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IN THIS ISSUE

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MAY 2006
VOL. 28, NO. 5 • (pages 49-60)

Rising number of obese patients pose special liability risks

You can't use excuse that extra large patients are a rarity

(Editor's note: This is part one of a two-part series on the liability risks associated with treating morbidly obese patients. This month, Healthcare Risk Management *explores the obligations to prepare for these patients. Next month's issue will detail how one insurer has provided specific guidelines to mitigate the risk.)*

The rise in bariatric surgery and the trend toward Americans getting ever larger is creating a new liability threat that risk managers must address proactively, according to warnings from several attorneys and health care leaders. These extra large patients can be difficult to manage without significant changes to equipment, staffing, and policies within your institution, and failure to make those accommodations can leave you on the wrong end of a lawsuit.

HRM wins national award for impostors coverage

The Society of Professional Journalists has awarded the coveted Mark of Excellence award to *Healthcare Risk Management* for its coverage of the incidents in which people posed as surveyors from the Joint Commission on Accreditation of Healthcare Organizations to gain access to hospitals across the country. **(See *HRM,* June 2005, p. 61.)**

An investigation by *HRM* revealed that the impostors most likely were terrorists planning attacks at some later date. The fake surveyors most likely were assessing the hospitals to determine their capacity for treating casualties from an attack, how to hamper the hospitals' response, or how to attack the hospitals themselves, according to security sources and terrorism experts.

This is *HRM's* second Mark of Excellence award. The newsletter also was honored for the 2001 coverage of a hospital's risk management efforts related to a television show taped on the premises. **(See *HRM,* November 2000, p. 121.)** ■

Extra large patients are showing up more often in emergency departments, surgical units, and practically every other area of a health care operation, reports **Stuart Hochran**, JD, MD, a practicing physician and an attorney with Garfunkel Wild in Great Neck, NY. If your organization participates in any bariatric surgery, the number of these patients and your obligation to accommodate them will rise accordingly.

"About 20% of all patients are now morbidly obese, and the majority of them are looking at the possibility of bariatric surgery," he says. "More hospitals are looking at bariatric surgery as a profit center, and smaller facilities are getting involved with that type of care. There's no question that the volume is increasing, the obligations are increasing, and the risk is increasing."

With the trend toward more bariatric surgery being done as outpatient procedures, the risk of these post-op patients showing up in your emergency department continues to grow. But bariatric surgery is not the only way you will see these patients in your facility. Hochran notes that any health care provider is likely to see morbidly obese patients on a regular basis, more often than would have been common in past decades.

Hochran recalls the years in which he worked as a physician with the New York Giants football team and had to have extra large blood pressure cuffs, stronger tables, and all types of super-sized medical equipment for players who were two or three times the size of an average person.

"Now we have to have that same equipment in a community hospital," he says. "These patients are in a world that doesn't fit them in many cases, so they can come to your hospital and you will find that the blood pressure cuffs don't fit, the gowns are nowhere near big enough to cover them, and the table falls over when you put them on it."

Even the most mundane items, such as wheelchairs, may not be adequate for extra large patients, warns **Carson Liu**, MD, the medical director for the Surgical Weight Control Center at Olympia Medical Center in Los Angeles. Liu has performed more than 900 bariatric surgeries. Another important consideration is imaging equipment, such as scanners that may not be wide enough to accommodate the patient's girth or strong enough to support the weight. Many scanner tables can hold only 350 pounds, he says.

"A very important concern is the risk to staff from having to lift these patients and move

EXECUTIVE SUMMARY

Health care providers are seeing more morbidly obese patients and must be prepared to accommodate their special needs. Failure to do so sets you up for malpractice lawsuits and violations of government regulations regarding disabilities.

- Extra large patients are common enough that most facilities must be prepared for them.
- Lack of adequate equipment is the most likely cause of an obesity-related lawsuit.
- The informed consent process must spell out the special risks these patients face.

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

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (ahc.customerservice@thomson.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), $495. Outside U.S., add $30 per year, total prepaid in U.S. funds. For approximately 18 CE nursing contact hours, $545. Discounts are available for multiple subscriptions. For pricing information, call Steve Vance at (404) 262-5511. 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 $87 each. (GST registration number R128870672.)

Healthcare Risk Management is approved for 12 nursing contact hours. Thomson American Health Consultants is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. This activity is valid 24 after the date of publication. Provider approved by the California Board of Registered Nursing, Provider Number CEP 10864, for approximately 12 contact hours.

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

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them around. Moving them on and off tables for surgery or moving their limbs when the patient is asleep can be much harder than with the typical patient," he says. "There is special equipment that you can use to help move overweight patients, but this is an area in which you risk staff injuries and workers' compensation costs if you don't address this."

Injuries to the patient or staff are likely if a hospital does not prepare for extra large patients, Liu warns. The expense is justified for most providers because sooner or later a morbidly obese patient will need care. If you are not prepared, you risk regulatory violations by sending the patient away or other liability if someone is injured. Some of the equipment is expensive, but "you have to weigh the cost of making these changes against the cost of a lawsuit or a workers' comp case," Liu says.

Less than standard of care?

Hospitals are obligated to provide the standard of care to all patients, and that includes obese patients, Hochran says. **(See p. 52 for more on how obese patients are protected under some government regulations.)** He recently represented an obese patient who was injured when a table collapsed under her weight, and the hospital settled the claim for an undisclosed amount.

Obese patients who receive less than the standard of care and are injured as a result may have a good case in court, says **Roy W. Breitenbach**, JD, a partner with Garfunkel Wild. With regard to malpractice risk, health care providers are found liable in malpractice cases if it is established that their treatment of a patient deviates from the ordinary standard of care in the medical profession, he says.

"To the extent that a medical malpractice plaintiff who is morbidly obese can show that the medical care he/she received fell below the ordinary standard of care — because of unavailability of specialized equipment — and the provider is the cause of this deviation, there may be medical malpractice liability," he explains. "Essentially, the plaintiff would need to have a qualified medical expert testify that it is the ordinary standard of care to have the equipment at issue in stock and at the ready to treat patients."

Hochran and Breitenbach caution that risk managers should not rely on the excuse that morbidly obese patients are a rarity and therefore you should not be held responsible when you were ill-prepared to accommodate them. That argument won't stand up to the statistics showing the number of obese Americans, Hochran says. These days, they are just too common to think they won't show up in your facility.

"And if you do bariatric surgery or allow physicians to do it at your hospital, you're inviting these patients into your facility; and that means you absolutely must be prepared for them," he says. "Juries will be sensitive to the need for accommodation, and courts are going to demand that you provide them care that is comparable to anyone else's care." **(For an account of one case in which a morbidly obese woman sued after a hospital could not accommodate her size, see the *Legal Review & Commentary* supplement in the March 2006 *Healthcare Risk Management*, p. 3. Three hospitals settled for $500,000, and a jury ordered the neurologist to pay $5.6 million.)**

SOURCES

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Assess equipment, policies with large patients

So what should a risk manager do to ensure extra large patients are well accommodated? An assessment of equipment, policies, and procedures is in order.

Failure to have adequate equipment on hand is the most likely way you could find yourself facing a lawsuit from an obese patient, Hochran says. Facilities should have equipment that can handle obese patients — everything from extra large blood pressure cuffs and longer needles that penetrate through fat layers, to beds specially made for big patients. **(See p. 52 for tips on how to accommodate obese patients.)**

Train staff to accommodate these patients and to be sensitive to their concerns, Hochran says. Staff should understand that obese patients often are embarrassed about their size and their special needs, he says. Staff should be careful not to make

any disparaging remarks or complain about having to accommodate the patient's size. Sensitivity training not only helps the patient feel less shame and discomfort while under your care, but it also helps avoid creating disgruntled patients who will react to any bad outcome by calling a lawyer, Hochran adds.

Avoid this 'serious mistake'

However, another major risk involves inadequate informed consent. Hochran says that health care providers can go astray with a well-intended effort to make these patients feel just like anyone else and avoiding the obvious issue of extreme obesity.

"The informed consent process should include a clear discussion of the inherent risks that come along with surgery or treatment on an obese patient, things like delayed wound healing, infections in folds of skin, circulation problems," Hochran explains. "It is a serious mistake if you try so hard to treat these patients like everyone else that you avoid talking about some of the serious health issues involved. They will not heal like a thin person will heal, and their complication rates are not the same." ■

Tips for working with large patients

The American Society for Healthcare Risk Management (ASHRM) in Chicago recommends that risk managers assess their organization's readiness for treating obese patients. In addition to equipment needs and changes in policies and procedures, clinical strategies must be adequate.

ASHRM's recommendations were compiled by **Ann Abke**, RN, ARM, FASHRM, a loss prevention specialist providing risk management support to Catholic Healthcare West's 42 hospitals in California, Nevada and Arizona.[1] These are

Obese patients covered under EMTALA, ADA

Hospitals and physician offices must accommodate obese patients or risk running afoul of the Emergency Medical Treatment and Labor Act (EMTALA), the Americans with Disabilities Act (ADA), or the Rehabilitation Act, cautions **Roy W. Breitenbach**, JD, a partner with Garfunkel Wild in Great Neck, NY.

Hospitals and physician offices are considered public accommodations for purposes of the ADA and, to the extent that hospitals or physician practices are Medicare or Medicaid participants, they also are governed by the requirements of the Rehabilitation Act, Breitenbach explains. Both of these federal statutes prohibit public accommodations or recipients of federal funds from discriminating against persons based on their disability — in this case, extreme obesity. These statutes also require that organizations make "reasonable accommodations" to disabled persons — such as changing policies or procedures, offering auxiliary aids or services, or providing adaptive equipment — that would enable them to receive the same services from the public accommodation that nondisabled people receive.

Breitenbach notes that for the last decade, the question of whether obesity is considered a disability for purposes of the ADA or the Rehabilitation Act has been hotly contested. The answer still is not certain, he says, but the trend is for courts to determine that obesity is a disability in many but not all cases.

"The trend of the cases holds that obesity, in and of itself, is not a disability, unless there is an identified physiological condition underlying and causing the obesity," he says. "If such a physiological condition is the cause of the obesity, then the obesity could be considered a disability if the condition significantly impacts a major life activity, such as walking or working."

Finding a physiological condition that contributes to the obesity is not a high hurdle, and Breitenbach notes that there is no way for you to know whether that condition is met when the patient first enters your hospital. Therefore, there is no way to know up front that certain obese patients are protected by the ADA and Rehabilitation Act. ■

some of the clinical risk strategies that ASHRM recommends:

• Vascular access may need to be assisted by ultrasonography.

• Physiologic response to analgesia and sedation may be different in the obese patient, so doses should be carefully calculated and titrated incrementally.

• For injections to be deposited intramuscularly, the location needs to be chosen carefully and the fatty subcutaneous layer compressed with one hand when using a 1.5-inch needle.

• Consult a pharmacist to determine whether dosing should be based on lean, ideal, or proportion of actual weight.

• Alert staff that management of the airway can be extremely difficult and problematic in that these patients desaturate (lose oxygen carried by hemoglobin in the blood) more quickly than nonobese patients. Formulate an airway management plan when first encountering the obese patient.

• Have "rescue" alternative airway devices readily available. Confirm endotracheal intubation by three or more methods, including caponometry or capnography.

• Monitor the patient for fatigue of respiratory muscles — hypercapnia may be increasing.

• Know the capacity of the facility's diagnostic radiology equipment. If unable to accommodate the patient in your facility, identify a facility in the area that has the capability. Develop a plan of action to expedite transfer to another facility for the tests if necessary and appropriate.

• If uncertain as to how best to adapt care to a problem, the patient may be the best one to make the determination. This is considerate and affords the patient some control over the situation. Simply ask the patient, "What works for you?" or "How has this been done for you in the past?"

• Assess equipment for weight limit, width, and length. This includes gurneys, side rail supports, gowns, linen, bedpans, commodes, blood pressure cuffs, wheelchairs, scales, walkers, bathroom doorframe, toilets, wall mounted grab bars, patient chairs, lateral transfer devices, door widths to ancillary departments, elevators (weight limits), ancillary department tables/gurneys, lifting devices, crutches, extension tubing for Foley catheters, and restraints.

Reference

1. Abke A. Strategies for risks presented by obese patients in the ED. *ASHRM Journal* 2005; 25:33-35. ■

Follow guidelines closely to avoid gainsharing trouble

(Editor's note: This is the second of a two-part series on the risks of gainsharing agreements and how to structure them safely. Last month's report discussed the potential danger, and this month's story explains how to make sure a gainsharing agreement is structured properly to reduce the risk.)

There has not yet been a major case illustrating the perils of poorly constructed gainsharing agreements, probably because everyone is so scared of the potential penalties that they go to great lengths to make sure everything is on the up and up, says **Barron Bogatto**, JD, a partner in the health care and business Transactions sections of Jackson Walker, a law firm in Houston. Bogatto says that's the right approach: Use extreme caution.

The penalties for violation of the statutes involved in gainsharing are substantial. In addition to exclusion from the governmental insurance programs, Bogatto notes that violations of the anti-kickback statute could include a felony with $25,000 fine or imprisonment up to five years, or both. Civil monetary penalties can include a $50,000 fine plus three times the amount of damages.

Stick to the guidelines, and make sure you dot every "I" and cross every "T" when entering into any gainsharing agreement. That's the advice from the experts who say straying off the well-marked path could result in serious liability for a health care provider.

Gainsharing agreements allow hospitals to have more say in what medical devices physicians use,

EXECUTIVE SUMMARY

Gainsharing agreements can pose serious liability risks, but much of the danger can be avoided by adhering to guidelines on how the agreements should be structured. There also are features to avoid.

- Agreements must be very specific.
- The agreements must ensure that any savings are valid and not the result of passing on costs to patients.
- Profits must be distributed to physicians on a per-capita basis.

EXECUTIVE SUMMARY

Kaiser Permanente is implementing a standardized preoperative briefing to encourage communication among team members. The system helps reduce errors and improves care, Kaiser officials say.

- Preoperative briefings are more than just a "timeout."
- The surgeon leads the briefing, but everyone participates.
- The briefing helps team members plan for contingencies.

which in turn yields savings by streamlining the purchasing process and focusing on items that are of the same quality but cost less. The financial benefits can be significant, but there is a risk of violating federal and state laws and regulations. For instance, the Federal Civil Monetary Penalty Statute imposes financial penalties upon hospitals that knowingly make payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries.

The federal Anti-Kickback Statute also prohibits anyone from knowing and willingly paying or receiving any payment for referring patients for the provision of items or services for which payment may be made under a federal health care program. And, the federal Self-Referral Law, commonly known as the Stark Law, prohibits physicians from referring Medicare and Medicaid patients for the provision of certain "designated health services" to an entity with which a physician has made a financial relationship.

The federal government has made clear that gainsharing can be acceptable as long as you follow certain guidelines, Bogatto explains. While the guidelines from the Office of the Inspector General (OIG) stem from consideration of specific gainsharing agreements, Bogatto says they can be applied to any proposed gainsharing arrangement. **(See p. 55 for a summary of the OIG guidelines.)**

"The OIG has under certain factual scenarios deemed certain safeguards sufficient to alleviate the risks it normally associates with such gainsharing ventures," he says. "Health care providers now have reason to believe that they can design certain limited gainsharing programs utilizing product standardization, which would be acceptable to the OIG, to incentivize their physician staff to work with them in order to appropriately hold down costs of patient care."

The OIG guidelines make clear that the government doesn't mind a provider saving money through gainsharing as long as you can prove that the agreement does not negatively affect patient care and may even improve it, says **David Winkler**, JD, a partner with Zumpano Patricios in Miami, FL. This is an area in which risk managers can make a significant contribution by ensuring that evidence is in the agreement, he says.

"You want to be able to show in a written policy that the reason you want people using this particular heart stent is that it's the best thing out there, and it has a proven track record of fewer complications," he says. "So the risk manager can provide the backup for these decisions concerning modification of physician behavior. The cost savings may come from fewer complications, or it might be that the stent is just cheaper than others, but you want to be able to show that this is the best thing for your patients, bottom line."

Risk managers must keep in mind that it is very risky to focus on how much money you can save with the gainsharing agreement without putting just as much effort into justifying why a certain medical product is best for your patients, Winkler says. Let other departments get excited about the cost savings, he says. Risk managers should look at the agreement in the same way as an OIG official and demand evidence that the agreement is safe for patients.

The OIG guidelines also state that any gainsharing agreement must be limited in duration and that any savings must be split with physicians on a per-capita basis, not based on how much that physician contributed. That guideline helps avoid situations in which as single physician is encouraged to cut corners so that he gets a bigger payoff from the gainsharing agreement, Winkler says.

"You also should tell patients what's going on," he says. "Have a letter that says, 'Because of quality-of-care issues and the need to provide cost-effective care, we utilize the following items.' And you can say that there are other treatment options available if they object."

In addition to offering the guidelines for how to structure an arrangement, the OIG outlined some features that can be problematic and therefore should be avoided. Bogatto says these are some potential problems that risk managers should watch out for in any proposed gainsharing agreement:

- There is no demonstrable direct connection

SOURCES

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between individual actions and any reduction in the hospital's out-of-pocket costs (and the corresponding "gainsharing" payment).

• The individual actions that would give rise to the savings are not identified with specificity.

• There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

• The quality of indicators is of questionable validity and statistical significance.

• There is no independent verification of cost savings, quality-of-care indicators, or other essential aspects of the arrangement. ■

Guidelines from OIG help make gainsharing safe

Barron Bogatto, JD, a partner in the health care and business transactions sections of Jackson Walker, a law firm in Houston, provides this summary of the gainsharing guidelines offered by the Office of the Inspector General (OIG). In order to pass muster with the OIG, a gainsharing agreement must meet these tests:

1. The specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the proposed arrangement would allow for public scrutiny and individual physician accountability for any adverse effects.
2. The parties provided credible medical support for the position that the implementation of the recommendations would not adversely affect patient care. Also, the implementations would be reviewed periodically to ensure they are not having adverse affects on clinical care.
3. The payments under the proposed arrangements were based on all procedures, regardless of the patient's insurance coverage, subject to a cap on payment for federal health care program procedures. Moreover, the procedures to which the proposed arrangements applied were not disproportionately performed on federal health care program beneficiaries. Also, the cost savings would be calculated on the hospital's actual out-of-pocket acquisition costs, and not an accounting convention.
4. The arrangements used objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the physician group.
5. The product standardization portion of the proposed arrangement further protected against inappropriate reductions in services by ensuring the individual physicians still would have available the same selection of devices after implementation of proposed arrangement as before such implementation. The proposed arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.
6. The hospital and the physician group would provide written disclosures of their participation in the proposed arrangement to the patients whose care may be affected by such arrangement. The patient also would be provided an opportunity to review the cost savings recommendations prior to admission hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure).
7. The financial incentives under the proposed arrangement were reasonably limited in duration and amount.
8. The profits were distributed to physician group members on a per-capita basis, thereby mitigating any incentive for an individual surgeon to generate disproportionate cost savings. ■

Pre-op safety briefings help reduce errors, improve care

Health care giant Kaiser Permanente is introducing the idea of a "preoperative safety briefing" to all of its facilities with the aim of encouraging more communication among surgical team members. Kaiser's preliminary experience with the concept suggests that the technique can help reduce adverse events, including sentinel events such as wrong-site surgery, and aid team members in preparing for contingencies during the procedure.

The preoperative safety briefing was modeled on a similar strategy used in the airline industry, explains **Douglas Bonacum**, MBA, vice president of safety management with Kaiser Permanente in Oakland, CA. Commercial pilots routinely go through a checklist and discuss the upcoming flight before the plane ever leaves the ground, he says, and now Kaiser wants operating teams to do the same thing before a scalpel ever touches skin.

A six-month trial of the system was so successful at Kaiser's Anaheim Medical Center in California that it is being implemented in all of the company's 30 hospitals across the country. The preoperative safety briefing pilot began in February 2002, and six months later the statistics showed that it had improved care at the Anaheim facility. The hospital went from three wrong-site surgeries in the year before the trial to zero during the trial period, Bonacum says.

The new system also has a positive impact on employee morale and perception of the hospital's overall safety, he says. During Anaheim's trial, employee surveys found there were a 19% increase in employee satisfaction and a 16% decrease in nurse turnover. Additionally, most employees' perceptions of the safety climate in the operating room increased from "good" to "outstanding" after implementation of the pilot.

During the trial, the operative teams caught a number of near-misses because of improved communication, says **James DeFontes**, MD, a Kaiser anesthesiologist who developed the preoperative safety briefings. Those near misses include missing blood products and instruments.

The preoperative safety briefing is an opportunity for all members of the surgical team to have a conversation about the upcoming surgery, reports Bonacum . Everyone in the room — the surgeon, anesthesiologist, scrub nurse, techs, anyone participating in the procedure — should participate.

"It's a time to share information that may be relevant to their teammates prior to surgery, a time to make sure everyone is on the same page," Bonacum says. This differs somewhat from the historical way of doing things in the operating room, which is to assume that each person is a subject matter expert and knows what they need to know for this surgery, he says. "That can still be true, but this method encourages them to share that information with others and see how that exchange might be useful," Bonacum says.

In introducing the idea to hospital staff and physicians, Kaiser used the analogy of an airline cockpit and pointed out that most of us have seen the pilots going through a checklist as we boarded a plane. Wouldn't that same level of communication be good for the operating room, DeFontes asked. And don't you all have some knowledge that could be useful to others?

Examples of the useful exchanges include the anesthesiologist who volunteers that there are certain risks to the patient's airway during this surgery and that the patient is considered high risk by the anesthesiologist even if he is not by the surgeon. That could lead to a discussion of how the team, together, can best manage that risk. Similarly, the surgeon may offer an overview of the exact technique he or she will use, what problems the patient has previously has in surgery, and any particular needs during the procedure.

"That's an opportunity for everyone else to realize that they may need to have a particular instrument or supplies ready, or be ready to respond to certain outcomes," Bonacum says. "They can spot supplies or additional staff they didn't realize they needed, and they can mentally prepare contingency plans."

DeFontes says preoperative briefings help everyone in the room function more as a team rather than individual experts. The culture of many surgery departments is such that people don't come together as a team until the first incision is made, and by then it's a little late for some information to be useful, he says.

"It's a chance for people to verbalize those little things that are on their minds," DeFontes says. "You said you wouldn't need blood, but are you sure? Is this procedure going to be an hour or hour and a half? Do you want the patient awake after surgery or asleep through the night?"

The briefing might include broad statements, such as the surgeon saying he is anxious about the procedure and concerned about the outcome. While not specific, that statement puts people on

(Continued on page 58)

SOURCES

For more information on the Kaiser Permanente safety briefings, contact:

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- **James DeFontes**, Anesthesiologist, Kaiser Permanente. E-mail: james.defontes@kp.org.

WHEN and WHERE?
In the operating room-post induction, precut regardless of anesthetic techniques. For local cases, the team meets before the patient is brought into the operating room.

The following tool has been developed as a guide for use during the Safety Briefing.

HUMAN FACTORS
Orange County Service Area
Safety Briefing

Surgeon	Circulator	Scrub	Anesthesia
•ID patient and site	•Identify patient site and marking	•What special instrumentation do we need?	•What type of anesthesia will be used?
•What type of surgery?	•Allergies?	•Are there any instruments missing from the tray?	•Risks?
•Realistic Time Estimate	•Verification of Medication on the back table	•Are all the instruments working?	•Should we anticipate any problems?
•What is the desired position?	•X-ray available and other special services, (i.e., X-Ray, Pacemaker, Cell Saver, Sales Rep, Laser)	•Do they have any questions about the instruments?	•Any special needs – positioning, medications?
•Any special equipment needed?	• Blood available?	•Do we have all the instruments?	•Special Lines driven by Anesthesia
•Is this a standard procedure or are there special needs?		*What type(s) of sutures or staples are needed	
•Are there any Anticipated problems?			
•Will we need pathology?			
•Is a Radiology C-arm or portable X-ray requested, and will it be needed?			
•Are there any special intraoperative requests, i.e., wake-up, hypothermia?			
•Plan to transfuse? "Wet versus Dry"			
•Use of drugs on the field?			
•Do you want lines?			
•Postop pain management-special request (CLE, blocks, etc.)			

Human Factors addresses the interpersonal skills generally implicated in adverse outcomes. It is about detecting threats to patient safety, avoiding errors, and managing in a team–based environment. In Orange County, the primary concept applied in the perioperative setting is the use of briefings similar to the pre-flight briefings in the aviation industry.

A Safety Briefing is an opportunity for team members to share pertinent information regarding the patient's care prior to and during the surgical procedure. This allows all team members to share the same mental model.

WHO participates in a Safety Briefing? There are 4 roles in a Safety Briefing, each equally important. A Safety Briefing is the responsibility of the entire team; however, the circulator is responsible for initiating the Safety Briefing.

WHEN & WHERE does a Safety Briefing occur? In the operating room-post induction, precut.

Source: Kaiser Permanente, Oakland, CA.

alert, DeFontes says. The briefings also help unify a team when the members have not worked together before and don't know each other's habits, preferences, and needs.

Kaiser provides a checklist of suggested questions for key team members but doesn't require that they do down the list and discuss each item. They questions are used more as a prompt for any issues that may be pertinent in the surgery at hand, Bonacum says. **(See p. 57 for an educational flier from Kaiser that includes the suggested questions.)**

Hospitals educate staff and physicians with a short classroom session and role-playing exercises, Bonacum says. The role playing is important because the discussions in a briefing don't come naturally to all team members, he says. The time away from work for the education sessions, usually no more than an hour per person, are the only expense in implementing the system. ■

Safety briefing held before any incision is made

The preoperative safety briefing in use at Kaiser Permanente hospitals always is held before any incision is made, but other than that direction, Kaiser leaves it up to individual hospitals to determine when to do it. The Anaheim facility conducted briefings after anesthesia was introduced, but some others are doing it with the patient awake.

Douglas Bonacum, MBA, vice president of safety management with Kaiser Permanente in Oakland, CA, notes that the latter method can involve the patient in the conversation, which is consistent with trends toward more patient involvement in their care.

The surgeon should lead the process, he says, because his or her position as captain of the ship gives the briefing credibility. As the team is finalizing preparations for the surgery, the surgeon gets everyone's attention and calls for a preoperative briefing. The surgeon usually begins by summarizing the case, identifying the patient by name, and stating what procedure will be one, what technique will be used, where the operative site is, and any other information that might be useful.

"Then he or she will turn to the anesthesiologist and ask for similar input, and then probably the scrub nurse, and so on around the room," Bonacum says. "This usually takes just a couple minutes total, though they can take as long as necessary if an issue comes up that needs to be discussed."

Kaiser already was developing its preoperative safety briefings when the Joint Commission on Accreditation of Healthcare Organizations started requiring a "timeout" before surgeries to verify key information. The Joint Commission timeout calls for teams to stop all work for a moment and confirm that they have the right patient and are about to do the right procedure at the right site.

Bonacum explains that the preoperative safety briefings should count as complying with the Joint Commission requirement, but they go beyond that. The preoperative safety briefings help teams avoid wrong-site surgery, but they are more expansive in their potential to improve the surgery overall, he says.

"We recommend you incorporate the time out into the briefing, to actually say during the briefing that you're having the timeout," Bonacum says. "That ensures that you are complying with the Joint Commission requirement, and the rest of the briefing goes on beyond that." ■

Fingerprint scanners help improve record security

The emergency department can be an especially difficult place to balance the need for security of patient records with easy access for physicians and staff, but one hospital in Chesterfield, MO, is finding that a high-tech solution can do the job.

Sisters of Mercy Health System began testing fingerprint readers in the emergency department of its St. Louis facility last July and reports good results. The system now has about 40 devices in its emergency department and another 40 in administrative offices.

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SOURCES

For more information on the Sisters of Mercy fingerprint scanner system, contact:

- **Michael Gutsche**, Director of Security and Disaster Recovery, Sisters of Mercy Health System, 14528 S. Outer Forty, Suite 100, Chesterfield, MO 63017. Telephone: (314) 579-6100.
- **Sentillion**, 40 Shattuck Road, Suite 200, Andover, MA 01810. Telephone: (978) 689-9095. E-mail: info@sentillion.com. Web: www.sentillion.com.

The emergency department had a particular need for such high-tech solutions because it is common for several people to share the same computer terminal, explains **Michael Gutsche**, director of security and disaster recovery for Sisters of Mercy. It was too time-consuming for each person to log on and log off each time he or she needed to access a patient record, he says, and patient privacy demands that the records not be accessible without some sort of access control. Leaving the system logged in all the time for quick access to the records risked violating the Health Insurance Portability and Accountability Act he notes.

Sisters of Mercy chose a system that uses fingerprint scanners and identification badges that can automatically unlock a computer when the authorized user approaches. The system was made by Sentillion in Andover, MA. Each person authorized to use the computer terminal wears a special "proximity" badge that looks similar to any other plastic identification badge. When the user approaches within a few feet of the terminal, the computer automatically unlock. The user verifies his or her identity by placing a finger in a small reader.

"In effect, the proximity badge is the log-in and the fingerprint is the password," Gutsche says. "I walk up, put my fingerprint down, and in just a few seconds I'm working on the document I need."

When the user is finished, he or she can just get up and leave. The system senses that the person no longer is at the computer and immediately logs out of the system. An extra bonus is that the next time the user sits down at the terminal, the computer will automatically open the files left open when the doctor last left.

The new system also helped the hospital achieve "single sign-on" for the key computer system in the emergency department, Gutsche says. Single sign-on is the elimination of multiple systems that require users to keep track of many different log-ins and passwords — a goal of many health care systems, Gutsche says.

"The system we settled on provided speed and ease of use, while at the same time improving security," Gutsche says. "When you make a security system easy to use, you greatly improve compliance because if a system is too complicated or requires too much effort, users will come up with their own workarounds that usually are not a good idea."

Sisters of Mercy won't reveal how much it spent on the system, but spokeswoman **Julie Yeager** says, "We anticipate a cost savings for the system due to time efficiencies which directly impact patient care by increasing caregivers' time at the bedside." ■

Insurer drops rates after Texas adopts tort reform

The Doctors Company, a medical malpractice insurer based in Napa, CA, reported recently that premiums for new and renewing policyholders in Texas would drop by an average of 18%, a direct response to tort reform adopted by the state in recent years.

Richard E. Anderson, MD, FACP, chairman and CEO of The Doctors Company, released a statement saying, "We congratulate Texas voters for passing reforms which improved the medical malpractice environment . . .," and urging other states to follow the same course.

In 2003, Texas passed Proposition 12, a landmark tort reform law capping pain and suffering awards in medical malpractice cases. Proposition 12 stabilized the Texas medical malpractice marketplace and benefited physicians and patients, says **Howard Marcus**, MD, chairman of the Texas Alliance for Patient Access. "Medical liability reform has resulted in a broader scope of insurance options for doctors," he reports. "Texas has

SOURCES

For more information on the rate reductions in Texas, contact:

- **The Doctors Company**, 185 Greenwood Road, Napa, CA 94558. Telephone: (800) 421-2368. E-mail: info@thedoctors.com. Web: www.thedoctors.com.
- **Howard Marcus**, Chairman, Texas Alliance for Patient Access, P.O. Box 684157, Austin, TX 78768-4157. Telephone: (512) 465-1516.

seen a statewide gain of 81 obstetricians, 93 orthopedic surgeons, and 263 emergency medicine specialists since Proposition 12 passed two years ago."

Texas physicians will see premium reductions ranging from 10% to 45.8%, depending upon location of practice, area of specialty, and coverage limits, according to the insurer.

The company noted that its decrease includes significant premium reductions for critical specialties traditionally excluded from insurers' rate reductions including obstetrics and gynecology and neurosurgery. ■

CE objectives

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

- **Describe** legal, clinical, financial, and managerial issues pertinent to risk management in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **Identify** solutions, including programs used by government agencies and other hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice. ■

CE Questions

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

17. What does Carson Liu, MD, recommend regarding the purchase of equipment to handle extra large patients?
A. The expense is rarely justified for any facility.
B. The expense is justified only for a bariatric surgery center.
C. The expense is justified for most providers because even if your facility doesn't do bariatric surgery, sooner or later a morbidly obese patient will need care.
D. The expense is minimal and inconsequential.

18. According to Stuart Hochran, MD, JD, and Roy W. Breitenbach, JD, what is the likelihood of successfully defending a claim by saying the extra large patient is too rare to require accommodation?
A. Very likely to be successful for any provider
B. Very likely to be successful for rural providers
C. Very unlikely to be successful for any provider
D. Very unlikely to be successful for a large hospital but likely to be successful for others

19. Regarding whether to tell patients of gainsharing agreements, what is the advice of David Winkler, JD?
A. You should always tell them.
B. You should never tell them.
C. You should tell them only if they ask.
D. You should tell them only if the agreement leads to an adverse outcome.

20. According to Douglas Bonacum, MBA, when should preoperative safety briefings be conducted?
A. Always before any incision is made, but otherwise the hospital can determine the exact time.
B. Always after the first incision.
C. Always before anesthesia is induced.
D. Any time at all before or during surgery.

Answers: 17. C; 18. C; 19. A; 20. A.

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

Ineffective, delayed treatment of sepsis leads to double amputations and $3.6 million settlement

By **Blake J. Delaney**, Esq.
Buchanan Ingersoll
Tampa, FL

News: A baby boy in extreme pain was taken by his mother to the doctor, who performed several tests on the child. While the mother and her baby were awaiting the test results, the boy's lips turned purple and he began vomiting. The pediatrician, after some delay, eventually advised the mother to rush the boy to the ED, where doctors diagnosed the child as hypoxic and positive for *Streptococcus pneumoniae*. Doctors delayed antibiotic therapy, but when such therapy eventually commenced, the boy was given an ineffective type of antibiotic at an ineffective level. The child eventually required multiple surgeries, and both arms and both legs were amputated. Before trial, the parties settled the case for $3.6 million.

Background: The mother of an 11-month-old baby took her son to the pediatrician after he was experiencing temperature spikes up to as high as 105° F over the preceding night. The child had been pulling at his ears, and he had significant nasal congestion. After determining that the boy had a fever, the doctor indicated to the mother that her son could be suffering from sepsis, a severe illness caused by an overwhelming infection of the bloodstream by toxin-producing bacteria. The doctor ordered, on an emergent basis, a complete blood count differential/smear blood culture, a urinalysis, and a urine culture.

The mother and baby then proceeded to a nearby hospital from the doctor's office so that laboratory tests on the infant could be completed. After the testing was concluded, they returned home to await the test results. The pediatrician subsequently called, informing the baby's parents that although he was waiting on the blood culture to fully grow out, the rest of the blood work was normal and they should not be concerned. The parents were advised to keep their son hydrated.

Later that day, the baby boy's lips turned purple. He was acting lethargic and continuing to pull at his ears. The pediatrician instructed the mother to increase her son's intake of fluids, but she could not get him to drink anything. She called the doctor's office again, at which point a second pediatrician similarly instructed her to force fluids into the boy. After another hour of unsuccessful attempts to get her son to drink, the boy began vomiting. The mother called the doctor's office, and she was advised to take the child to the ED.

The ED physician found the boy to have purple ears and a rash around his nose and one of his cheeks. He also was obtunded and suffering from a deficiency in oxygen reaching his bodily tissues. After some delay, an evaluation showed that the baby had a large abscess in his ear. Doctors ordered a spinal tap, which was positive for *S. pneumoniae.* Nevertheless, doctors again delayed before starting antibiotic therapy. Eventually such therapy was ordered in the form of ampicillin,

but nurses initially administered an ineffective dosage level. Had anyone checked the results of the blood culture that had been taken earlier in the day by the baby's pediatrician, they would have realized that ampicillin would not be as effective in treating the boy's condition as vancomycin.

After the antibiotic therapy commenced, another delay occurred before blood gas studies were conducted to detect any impairment in the child's processing of alveolar gas exchange. When the tests finally were performed, doctors failed to respond to the results indicating metabolic acidosis. Hospital personnel eventually decided that the baby should be transferred to another hospital. At the second hospital, doctors realized that the baby should have been treated with vancomycin. The change in antibiotics, however, was too late to save the child from requiring multiple surgeries. He eventually had both arms and both legs amputated.

The baby, through his parents, sued the doctors and first hospital involved in his care. He alleged that the defendants acted negligently in providing treatment. The plaintiff claimed that proper interpretation of the blood culture lab report and an earlier recommendation of going to the ED would have resulted in earlier treatment with vancomycin and no permanent injury. During the pretrial phase, the parties reached a settlement of $3.6 million.

What this means to you: "This case presents the age-old query as to how something this horrific could have occurred given the advancement of modern medical diagnostics and treatment," says **Lynn Rosenblatt**, CRRN, LHRM, director of quality and risk management at HealthSouth Sea Pines Rehabilitation Hospital in Melbourne, FL. She recognizes several areas of concern associated with the pediatrician's conduct in this case, not the least of which is that he suspected an infection but did not act with a sense of urgency.

"Generally with ear infections and upper respiratory symptoms in infants, physicians will initiate antibiotic therapy even before the final cultures are available because waiting is a greater risk than selecting an inappropriate drug," she says. Perhaps significantly, there was no mention in the scenario of any other prescriptions to dry up the secretions that were causing the child considerable earache and respiratory congestion.

Rosenblatt also is concerned that when the mother contacted the pediatrician and informed him that her child's condition had deteriorated and that he had "purple lips," the physician still did not react to the seriousness of the symptoms. "A child with lethargy and cyanosis of the lips is most likely suffering from respiratory insufficiency and/or metabolic acidosis, both of which are life-threatening conditions," she notes.

Indeed, by the time the mother called back informing the pediatrician of her son's worsening condition, the lab should have provided preliminary results of the blood culture.

Additionally, Rosenblatt recognizes the lack of any reasonable explanation for the advice to force fluids, given that such advice alone would seem totally inadequate under these circumstances. In fact, it is even more baffling that a second physician provided the same advice, apparently without questioning the situation further. "This series of events raises the question as to whom the mother spoke, as it is difficult to believe that a physician would have dismissed the parent's concern in such a blatant manner," she points out.

The narrative indicates that the parents were informed that the lab values were normal, but it does not say that the pediatrician called them himself. Also, since this child had an upper respiratory infection, it is not surprising that the urinalysis was negative, Rosenblatt says. "What is surprising is that the blood was also said to be normal," she says. "A child with fever — particularly a high fever — an ear infection with significant nasal congestion, and a differential diagnosis of sepsis would likely have an abnormally high white count." In her experience, other blood values also could be outside normal ranges, depending on the virulence of the causative organism.

Rosenblatt questions the pediatrician's practice of informing the parents that the child's lab work was normal despite the child's symptoms and his own belief that the patient had a primary blood stream infection. She contends that standard practice would dictate that the physician question the lab results under these circumstances.

Indeed, a related issue of concern for Rosenblatt is who reviewed the lab work before contacting the parents. "If the physician did not review the results himself, could an office worker have called and unknowingly provided the results of another child's lab work? Did the mother speak directly to both physicians when she called back? Were her concerns relayed by the office staff to the physician? Did the office staff actually speak with the physicians when the mother called, or did they just

tell her that they had?" she questions. Although the answers to these questions are unclear from the scenario, they show the types of inquiries that risk managers should ask to prevent similar situations.

Clearly, Rosenblatt is concerned with the treatment provided by the pediatricians in this case. In large offices, she notices how physicians rush from one patient to another writing orders, and they leave the follow-up to the office staff (often a nonlicensed medical assistant). Patients who call in with serious issues rarely speak directly to a physician, and phone calls are usually left to the end of the day before messages are relayed. At that point, the physician may not sense the urgency, and he or she may choose to leave it for the next morning.

Furthermore, although labs communicate "panic results" to the office as soon as the information is available, in the real world this information may not be communicated to the physician immediately.

Sometimes, such results can sit on a message board or fax, which causes them to be forgotten until much later. After all, physicians' offices are frequently busy and, depending on the number of physicians and their specialty, can be minefields for potential malpractice claims.

"Getting the right results to the right patient and prescribing the right medications can be daunting under the best of times," Rosenblatt says. "When one adds in the factor that most office help is unlicensed, the formula for a disaster is in place."

Despite the shortcomings of seeing patients in the office setting, physicians are encouraged by managed care to treat in the office rather than send the patient to the hospital. Although the factual scenario does not reveal what the child's insurance was, or if he had any at all, the only plausible explanation for the pediatrician's conduct is a tightly managed HMO, perhaps a Medicaid Managed Care plan, or no insurance at all. Otherwise, it is unclear why a pediatrician examining an 11-month old child with significant respiratory congestion including an obvious middle ear infection and the tentative diagnosis of sepsis did not immediately admit the patient to the hospital for intravenous (IV) antibiotics and hydration, or at the very least admit the child to a 23-hour pediatric observation unit.

Rosenblatt recognizes that another alternative, also costly, would have been to send the mother and child to the ED, where the lab results would have been reviewed and acted upon without undue delay. "It does not make sense that the physician would not have insisted that the mother and child await the results in order to act as quickly as possible on a probable diagnosis," she says.

Due to the pressures of managed care, national, state, and local governments are looking hard at HMOs and the emphasis on the bottom line. Rosenblatt comments that the message is clear that the HMO has an obligation to provide the same quality of care and access to needed treatment to enrolled beneficiaries as any prudent health care provider would provide in a freedom of choice situation. "The push is on in many states for large physician practices to assume more of an affirmative duty to ensure quality and acceptable standards of care," she says. "Quality and risk professionals see physician practice patterns as the best opportunity at a basic level to correct many serious mistakes that occur as a direct result of a poorly organized practice environment."

"Getting the right results to the right patient and prescribing the right medications can be daunting under the best of times. When one adds in the factor that most office help is unlicensed, the formula for a disaster is in place."

From the facts presented, it appears the second facility was better equipped to handle complicated pediatric cases. Therefore, Rosenblatt advises, the pediatrician should have instructed the mother to go there rather than the smaller hospital that clearly was lacking the expertise for a case of this magnitude. "Again, one can surmise that if this was an HMO case, the first smaller hospital was in-network, while the second may not have been," she says.

Much of this is speculation, as there is insufficient information in the narrative to say conclusively if this analysis has basis in fact, Rosenblatt says. "Nevertheless, if these conclusions are correct, it speaks to the commonly held belief that physicians in managed care networks are often so overworked and intimidated by the managed care organization that they fail to provide a full and accurate assessment of a patient's symptoms followed by appropriate treatment," she says.

Hospitals employ quality and risk experts to assist in developing best practices so that this type of catastrophic situation can be avoided. In this case, says Rosenblatt, the ED missed all the

clues, and it could have benefited from a critical practice pathway.

"Such tools provide step-by-step guidance to physicians, nurses, and other clinicians as to their role in managing the case and the point at which intervention is required," she says. "This allows for consistency and provides a framework for a quality level of care."

Unfortunately, the treatment received by the patient did not improve after his parents were directed to take him to the ED. "The pediatrician should have called ahead and informed the [ED] physician of the child's condition and what preliminary treatment had transpired," Rosenblatt says. She advises that pass through of patient information from one care setting to another is one of the National Patient Safety Goals endorsed by the Joint Commission on the Accreditation of Healthcare Organizations and supported by the American Medical Association and other health care quality organizations.

"Had that occurred in this case, the [ED] physician would have had more information and an accurate timeline of the child's illness," Rosenblatt says. "Some of the delays that occurred may have been avoided." For example, the ED would have been aware that blood had been drawn in the hospital lab earlier that day and that the results were merely a phone call away. Furthermore, speaking directly with the pediatrician of record would have provided the ED physician with sufficient information to arrive at a differential diagnosis of possible septic shock, respiratory insufficiency, and metabolic acidosis.

The importance of this preliminary communication cannot be underestimated. "Early recognition of this child's situation may have prompted the emergency room staff to respond in more aggressive manner, a course which was certainly warranted given the child's rapidly declining condition," Rosenblatt says.

The fact that the boy had an ear infection was fairly obvious, but there also was every indication that he had bacteremia. "Given the fact that streptococcus is a common organism in children and extremely dangerous in one so young, the [ED] physician was remiss in not ordering a reasonably broad-spectrum antibiotic immediately," she says, noting that vancomycin generally is the drug of choice in a situation such as this.

Finally, "although this case screams urgent care, apparently there was no sense of an emergency," says Rosenblatt. For example, given the child's respiratory difficulty and the fact that he was obtunded, blood gases should have been ordered without delay on arrival. Supplemental oxygen also should have been a consideration, an IV for hydration and delivery of continuous antibiotic therapy should have commenced upon arrival, a simple chest X-ray may have been appropriate to rule out pneumonia, and, given that the spinal fluid was positive for bacteria, a simple Gram stain could have provided some indication of the sensitivity even if the specific organism had not been identified, she advises.

All in all, the series of events that transpired at the first hospital seems to indicate either an ED staff that was not properly trained to deal with sick children (as opposed to injured ones) or a staff that was so rushed that they failed to properly triage this case and provide the appropriate care in a timely manner, she says. "Both situations are entirely possible given the delays, the ineptitude of the physician in properly diagnosing a very ill child, and the medication calculation error made by the nurses," Rosenblatt concludes. ■

HIPAA Regulatory Alert

Supplement to Healthcare Risk Management and Hospital Access Management

Administrative simplification enforcement rule in effect

Rule reinforces HHS approach to enforcement, experts say

The Department of Health and Human Services published the final enforcement rule for all HIPAA Administrative Simplification rules with an effective date of March 16, 2006. The final enforcement rule applies to the HIPAA EDI, privacy, and security rules, and the HIPAA unique identifiers.

Officials with the Segal Co., a benefits consulting firm, say the final rule reinforces the department's basic approach to enforcement — it will rely on complaints to identify violations, seek voluntary compliance through informal means, and provide technical assistance to help covered entities comply. It only will open a process that could lead to civil money penalties if a complaint is not resolved informally.

To open a process leading to monetary penalties, HHS must issue a "notice of proposed determination" that includes, among other things, a description of an alleged violation and the amount of the proposed penalty. The department has the authority to assess a penalty of up to $100 per day for each violation (a maximum of $25,000 per calendar year for identical violations).

Factors affecting the amount of a proposed penalty, according to Segal's *Capital Checkup*, are the nature of the violation, the circumstances (including the consequences) of the violation, the degree of the covered entity's culpability, the covered entity's history of compliance or noncompliance with the Administrative Simplification rules, and the financial condition of the covered entity.

Generally, the rule says a covered entity is liable for the acts or omissions of any agent, including a work force member, acting within the scope of the agency. But there is an important, limited exception for business associates. Segal's analysis says a covered entity is not liable for the acts or omissions of business associates if (1) the covered entity has a written business associate contract in place with that business associate and the contract complies with the applicable HIPAA privacy and security rule requirements, and (2) if the covered entity knew of a pattern of activity or practice of the business associate and the covered entity took reasonable corrective action.

Seattle technology attorney **John Christiansen** tells *HIPAA Regulatory Alert* he was somewhat surprised that the violation definitions in the new law are stronger than had been expected and have the potential for greater penalties.

The bottom line for organizations

While acknowledging that the Department of Health and Human Services intends to remain complaint-driven in its enforcement approach and work cooperatively with entities that are making a good faith effort, Christiansen says the department could use the concept of continuing violations to rack up huge civil monetary penalties if necessary to make a point.

"It's clear they are not funding investigators and responders well and so will remain complaint-driven," he says. "But they have a lot of leverage if they do go after a problem."

Christiansen says he also can see the strengthened violation definitions being used by trial attorneys involved in commercial disputes in which HIPAA violations are among the concerns being raised. "If I were litigating, I could write quite a brief now that we have this much specificity," he says.

The bottom line for organizations, he says, is the need to make a good faith effort to comply with the rules. "If you are acting in good faith, the department is supposed to meet you and

work with you collaboratively," he explains. "But if something major happens, regulators may see a need to intervene and have a lot at their disposal."

Christiansen says the final rule is an improvement of the draft due to the greater clarity and specificity that was included.

Contact John Christiansen at (206) 301-9412 or e-mail john@christiansenlaw.net. ■

Survey suggests shift toward long-term benefit

55% of providers compliant with security standards

The latest U.S. Healthcare Industry HIPAA Survey sponsored by the Healthcare Information and Management Systems Society and Phoenix Health Systems indicates participants in the health care system view the HIPAA privacy and security standards as building blocks for web-based communication structures rather than simply a compliance burden.

"Most states are either developing or considering involvement in a regional health information organization," the survey says, "for the purpose of electronically exchanging health information across defined regions while still protecting patient privacy and ensuring data security…Individual health care organizations are internally institutionalizing the concept of a secure health care environment that protects patients' rights without sacrificing or interfering with quality care. They are also incorporating these principles into the fabric of new community health networks that streamline and enhance the continuum of care. Many organizations are expanding their use of electronic transactions through these infrastructures, as federally required standardization begins to deliver on its long-standing promise of administrative simplification. HIPAA's impact on the health care industry is evolving from 'compliance' to an emphasis on new, electronically based opportunities for better communications across the continuum of care, and greater patient safety, cost-savings, and overall efficiency."

Participants in both the payer and provider surveys indicated HIPAA implementation has resulted in greater attention to patient privacy and data security by their employees and increased consumer confidence. Some 22% of providers are implementing return-on-investment initiatives related to HIPAA, with 88% of them expanding use of standard electronic transactions. Other initiatives include adoption of computerized practitioner order entry and conversion to electronic medical records.

Some 55% of providers reported compliance with HIPAA security standards, along with 72% of payers. The majority of non-compliant organizations projected full implementation of security standards within six months, although the report authors noted that group gave a similar time projection in the summer 2005 survey. Data security incidents continue to plague at least one-third of both payers and providers.

HIPAA transaction use growing

Adoption of HIPAA transactions has increased steadily over the last year and, as of January 2006, 84% of providers and 73% of payers reported being able to conduct all HIPAA standardized health care transactions. Some 67% of payers said they were actually conducting all HIPAA-required transactions, and 66% of providers reported conducting more than one-half of the standard transactions.

The report said privacy compliance levels remain consistent with previous survey results over the last two years — 80% of providers and 86% of payers reported in January they had met privacy rule requirements.

"It can be inferred that a core group of about 20% of covered entities is either unable or unwilling to implement federal privacy requirements," the authors said.

But even among compliant organizations, there are implementation gaps in certain areas, including establishing business associate agreements, monitoring internal privacy compliance, and maintaining an accounting of disclosures.

The incidence of privacy breaches in organizations has remained flat but high at 60% over the past six months. The percentage of payers reporting privacy breaches increased from 45% in July 2005 to 66% in January 2006. The majority of organizations experienced between one and five such breaches, but more than 20% experienced six or more.

Download the survey report from www.hipaadvisory.com/action/surveynew/results/winter2006.htm. ■

Info-Tech Research Group says HIPAA is 'ineffective'

With only one enforcement criminal conviction recorded since 1996, HIPAA is failing to meet its mandate, according to Info-Tech Research Group. "HIPAA is a toothless tiger," says Info-Tech analyst **Ross Armstrong**. "The first problem is that HIPAA is complaint-driven, and complaint-driven enforcement doesn't work. The second problem is that in the one HIPAA-related conviction that has occurred, only the individual was charged and not the organization itself. If HIPAA is to be truly protective and useful, health care entities and their executives must be held accountable in the same way that Sarbanes-Oxley holds CEOs and CFOs responsible."

Armstrong also questions the government's commitment to enforcing HIPAA, noting a Government Accountability Office (GAO) report that the FBI can't account for all of the $379 million it was given from 2000 to 2003 to investigate HIPAA-related frauds.

Some of the money reportedly was shifted to counter-terrorism efforts, but no one could verify that the rest was properly spent on HIPAA, the GAO said.

"One conviction that netted $9,000 in penalties hardly seems worth an investment of over a third of a billion dollars," Armstrong says. "Without proper government agency oversight, it comes as little surprise that there has been only one HIPAA conviction."

Armstrong tells *HIPAA Regulatory Alert* the difference between aggressive enforcement of other information technology-related laws and HIPAA is striking.

"There's been a lot of enforcement success under Sarbanes-Oxley and the Fair Credit Reporting Act," he says, "with a lot of revenue coming to the government. But because HIPAA is complaint-driven, no one is held accountable for privacy breaches."

The one criminal conviction involved a charge by the victim against a health care worker for identity theft, according to Armstrong, and no action was taken against the covered entity for which the convicted person worked. "If HIPAA is to be truly protective of privacy," he says, "entities also must be held accountable."

Armstrong refers to surveys by the Healthcare Information and Management Systems Society and Phoenix Health Systems indicating there still is a significant amount of non-compliance with HIPAA requirements.

Covered entities, he states, say there is no adverse public relations effect in not complying with the law and also little fear of government action against them. "There are lots of potential penalties [in the enforcement rule]," he says, "but if they are not being enforced, no one cares."

Armstrong says Info-Tech's consulting business does a lot of work in health care but rarely is asked to work on HIPAA issues, another signal to him that there is little concern.

Contact Ross Armstrong at (888) 670-8889. ■

MGMA concerned about e-claims standards

Group urges incentives for providers

The Medical Group Management Association (MGMA) has raised concerns about electronic claims attachments with federal officials.

In a letter to Centers for Medicare & Medicaid Services (CMS) Administrator Mark McClellan, MGMA said its members support administrative simplification and believe that, once properly implemented, e-claims attachments can streamline an important billing transaction for medical group practices. It raised 11 general issues for consideration:

1. Standards should be flexible and scalable. MGMA said any standards for electronic claims attachments should take the wide variety of clinical specialties and settings into account.

"The final standard must be both flexible and scalable to encourage adoption by both small and large health care organizations and physician specialties processing both low and high volumes of claims attachments," it said. "Flexibility will allow doctors to consider critical factors such as clinical quality, safety, efficiency, and integration with existing practice management software and electronic health record systems when making an investment."

2. No undue burdens on providers. MGMA said it is critical that CMS develops a final rule that doesn't impose undue financial burdens on physician practices.

3. Promote the security and privacy of patient

data. MGMA said electronic claims attachments must maintain HIPAA security and privacy standards as part of their core features and CMS should provide guidance on the critical issues surrounding the minimum necessary provision of the privacy regulation.

4. Incentives for providers. The association calls for realigning incentives by promoting appropriate public and commercial reimbursement programs. MGMA said it has supported the concept of a federal program of tax credits for physician investments in health technology that could serve as a significant incentive. Also, a federally guaranteed loan fund for physician health technology investments, coupled with loan forgiveness for service to medically underserved populations, could be an effective stimulus to e-health adoption.

5. Technology savings accounts. MGMA wants the federal government to explore methods to assist medical practices in acquiring health information technology. It suggests technology savings accounts would provide a reduced level of taxation for funds designated for practice health information technology and says such accounts could enable group practices to pay for current expenses and save for future qualified health information technology expenses tax-free. Unspent account balances could accumulate interest.

6. Stark regulation safe harbor. According to MGMA, anti-kickback and self-referral concerns prevent some health care organizations from offering free or discounted technology to medical practices.

The association wants government approval of legal protections, such as safe harbors and regulatory exceptions, to facilitate health technology implementation.

7. Development of clinical and administrative crosswalks. CMS should develop and freely make available crosswalks between ICD, CPT, and LONIC code sets, MGMA says.

8. Staggered compliance dates. MGMA calls on the federal government to stagger implementation dates to give clearinghouses and health plans time to upgrade and test systems before provider information takes effect. It says piloting of the e-claims attachments standard should be completed before full national implementation to identify and correct problems.

9. Development of a national rollout plan. CMS should initiate a national rollout plan taking into account requirements of each impacted industry sector, MGMA recommends.

10. Continued consultation with the physician practice community. MGMA encourages CMS to continue its outreach to physicians to ensure their requirements and concerns are addressed.

11. Industry outreach. MGMA says physician practices will need substantial education before they are fully aware of and comfortable with e-claims attachments. And CMS also should be communicating with the software vendor community to encourage them to move forward with product development as quickly as possible.

More information is available at www.mgma.org. ■

Ohio court puts state open records law over HIPAA

The Ohio Supreme Court says the state's open records law takes precedence over HIPAA privacy requirements. The court ruled in a case brought two years ago by the *Cincinnati Enquirer* when it sought to compel the city health department to disclose addresses of homes and businesses ordered to remove potentially hazardous lead paint.

"Ohio has a long-standing public policy committed to open records," wrote Justice Terrence O'Donnell in the unanimous decision. "The Cincinnati Health Department and its commissioners have a clear legal duty to make the lead citations available." The department had argued that releasing the information would violate HIPAA privacy regulations because lead citations are based in part on blood tests of children.

Lawyers for the newspaper argued that the more than 300 lead citations the newspaper requested were public records that revealed a potential threat to public health.

They said the citations did not include names of children tested, Social Security numbers, or any other personal medical information. The newspaper also argued the health department, unlike hospitals and other providers, is not covered by HIPAA.

While the state open records law says a record is open unless prohibited by federal law, HIPAA says medical records are private unless state law requires them to be open. The seven Supreme Court justices decided that when the two levels of law conflict, state law should be followed. ■