compare them to HIPAA," he points out.

"Be sure your records are linked in such a way that you can find any and all information related to billing, medical treatment, and claims filings. You must be able to pull together all of the information . . . within 30 days."

The good news is that most state regulations are more stringent than HIPAA requirements. "If the state requires more than HIPAA, you follow the state requirements," says Callahan.

As you go through your assessment, be sure to look not only at your policies, but at your actual practice as well, suggests Callahan. "We're finding that most problems are related to sloppiness," he says. The most typical problems in hospitals are:

- **Medical records sitting on a desk or countertop in an area that is open to public traffic.** Records can be left in a designated place for physicians to sign or to enable easy access for nurses, but they must not be left in an area in which nonhealth care providers travel.
- **Computer monitors that display patient information are positioned so that people in the reception area can see them.** Turn your monitors or rearrange desk areas so that only the employee can see the information.
- **A scheduling whiteboard that includes patient names, procedures, or surgeons, on which nonhealth care providers can see names.** Make sure this information is placed in a location that is seen only by appropriate health care personnel.
- **A sign-in sheet contains not only the patient's name but also some other identifier such as procedure or reason for coming into the facility.** Sign-in sheets are fine, as long as they don't contain other information that is related to the patient's medical history, Callahan points out.

As you review your HIPAA readiness, remember that patients may come to you and ask for an accounting of how their protected health care information was used and to whom it was given, says Callahan.

"Be sure your records are linked in such a way that you can find any and all information related to billing, medical treatment, and claims filings," he says. "You must be able to pull together all of the information, along with the log sheet showing how the information was shared, within 30 days."

This requirement means that you may have to find parts of records in radiology, laboratory, pharmacy, quality assurance, accounting, and any number of other areas, he says. You also want to work with your information technology department or consultant to make sure additions can be made easily to the record, because Callahan points out, "In addition to giving the patient the right to inspect records, the patient also may amend the record, so make sure you have that capability in place."

Question: Does the signed acknowledgement of notification of privacy rights have to be a separate form?

Answer: "Home health agencies are extremely concerned about the amount of paperwork that patients must review, and in some cases, sign, especially during the initial or admission visit. Agency staff members are acutely aware that patients and/or their family members often are ill, tired, in pain, afraid, and worried during the initial visit," says **Elizabeth E. Hogue**, Esq., a home health attorney in Burtonsville, MD. This means that reviewing and signing multiple forms is quite burdensome to many patients, she adds.

The revisions to the final privacy regulations of HIPAA generally require patients to sign an acknowledgement that they have received an

agency's notice of privacy rights at the first service delivery, Hogue points out. Because this is yet another form that patients must sign upon admission, many agency managers would like to include the acknowledgement along with other consent forms so that patients only have to sign once, she says. As long as your process is consistent with the final privacy regulations, you may include the acknowledgement required by HIPAA in a form along with other items, she says.

Here is what the revisions to final regulations published in the Aug. 14, 2002, *Federal Register* say on this subject:

"The department also agreed with commenters that the notice acknowledgement process must be flexible and provide covered entities with discretion in order to be workable. . . . The rule requires only that the acknowledgement be in writing and does not prescribe other details such as the form that the acknowledgment must take or the process for obtaining the acknowledgment.

"For example, the final rule does not require an individual's signature to be on the notice. Instead, a covered health provider is permitted, for example, to have the individual sign a separate sheet or list, or to simply initial a cover sheet of the notice to be retained by the provider. . . . In addition, those covered health care providers that choose to obtain consent from an individual may design one form that includes both a consent and the acknowledgement of receipt of the notice.

"Covered health care providers are provided discretion to design the acknowledgement process best suited to their practices."

Question: What information can discharge planners give home health agencies without a patient's permission?

Answer: Because gathering complete and accurate information upon home health admission is important, many home health managers are concerned that HIPAA regulations will restrict the type and amount of information that can be given upon patient referral.

Not so, according to Hogue.

"Home care providers should not expect any change in the ability of discharge planners, social workers, or case managers at referral sources to share information with agencies about patients they want to refer once the HIPAA privacy regulations in effect on April 14, 2003," she says.

"First, this is because revisions to the final regulations allow providers to share information for treatment, payment, and health care operations without patients' consent or authorization," she says.

Since hospitals and long-term care facilities, for example, are required by Medicare conditions of participation to provide discharge planning services, sharing information to comply with this requirement may fall within this exception to the need for consent or authorization, she adds.

This same exception allows providers to share information with other providers for treatment and payment purposes, points out Hogue. This portion of the exception also may serve as the basis for sharing such information since the information is necessary for other providers to render services to patients, she adds.

Staff responsible for discharge planning may be concerned, however, about referrals to entities that their employers own or in which they have a financial interest, Hogue says.

Concerns may be based on the section of the revised final HIPAA privacy regulations that state that patients' authorization is needed for marketing purposes, she says.

"Because discharge planners are making referrals to other entities owned by their hospitals, they may be concerned that such referrals constitute marketing services that require authorization from patients," she explains. On the contrary, the revised final HIPAA privacy regulations make it clear that such activities constitute case coordination, not marketing, for which patients' authorizations are not needed, she adds.

"Anecdotally, we are already hearing reports of discharge planners who misunderstand the HIPAA privacy requirements," Hogue says. What should agencies do when the discharge planners in their hospitals misunderstand the above requirements?

"The best course of action may be to go to the designated privacy official within the organization to ask for clarification and communication with discharge planners," she suggests.

[For more information about compliance, contact:

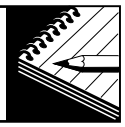
*• **Michael R. Callahan**, Partner, Head of HIPAA Section, Katten, Muchin, Zavis, Rosenman, 525 W. Monroe St., Suite 1600, Chicago, IL 60661-3693. Telephone: (312) 902-5634. Fax: (312) 902-1061. E-mail: Michael.Callahan@kmzr.com.*

For resources on compliance, contact:

*• **The Department of Health and Human Services' Office of Civil Rights** has released a new guidance document to address frequently asked questions*

about the medical privacy rule. Web: www.hhs.gov/ocr/hipaa/privacy.html.

• ***Workgroup for Electronic Data Interchange**, 12020 Sunrise Valley Drive, Suite 100, Reston, VA 20191. Telephone: (703) 391-2716. Fax: (703) 391-2759. Web: www.wedi.org.]* ■

GUEST COLUMN 

Make these changes to avoid HIPAA violations

By **Kathleen Catalano**, RN, JD
Director of Regulatory Compliance
Provider HealthNet Services
Addison, TX

If you don't comply with HIPAA privacy regulations, you may face civil penalties of up to $25,000 for each requirement violated, and criminal penalties of up to $50,000 and one year in prison for obtaining or disclosing protected health information.[1,2]

The regulations are not going to go away. They require a culture change on the part of each and every ED in the way care is rendered.

The best way to avoid problems with HIPAA is to objectively look at your own actions as you carry out your duties in the ED. Here are changes to make immediately:

• Never use a patient's health information inappropriately.

You may divulge only information that is necessary to diagnosis or treat the patient. For example, if a delirious patient tells you that he has just gambled away the family's life savings, when giving the report to the next shift, you would relay information about the patient's vital signs, delirium, and the fact that the patient was ranting and raving. The specifics of what were said would not be given.

In the past, a family would bring their aging mother to the ED and wait until the nurse came out to tell them about their mother's condition. That practice no longer will be acceptable. Now, as long as the patient is lucid and able to make the determination, he or she will be asked to designate a member of her family to receive updates.

What if the patient is not in a condition to designate someone? You can assume that it is very likely that the person accompanying the patient to the hospital did so at the patient's request and/or because of a relationship. For example, a husband brings his wife into the ED. His wife is unable to focus and seems confused. It is very likely that the wife would want her husband to be kept abreast of her condition. Again, you should provide only the minimal amount of information that is necessary.

• Don't allow others to hear confidential information.

Protection of health information is very difficult in the ED due to cramped space, lack of auditory privacy, and because of the crisis mode that seems to be the norm.

It is easy to forget that there is another patient on the other side of the curtain and that what you're saying is in all likelihood being overheard by many individuals. In many EDs, the patient rooms circle the nurses' station. Thus, if family members stand outside of the patient's room, they often can hear much of what is being said.

Do you talk about one patient when you're in the presence of another patient or the other patient's family? We forget about people overhearing our conversations because we are in the treating mode. As caregivers, we must get a patient's medication stat and there's not much time to think about hushed voices or whether someone is observing what we're writing.

Sit back, watch and listen. Do you hear staff talking about patients in an inappropriate manner?

If you overhear inappropriate statements, you can do several things. You could report it to your nurse manager or ED director, discuss it with the person making the statements, or call your compliance hotline and give a description of what occurred so that the issue will be addressed.

Protecting privacy

• Make sure that patient information is not visible to others.

You often can improve the privacy in your ED simply by changing the location of objects. Here are some examples:

— Computer monitors and fax machines. Can a patient's medical records be viewed by people who have no right to the information? If so, move the computer or monitor to conceal protected information.

If individuals other than caregivers can see documents being faxed, the machine should be moved.

— ***Documents at the nurses' station.*** Are papers such as the operating room schedule visible if you stand at the nurse's station? If so, keep materials in a closed folder or turn them over so they aren't visible for all to see.

• **Find a way to protect privacy at triage.** Do patients have vitals taken and an assessment performed in front of registration clerks? When the patient answers questions posed by the triage nurse, can the responses be heard throughout the ED lobby? A door or curtained windows are good solutions, but they need to be shut whenever a patient is being triaged.

• **Change the flow of traffic in your ED.** Think about the configuration of your ED. Is there a different way to route families and visitors so they don't hear and see everything that is occurring in the ED? See if you can change that flow. Just because it's never been done, doesn't mean it shouldn't be done.

[Editor's note: Catalano can be reached at Provider HealthNet Services, 15851 Dallas Parkway, Suite 925, Addison, TX 75001. Telephone: (972) 701-8042. Fax: (972) 385-2445. E-mail: Kathleen.Catalano@phns.com.]

References

1. 45 CFR §160.306 and §160.312 (2000) for Civil Enforcement.
2. 42 USC 1320d-6 (HIPAA Sec. 1177) for Criminal Enforcement. ■

URAC handbook explains HIPAA security rules

The lack of a final HIPAA security regulation means that your organization doesn't have to provide security for your patient data, right? Wrong, according to a new handbook published by URAC. Your organization already has to protect patient data under HIPAA privacy rule, the book points out.

HIPAA Handbook: What Your Organization Should Know About the Federal Security Rule is the third in a trilogy of books published by URAC focusing on HIPAA.

The book was issued to help the health care industry cope with the uncertainty surrounding the HIPAA data security regulation. It includes explanations and strategies by the national's leading experts for meeting security requirements under HIPAA.

"The health care industry has been waiting for years for the final HIPAA security standard to be published. Nevertheless, regulators of all stripes believe that data security is good business practice and health care entities should not wait for the regulation," says **Dennis Melamed**, lead editor and author of the handbook.

The most recent publication is $65 and is available through the URAC web site at www.urac.org. The trilogy of HIPAA books is $175. ■

Correction

In the January/February issue of *HIPAA Regulatory Alert*, the article "How to draft documents for HIPAA implementation" incorrectly stated that "a provider with a direct treatment relationship must have patient consent in order to use or disclose protected health information for treatment, payment, or their own health care operations." Under the final rule, such consent is not mandatory. ■

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

Adverse drug reaction leads to death and an $830,000 verdict in Kentucky

By **Jan Gorrie**, Esq.
Buchanan Ingersoll Professional Group
Tampa, FL

News: A 59-year-old man was admitted to the hospital for elective angioplasty. Ten hours after surgery, he experienced a severe adverse reaction to anti-clotting medication and suffered intracranial bleeding. He had a seizure, went into a coma, and died one week later. The patient's estate brought suit against the cardiologist and the hospital for negligence. While the doctor was exonerated, the hospital was found liable, and the jury awarded the plaintiff $830,000 in damages, which included $100,000 for the widow's loss-of-consortium claim.

Background: The 59-year-old patient had a family and personal history of cardiac disease. Shortly after being re-elected to a second term as sheriff, he underwent elective angioplastic surgery. The procedure began in the early evening and concluded, with some minor complications, around midnight. Following surgery, the cardiologist ordered the drug ReoPro, a blood thinner for preventing post-surgical blood clots, for the patient. In a very small percent of patients, ReoPro causes a potentially fatal reaction called thrombocytopenia, an extreme decrease in blood platelets. To avoid this, the ReoPro package insert indicates that within two to four hours after receiving the medication, patients should be tested to monitor their platelet count.

In this case, it was five hours after ReoPro was administered that the hospital ran a routine blood test. By the time test assay results were completed and posted, it was around 8 a.m. Over the course of eight hours post-surgery, the patient's blood platelet count had dropped to 12,000 when the normal and expected level ranges from 150,000 to 390,000. The lab reported the results to the patient's nursing station and labeled the results "panic level." The data was not appreciated as an emergency and staff did not mobilize a response. It was not until another hour and 45 minutes had passed, at 9:45 a.m., that the lab result was finally recorded by the medical staff, but the results still were not acknowledged as a crisis situation. Coincidentally, also at around 9:45 a.m., the sheriff experienced a seizure related to post-surgical, intracranial bleeding. He went into a coma and died one week later.

The plaintiff's estate brought suit against the cardiologist and hospital. The plaintiff claimed the doctor should not have initiated the surgery so late in the evening, when the full complement of support staff was not available. The plaintiff also claimed the cardiologist was negligent in not issuing a STAT or timed order to test the patient's blood platelet level in conjunction with prescribing ReoPro, as recommended in the prescription drug's package insert. The plaintiff claimed that if the blood test had been performed in a timelier manner, the condition would have been discovered hours sooner and the resulting intracranial bleeding and subsequent seizure, coma, and death could have been averted.

As to the hospital, the plaintiff alleged that staff committed an unwarranted delay in testing the blood platelet level in direct violation of a policy issued just months before the incident. According to the hospital's standard order, once ReoPro was administered, staff should have tested the patient's blood platelets in keeping with the prevailing medical literature's recommendations and cautions. The plaintiff also alleged that once the testing was complete, the hospital failed to appropriately transmit the results to the nurse's station.

The plaintiff maintained that the decedent could have been effectively treated until 6 a.m. Had the patient's blood had been drawn in a timely manner, the plaintiff alleged, four hours after the ReoPro was administered and tested after five hours, by 5 a.m., the life-threatening problem identified by the lab could have been recognized and properly addressed by the nursing staff and physician.

In the providers' defense, affirmative proof was introduced showing that proper staffing and adequate procedures were available to deal with the patient's complications the evening of the surgery as well as on the patient's unit the morning after. The defense argued that the etiology of the intracranial bleeding was complex and not related solely to the adverse reaction to ReoPro. Evidence presented by the hospital indicated that the intracranial hemorrhage was apparent prior to the patient's seizure. There was further defense proof that the patient's multicentric bleeding was extremely rare. The defense minimized the impact of the delay in testing the patient's blood platelets, noting that if the platelet count had been the only complication, it could have been successfully handled despite the delay. The defense also emphasized the decedent's underlying multisystem physiological problems leading up to the need for surgery, including other neurological and cardiac problems, as well as natural aging patterns.

The jury returned a defense verdict in favor of the cardiologist, but assessed $830,000 against the hospital. Damages included $100,000 to the sheriff's widow on her claim for the loss of consortium.

What this means to you: While not all medication errors result in patient death or harm, the higher the number of errors, the higher probability of harm. Some hospitals and health care providers are implementing electronic prescription order-entry systems to address the human and financial tolls that medical errors can cause. Computerized systems have been shown to prevent medication errors and improve medical outcomes. Not only can the systems eliminate paper orders, which are often written illegibly, they can also check physician orders for problems such as incompatible medication and patients' drug allergies as well as highlight potential adverse reactions. If the hospital in this case employed such a system, it probably would not have precluded the patient from receiving the prescribed medication, but it might have further re-enforced the need for more stringent patient monitoring.

This case presents one such case where a medication incident, which resulted in a potentially treatable adverse reaction, ultimately contributed to the death of a patient. Given the likelihood of this facility being accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), this case probably resulted in a sentinel event report.

"Hopefully, this type of event does not occur on a routine or regular basis; and in light of the outcome — even if not required to be reported as a sentinel event to JCAHO (if the facility was not an accredited hospital) or state agency — risk management should do an analysis of the incident and determine what went wrong, why it happened, and what processes or systems need to be changed so that it will not happen again," says **Stephen Trosty**, JD, MHA, CPHRM, director of risk management consulting at APAssurance Corp. of East Lansing, MI. "While it is never possible to prevent all complications, incremental improvements can prevent errors and save lives. The risk manager's assessment should involve all persons involved in the care (or lack thereof) of the patient from the physicians to pharmacists."

Although the cardiologist thought that his day had ended after performing successful angioplastic surgery, his duties are not complete until the patient has been discharged. Though the physician was not found liable by the jury, "in this particular case, the physician should have noted in the chart the need for a blood test in two to four hours after administration of the drug ReoPro," Trosty says. "Because this drug is known for causing a potentially fatal reaction in some patients, the noted physician's order should have been written as STAT or timed. As a further precaution, he also should have mentioned to the nursing staff the importance of timely testing of the patient's blood and looking

at the results as soon as received as a backup reminder to be sure it was done. Extra care could have been taken by the physician in ordering the testing and in stressing the importance of an immediate review of results, considering the potential for a very serious negative outcome."

As for the action and reactions of the hospital's nursing and laboratory staff, "it would have potentially changed the outcome (for both the patient and hospital) if the hospital personnel would have followed their own existing standard order and policy," Trosty says. "The standard order called for timely blood platelet monitoring in compliance with the drug package insert, but this order was ignored. An assessment of why the standard order was not followed should be conducted in order to prevent future occurrences of noncompliance. Further, all staff should be trained in existing policies, procedures, and standing orders and have ready access to them. If this training had not occurred, steps should to taken to assess why it had not taken place; for it is extremely difficult to defend against not following one's own standing orders/policies particularly in light of the outcome.

"By way of example, this particular case demonstrates the need for hospitals to be sure they have policies for using ReoPro and to assure that the policies follow the drug insert. Just as there should be policies on all high-risk drugs relative to giving the drug, testing a patient after the drug is given, and reviewing lab test results in a timely manner, the same should be true for this drug. In addition, the pharmacy should be able to put a colored label or notation on high-risk drugs or drugs requiring special attention and/or testing. The use of colored labels by the pharmacy should be accompanied with training and educating of nursing and other affected departments as to what the different colors mean. With proper implementation, even labeling can make it easier and quicker for staff to know that certain drugs require special care or attention. Even without a color-coded system, it is important to be sure that all nursing units, lab, pharmacy, and other relevant patient care departments have a list of high-risk drugs used in the hospital, including drugs requiring special monitoring or testing; list(s) should be updated regularly, should be checked to be sure they are the same for all departments, and should be related to existing formularies. Unfortunately, in this instance, despite the lab's appropriate 'panic-level' labeling, the notice was not acknowledged once the results were delivered to the nurses caring for this patient," notes Trosty.

"Further, the lab should have a policy for prioritizing the testing of orders for high-risk drugs even if no STAT order accompanies the blood specimen. This can help the lab know that certain tests need to be run before others and the results returned to the floor or unit ASAP and flagged as emergent, if so determined by the testing processes. It can also indicate which drugs should have a follow-up call to the floor after test results are sent up. There should also be a policy on how quickly all lab test results are to be reviewed and recorded after received on floor/unit. Optimally, this policy should apply to standard testing, STAT testing and time-ordered testing, with appropriate times for review and recording of results for each type of test. In this case, once the blood sample was drawn, it took three hours for the tests to be run and posted, and so it is unlikely that it was recognized as urgent," adds Trosty.

Once high-risk medications are delivered and administered, monitoring, follow-up reporting, and communication become essential.

"The lab should have a mechanism to emphasize or stress panic level on a report. There should be a way to place panic level or other warning messages in bold print or large letters or even use a special color sheet for these lab results. This type of highlighting can help alert nursing or clerical staff to the fact that this result has to be reviewed and acted on immediately. The facility may also want to consider implementing a call-back system whereby lab personnel would call the floor or unit with panic levels lab results to be sure that these results are seen and responded to in a timely manner. Hospitals should try to have as many backup/safeguard systems in place as possible in an effort to prevent or avoid error. This will enhance your patient safety program. Policies should cover appropriate response to test results with panic levels and the need to immediately check all returned test results to determine if panic levels exist for a given patient. This should be standard operating procedure on all floors and units and for all nursing, clerical, and physician staff. The one hour-and-45-minute delay in acknowledging critical lab results, as occurred in this case, should be recognized as too long for any type of abnormal test results returned to the floor," states Trosty.

In addition to developing appropriate policies and procedures for handling high-risk

medications, "risk management should also look at orientation and inservice programs for nursing (including clerical staff), lab, pharmacy, physicians, and other related departments to be sure that they include information about high-risk drugs, STAT lab orders, returning and receiving lab results with panic levels, and labeling of high-risk drugs. Orientation and inservicing should address what the proper actions are in all of these instances. Inservice training can also be used to review identified problem and high-risk areas or areas in which existing policies are not being adhered to," says Trosty.

Policies and procedures are useless if not followed, and so "to ensure that existing policies are appropriate and are adhered to, the hospital can also conduct a root-cause analysis of this occurrence. This will enable them to review the systems and processes involved in the event and to identify any needed revisions. There should also be a quality improvement and/or peer review process for nursing, pharmacy, laboratory, medical staff, and all other clinical/patient care departments. Particular emphasis should be placed on addressing high-risk patients, high-risk drugs/meds, and high-risk procedures. Quality improvement/peer review can also help to identify actual or potential problems and allow for interventions to prevent the problems from occurring or reoccurring. The process should review systems and processes that are involved in the interaction between multiple departments or units, and should encourage analysis of issues/occurrences that cross or involve multiple departments or units," adds Trosty.

"To the extent possible, evaluations should be made in a nonpunitive and nonthreatening manner and should encourage involved personnel to determine what might be improved rather than cause them to defend their particular action department. The importance of establishing a culture that does not consist of trying to place blame if an adverse event occurs should not be underestimated; for the ultimate goal should be to develop a patient safety culture in which systems or processes that require improvement or revisions can be identified and addressed. A culture which tries to find the guilty party responsible for the adverse occurrence and then punish that person does not foster the atmosphere needed to get people to complete occurrence reports accurately and completely, or to honestly and fully participate in root-cause analysis or other efforts that examine systems and processes for required improvements or revisions," concludes Trosty.

Reference

- *Riley vs. Jewish Hospital and Raible,* Jefferson County, (KT) Circuit Court. Case No. 99 CI 5198. ■