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'Safe passage nurse' improves patients' safety as they move through the system

Designated nurse coordinates multidisciplinary care

How would you like to increase occurrence reporting by 134% while improving patient safety and communication among your staff? If that sounds good, the Safe Passage Program, developed by Clarian Health Partners in Indianapolis, might be for you.

The Safe Passage Program led to Clarian's director of risk management and patient safety, **Kathy Rapala**, JD, RN, recently winning the first Todd Pickett National Patient Safety Award from the American Society for Healthcare Risk Management (ASHRM). The award is named as a tribute to a patient, Todd Pickett of San Diego, who died in an incorrectly applied patient safety restraint.

Rapala was instrumental in creating the Safe Passage Program in 2001, thought to be the first of its kind in the United States. It supports a culture of safety by designating a "safe passage nurse," someone dedicated to assisting the interdisciplinary team in a patient care unit as they take patients through the health care system. The model empowers frontline workers to anticipate a variety of scenarios and prevent errors by working together.

"With the safe passage nurse, we decided we didn't want just a safety nurse with a checklist," Rapala explains. "We wanted people to learn how to think about things differently."

Many staff trained in patient safety

At Clarian, Safe Passage is a collaboration between nursing and patient care services and risk management to safeguard all patients and staff and protect their rights to a safe passage through the health care system. Based on a zero-error tolerance model, the program operates throughout the entire Clarian health care system, which includes three hospitals.

Rapala says Clarian created the program as a by-product of its Synergy Model — the practice of matching patient needs with nursing expertise to

improve patient outcomes and satisfaction. Clarian is the first hospital in the country to implement this model for patient care.

So here's how it works: A team of more than 250 nurses and other clinicians including pharmacists and clinical engineers are specially trained in patient and staff safety. Each unit throughout the health care system has a Safe Passage nurse, who trains, oversees, and analyzes the unit by identifying areas for improvement.

Clarian leadership and the Clarian Board of Directors provide Safe Passage nurses time away from clinical or operational duties for training, safety-related initiatives, and monthly Safe Passage Council meetings. The Council includes staff from mother/baby, emergency and trauma center, and all three hospitals' multispecialty and intensive care unit.

Staff are empowered to make changes to improve work environments. Rapala says the Safe Passage Program provides a forum that strikes a balance between necessary efficiencies and reliability. When Safe Passage nurses and other frontline staff identify a barrier that increases risk, changes are made to prevent or reduce risks or remove the barriers.

Here are the goals of the Safe Passage Program:

- Provide nurses with a patient safety knowledge base that includes the most current patient safety information available.
- Provide a communications network from top to bottom and bottom to top.
- Prevent errors through planning for change and identification of gaps.
- Create a mechanism to analyze and learn from errors.
- Increase work efficiency and effectiveness.
- Provide a mechanism for process improvement through evidence-based practice.

Staff level participation is key

Rapala and her colleagues started out by giving a presentation to 10 interested nurses. The idea went over well with them but then not much more happened. So they went back to the drawing board and came up with a plan that would disseminate the idea throughout the entire hospital.

Clarian has 10,000 employees, so that was no easy task. The Safe Passage Council was one strategy, along with subcouncils on a local level at each hospital. They meet monthly and discuss patient safety issues that affect their specific areas — obstetrics or the emergency department, for instance. Originally, the councils were made up entirely of staff nurses with additional training in patient safety, but this year Clarian added pharmacists and other practitioners. But they're all staff level — that's the main requirement.

"The reason for that is that they know the actual work so well," she says. "In the past, we had administrators and managers looking at a problem, and the fact is that sometimes I'm not as

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familiar with work at the bedside as I need to be for solving a particular problem. It turns out that the staff level members have much better ideas than we do."

Once a month, all the councils meet as a group. Each local council brings up safety issues from their own settings and, more often than not, the other participants realize that the same issues could affect their own areas.

"The beauty of it is that we have all the problem solvers right there so they can start talking amongst themselves," she says. "It really raises the awareness immediately across all the settings."

Not easy to schedule meetings

Rapala says the administration of the Safe Passage Program has been challenging, in part because the staff level participants have such different schedules. Scheduling a meeting can be difficult, she says.

Each clinical unit at Clarian has a Safe Passage nurse who is responsible for letting the Safe Passage Council know about safety issues and for disseminating information to staff on their floor. Some units have one or two extra representatives — a change implemented when the original participants explained that they could not always make the meetings.

"With all the programs that recruit staff people to participate, ours has been very popular," Rapala says. "We think the reason is that this is all about how people work. People are asking them about how they work and how we can make that better, and people tend to be interested when you ask about their work."

Though the Safe Passage nurse is the floor's designated patient safety representative, other staff are involved in patient safety initiatives. The Safe Passage nurse, however, receives special training and education in patient safety, and then he or she is expected to pass on that knowledge.

Good results after three years

The Safe Passage Program has improved quality and reduced errors throughout the Clarian health care system, Rapala says. She cites these results:

- **More trust.** Instead of placing blame when an error is made, Safe Passage provides a process to analyze near misses. For example, if the wrong patient was taken for a procedure, but the error was caught, an analysis is done to reveal the work complexities that led to this near miss.
- **Improved communications**. Safe Passage provides tools to help practitioners communicate clinical concerns to attending physicians.
- **Increased reporting**. Occurrence reporting increased by 134% at Clarian in 2003 because of Safe Passage initiatives.
- **More staff involvement in decision making.** Because frontline staff are the best source to evaluate work design and work flow issues, Clarian now makes certain that no policy, procedure, improvement or technology is implemented without the consideration of the actual work environment, and that means consulting those on the front line.
- **Reduced errors**. Because its emphasis on improvement, analysis and training, Safe Passage helped identify that poorly designed and labeled bins caused the incorrect hanging of premixed intravenous fluids. Safe Passage has piloted standardized bins on key units, with a resulting decrease in incorrectly hung fluids. Systemwide implementation is under way.

Rapala says it is important to plot the reported incidents against serious and severe incidents. At Clarian, reported incidents are going way up but serious incidents are going down.

"Eventually, from a risk management point of view we would hope that has an impact on claims," she says. "But that will take a couple of years to start seeing."

Program is extensive

Clarian has an extensive root-cause analysis program and uses it to study far more than just the incidents required by JCAHO. Rapala says the analyses find across the board that communication, particularly concerning patient handoffs, is the No. 1 root cause of serious incidents and near misses.

"The great thing about the Safe Passage Program is that we now have a vehicle for saying we've noticed this trend and what do you guys think," she says. "They confirmed it hands down, so now that's a separate project we're working on."

Rapala says that Clarian also has started to quantify what potential problems are being caught out on the floor. She knew that was important in assessing the success of the program, but she also knew that staff did not want another form to fill out. So how do you track what staff are catching during a normal work shift?

"We just allow part of the monthly meeting for information sharing, people telling each other what they've caught, and what they've heard

about on their unit," she says. "We want them not only noticing the issues but also starting to fix them. Just this past month we got an occurrence report about a near miss and the nurse said because of the Safe Passage Program, she took steps to keep it from happening again."

More eyes and ears for patient safety

That's the ultimate goal of the Safe Passage Program, Rapala says. She wants to create an army of staff level patient safety experts who can recognize problems and solve them.

"The thing that some people don't like to hear is that it takes time," she says. "It takes two to three years to set up this structure so that it works."

And it also takes caregivers away from their duties. If you don't have top-level support for Safe Passage, you'll never be able to schedule staff level participants for meetings when their unit manager needs them working. At Clarian, participants report that they spend two to four hours a month on their Safe Passage activities in addition to the meeting time.

Rapala says the Safe Passage Program has been "one of the most effective risk management tools we've ever had." The reason is that the program provides a structure for disseminating information — such as an equipment hazard, for instance — throughout the entire organization quickly. The program also ensures a great many more eyes and ears are on alert for safety issues.

"The traditional risk management model has a couple of people in risk management who get the risk reports, but this model enlists a lot more people in the effort," she says. "You can't beat all that brainpower and all those people helping you get the word out." ■

Charity lawsuits may open the door for more scrutiny

Not-for-profit hospitals are a natural target for allegations that they are failing to serve the indigent community, and the latest lawsuits targeting them are not likely to be the last, according to an expert in health care law.

No matter how the lawsuits themselves turn out, they're turning up the heat on all health care providers and will result in closer scrutiny that many feel they could do without.

Much of the fallout will affect all health care providers, creating a higher standard for billing and collection practices, says **Jay Wolfson**, DrPH, JD, professor of health care law, finance and policy at the Colleges of Public Health and Medicine at the University of South Florida in Tampa. But the greatest impact will be on not-for-profit institutions, which will be watched very closely from now on.

Wolfson offered advice in a recent audio conference sponsored by Thomson American Health Consultants, publisher of *Healthcare Risk Management*. Wolfson cautions that risk managers must not take the lawsuits lightly. Even if the particular charges brought in the lawsuits do not result in payouts, the lawsuits could prompt closer scrutiny by state and federal regulators. No one wants that.

Don't underestimate lawsuits

Wolfson says there is a thin line between the allegations in these lawsuits and behaviors or policies that could be subject to federal investigations regarding kickbacks, fraud, and abuse, he says. And once people start prying into your institution because of the charges in these lawsuits, they may uncover all sorts of other things you'd rather not have to explain.

"The assaults by prominent, successful class action attorneys combined with the attention of state legislators regarding not-for-profit status places not-for-profit health care organizations at jeopardy of challenges to your tax-exempt status, and massive expenditures defending lawsuits and regulatory inquiries," he says. "There's also the risk of bad press, reduced donations, and reduced revenues."

The attorneys bringing lawsuits are a "formidable foe," Wolfson says, because they have extensive experience in class action lawsuits, including the action against the tobacco industry that yielded them millions of dollars.

Sarbanes-Oxley used as tool for scrutiny

The Sarbanes-Oxley law also injects a new level of accountability for how a not-for-profit's board performs, and Wolfson warns that community watchdogs and others are using law as a tool to get previously unobtainable information about the institution. Sarbanes-Oxley is the federal law that, among other things, requires greater accountability and disclosure from not-for-profit

Prepare for charges and have a response ready

Jay Wolfson, DrPH, JD, professor of health care law, finance, and policy at the Colleges of Public Health and Medicine at the University of South Florida in Tampa, offers this advice on how to counter not-for-profit lawsuits and avoid becoming a target for similar allegations:

1. **Perform** comprehensive, valid analyses of existing billing and collection practices.

2. **Develop** targeted training and education programs for intake, billing, and collections staff.

Improving your billing practices is a good way to improve your institution's image. Better intake will help identify actual and potential sources of payment. Make use of existing alternatives within the community to assist uninsured patients. Medicaid, local community health plans, and health plans for children should all be explored.

As much as possible, make arrangements in advance with patients and families regarding the payment of bills.

3. **Identify** alternative, flexible means by which to accommodate bona fide, medically indigent patients.

One method is to arrange for patients to acquire credit cards with banks so that the collection is divorced from the health care institution. You also should consider making flexible arrangements when patients request assistance to allow for longer term, smaller payments, without interest.

4. **Identify** alternative sources of funding services to the medically indigent.

5. **Perform** comprehensive, valid analyses of charity care, community benefits, and tax-exempt related activities.

6. **Catalogue and analyze** the scope of specific things you do that quality as "community benefit" and let the community know you do these things.

7. **Fill** the gap between tax benefits enjoyed and measurable community services provided.

8. **Develop** clear and uncompromised responses to these allegations:

— You use public monies to compete against other providers.

— You create additional, unneeded, expensive medical technology in the community.

— You contribute to higher costs of unnecessary services and inappropriate care.

— You detract from public funds that could be used to support education, public safety, transportation, and other community needs. ■

organizations, and it can create a way for federal regulators to find a cause of action. One can run afoul of Sarbanes-Oxley by not being responsible to communities or constituencies ostensibly being served, so that would fall in line with the allegations about charity care. Regulators also could use the law to find that boards are neglectful of their duties, have conflicts of interest, or misuse assets and engage in self-dealing.

Lawsuits bring unwanted attention

The recent lawsuits are bringing unwanted attention to the way not-for-profits operate, with strong criticism of how some are behaving more like for-profit entities. Critics point to the aggressive competition for contracts, sophisticated and aggressive marketing strategies, and the purchasing of physician practices and other assets.

The public perception also is that not-for-profits spend money lavishly, filling boardrooms with expensive wood and exotic art, and then they use "goonlike" collection methods to harass and intimidate the elderly and poor.

Wolfson notes that this is not the first time not-for-profit hospitals have been hit by accusations that they are failing to meet the needs of the uninsured and gouging the patients who can least afford it. About 14 years ago, there was a series of similar actions against Florida hospitals, alleging many of the same things.

"All of those cases were thrown out, but it took a lot of time and money," Wolfson recalls. "They're back now with better attorneys and more money."

The most recent legal claims stem from allegations that not-for-profits are gouging individual patients by requiring they pay full charges without any discount. Wolfson explains that billing practices alone, if patently discriminatory, may create opportunities for legal action, but not-for-profit

status raises the bar by adding on obligations and a set of expectations. Bottom line, it's easier to show that a not-for-profit's billing practices are discriminatory.

Know when you crossed the line

So how can you know when your own institution has crossed the line? Wolfson suggests looking for these exposures:

- Patently aggressive efforts to single out uninsured patients from others with balances due.
- "Goonlike" collection practices that just look bad, whether they're done by your own employees or an outside collection agency.
- Failure to create flexible alternatives for payments.
- Audits that may not clearly distinguish bad debt from charity care.
- Internal arrangements to cross-subsidize physicians for medically indigent patient care.
- Inaccurate cost accounting systems that prevent linkage of chargemaster charges with costs.
- Weakly documented cost-shifting realities — by product lines and payer classes.
- Direct or indirect tax subsidies, such as property or sales taxes.
- Legislative appropriations, such as those for trauma care or rural access.
- Charitable "funds" within the organization, which can create problems when donor funds are not directed to the area specified by the donor.

Charity care, bad debt not the same thing

Wolfson also cautions about blurring the line between charity care and bad debt. Don't let your finance department shift the debt around, transferring it from charity care to bad debt just to make the numbers look better, if that is not allowed by your state statutes. Many states have very specific definitions of each, he says, and you must adhere to those.

Many institutions have a lot of work to do, he says, but improving your billing and collections practices is job one.

"Don't take anybody's word for how it works. Get in there and go through the system yourself, see how it's down, follow a case, see with your own eyes what happens when a bill goes to collections," Wolfson says. "The billing practices we've allowed to develop over the years may not be allowed to continue. We have to become patently kinder and gentler in some respects." ■

Hospital files counterclaim, predicts lawsuits will fizzle

Some hospitals targeted by the spate of lawsuits against charity health care providers are fighting back, and one hospital executive tells *Healthcare Risk Management* that he expects the legal brouhaha to die out soon without any major payouts.

Florida Hospital, part of the nonprofit Adventist Health System, recently filed a counterclaim against Nicolas Arzate, a plaintiff in the national litigation spearheaded by attorney **Richard Scruggs**, JD. The Florida Hospital suit seeks more than $12,000 for a disputed hospital bill for an appendectomy. While risk managers and defense attorneys may see the move as appropriate in the face of the aggressive lawsuits, the counterclaim by the hospital made it a target for even more criticism of its policies.

The move, a first since the litigation began in June, immediately drew fire from the Consejo de Latinos Unidos, a national nonprofit organization that educates and assists minorities and the uninsured. **K.B. Forbes**, executive director of the Consejo, says, "Florida Hospital proved that they are a heartless organization and that they will sue anyone, anywhere to collect on these outrageously high hospital bills."

She goes on to say that the hospital "appears to seek the inalienable right to price gouge and financially destroy middle-class Americans, like the Arzate family. Florida Hospital's legal actions are nothing more than a disgraceful example of corporate greed."

Counterclaim required by statute

Not at all, says **Richard Morrison,** regional vice president of government relations for Adventist. He can't comment specifically on Arzate's case, but he says the counterclaim against Arzate is required by statute as part of the hospital's defense against the claim, he says. It does not represent any malice toward the plaintiff or a desire to punish him for filing the lawsuit, Morrison says.

"It's called a mandatory counterclaim," he says. "We didn't have any choice in whether to file it."

Morrison notes that there was no lawsuit against Arzate seeking payment. In every case in which Scruggs is alleging unfair treatment, Morrison says Florida Hospital still is owed money and had not

sued the patient for payment.

But the criticism from Consejo is just the latest round of claims that Florida Hospital, and the other defendants in the lawsuits, are heartless and only want to squeeze money out of people who don't have it. Observers have noted that the lawsuits were spawned in part by the way some hospitals, not necessarily Florida Hospital, were too aggressive in pursuing payment from indigent patients. Poor oversight of debt collectors has been cited as one failing by hospitals because the collection practices still are done in the name of the hospital even if a completely separate company is making the harassing phone calls.

Collection sometimes necessary

Nevertheless, Morrison says, hospitals are left with a tough choice when it comes to debt collection. No one likes to pursue patients over unpaid bills, but sometimes the hospital is forced into that position, he says.

"We tried to make contact with the patients to have them provide us with financial statements so we could get them qualified for discounts or Medicaid or other things, and there is a limit to what we can do when people do not cooperate with us," he says. "You're left with no other option but to pursue the debt through collections until you're shown otherwise, that the person cannot afford to pay it."

According to the Consejo, Medicare would have paid $4,018.58 for Arzate's appendectomy while a typical insurance company would have paid $4,498.46. Arzate was charged $14,853.47 — more than $10,000 more for the same care. Arzate made three payments totaling $2,200. The hospital is seeking $12,653.47.

Forbes says Florida Hospital appears to have demanded monthly payments of $1,000 after Arzate made an initial payment of $200. She characterizes Florida Hospital's collection practices as "vicious for a faith-based, so-called 'Christian' organization."

The Arzate family met with lawyers of the law offices of Archie Lamb in June 2004 and filed suit shortly thereafter. Lamb is affiliated with the Scruggs group. In November 2004, the Consejo dispatched a letter to the Internal Revenue Service asking them to investigate and revoke Adventist Health System's nonprofit status.

While some say the complaints about the details of debt collection practices and some of the price differential for insured and uninsured patients are legitimate, Morrison says the charity lawsuits are not having the impact that some risk managers may have feared when they were first filed.

"We're hoping that our court will be consistent with what other courts have done and toss these lawsuits out," he says. "They've been dismissed in four states and all on the same basis, that there is no legal basis for them bringing this action as it relates to any sort of implied contract about not-for-profits. The whole legal theory is just not holding up in court."

Monitor debt collection closely

Morrison says one lesson for the industry is that hospitals must be more proactive about their charity and discount policies.

"We have to work harder up front to let them know what information we need to verify their financial situation. It would be so much better if we could get that kind of cooperation up front so we can steer them toward the right kind of help instead of using all our resources on the back end to try to collect a debt, and then eventually find out that it can't be collected," he says.

Morrison also suggests monitoring debt collection agencies very closely. Pay particular attention if a collection agency is generating a lot of complaints. Don't get caught up in the legal separation between your hospital and the collection agency, he says. Your name is firmly attached to that debt, so anything the collection agency does to collect it will come back to you.

"You can't say you didn't know what they were doing," he says. "In the last 10 years, we let one agency go because we do have standards. We don't let them call people on weekends, for instance, because it violates our view of what the Sabbath is. Whatever your standards are for respecting people, you have to enforce that with the agencies." ■

JCAHO: Patient-controlled analgesia overuse warning

Patient-controlled analgesia (PCA) is a well-accepted method of delivering pain relief, but JCAHO is warning that well-intended family members and caregivers may be putting patients at risk by becoming involved in administering

patient controlled analgesia.

JCAHO urges risk managers to implement policies and procedures that will discourage anyone other than the patient from administering the pain medication.

PCA uses a computerized pump that is hooked up to the patient's intravenous line, allowing the patient to receive the pain medication by pressing a button. PCA provides the individual greater control in managing the pain, but the patient provides a built-in safety check in this system because an oversedated patient is not able to push the button to cause a harmful or even fatal overdose. JCAHO cautions that problems can arise, however, when a family member or health care professional bypasses that important safety feature by administering PCA.

This is called "PCA by proxy." In a recent *Sentinel Event Alert*, JCAHO president **Dennis S. O'Leary**, MD, said, "PCA by proxy errors are readily preventable and can be virtually eliminated through timely and appropriate education and training of staff and family members." Risk managers can read between the lines for an important warning: JCAHO considers this a hazard that is "readily preventable" and which can be "virtually eliminated" with staff training. That means JCAHO is likely to take a hard line when assessing a PCA by proxy death or injury at your hospital.

(The entire *Sentinel Event Alert* is available on-line at www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_33.htm.)

Nurse responsible for one by proxy death

Working with the United States Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP), JCAHO has developed guidelines for avoiding PCA by proxy. The first challenge, according to ISMP president **Michael Cohen**, RPh, MS, ScD, is overcoming the urge to provide more pain relief to someone who is suffering.

"PCA by proxy errors are usually the direct result of family members or health care professionals administering doses for the patient, with the intent of keeping them comfortable," he says. "This well-intentioned effort can result in oversedation, respiratory depression, and even death."

JCAHO reports that its database contains only one medication error related to PCA by proxy. However, reports submitted to the USP medication errors databases revealed a combined total of 6,069 PCA errors. Of this number, 460 resulted in fatality or some level of harm to the patient-impairment of the physical, emotional, psychological function or structure of the body and/or pain resulting there/from. Fifteen of the 460 cases were the direct result of PCA error by proxy — 12 cases attributed to family members, two to a nurse and one to a pharmacist, JCAHO reports.

Five of the 460 errors were fatal errors, including one by proxy error attributed to a nurse.

Most incidents occur in hospitals

The setting or location of the error was not identified in all cases, but 401 of the 460 cases occurred within the hospital with the majority of errors experienced in the patient care units. Other sites within the hospital included the post-anesthesia care unit, inpatient pharmacy, intensive care unit (surgical, medical, coronary/adult, pediatric and neonatal), oncology department, pediatric unit, maternity and labor and delivery unit, the operating room, outpatient surgery unit, endoscopy/GI lab, and preoperative holding area.

Cohen notes that it is not always improper for a nurse to administer PCA, in some situations in which the patient is unable to do so. But that use of PCA requires protocols and appropriate assessment tools to gauge the level of pain, sedation, and respiratory status, he cautions.

The ISMP reports that contributing factors in PCA by proxy errors involving health care professionals may include improper patient selection, inadequate patient monitoring, and insufficient training or education related to the selection of drugs, dosing, lockout periods and infusion devices.

Five policies to implement

The ISMP, USP, and JCAHO devised recommendations for how health care providers can avoid PCA by proxy incidents. The entire recommendations are in the *Sentinel Event Alert* on the JCAHO web site, but this is a summary:

1. Develop criteria for selecting appropriate patients to receive PCA and nurse-controlled analgesia.

This criteria-based selection process should consider the risk that PCA by proxy might occur. Some patients may not be appropriate candidates to receive PCA because of their age (infants and young children are not appropriate candidates); their mental state (confusion, agitation, restlessness); or due

to their level of consciousness, psychological stability, or intellectual capacity.

2. Carefully monitor patients.

Even at therapeutic doses, opiates can suppress respiration, heart rate and blood pressure, so the need for monitoring and observation is critical. Oximetry and/or capnography monitoring may be appropriate in some cases.

3. Teach patients and family members about the proper use of PCA and the dangers of others pressing the button for the patient. Provide written instructions to family members that instruct them NOT to administer PCA doses.

4. Alert staff to the dangers of administering a dose for the patient outside of a nurse controlled analgesia protocol.

5. Consider placing warning tags on all PCA delivery pendants that state, "Only the patient should press this button."

Alternatively, consider posting warning signs in all areas where PCA therapy is used that state, "Only the patient should press the PCA delivery pendant." ■

On its web site, a hospital apologizes for a fatal error

Taking the idea of full disclosure to another level, a Seattle hospital has posted a public apology to the victim of a medical error with apparently no regard to how that may affect the inevitable lawsuit from the family.

Robert Caplan, medical director of quality at the 270-bed Virginia Mason Medical Center, posted a public notice on the hospital's web site taking full responsibility for the error that, according to press reports, involved a technician mistakenly injecting a 69-year-old woman with toxic skin-cleaning antiseptic instead of a harmless dye.

"Recently, a preventable medical error occurred at Virginia Mason that we believe caused the death of one of our patients," Caplan wrote.

"We have offered our heartfelt apologies to the family of the patient and are doing everything we can to help them in this time of grief. But perhaps the only way we can make our apology real is to do everything we can to prevent medical errors in our system. Those efforts start with admitting that we make errors — as in this case, owning up to errors, learning from them and fixing the systems that allow them to happen," he noted.

Caplan went on to cite the 1999 Institute of Medicine report, which indicated that perhaps as many as 98,000 Americans die each year as a result of medical errors. "More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516). This is a stunning statistic," he wrote. "Virginia Mason has made a firm commitment to eliminate errors from our system entirely — by establishing processes that bring errors to the forefront for examination, and by developing systems to prevent such errors in the future."

Caplan explained that "open discussion of medical errors is essential, because it provides the best opportunity to understand what actually happened and to teach others the important lessons that have been learned." Talking about these issues openly is "painful and difficult, but only in doing so do we acknowledge the reality of the flawed systems that exist in health care today — and arm ourselves with information to do something about it." ■

JCAHO alters its patient safety goal requirements

Recent action by JCAHO of interest to risk managers:

• After hosting the recent National Summit on Medical Abbreviations with several other organizations, JCAHO modified the 2005 requirements for meeting National Patient Safety Goal 2b — "Standardize the abbreviations, acronyms and symbols used throughout the organization, including a list of abbreviations, acronyms and symbols not to use."

Now the goal applies only to all orders and all medication-related documents (a reduced requirement). It also applies to pre-printed forms, for which 100% compliance is expected (extends the requirement beyond handwritten documentation, but is a reduced requirement from that planned for 2005).

The minimum expected level of compliance for handwritten documentation remains at 90%, JCAHO reports.

Rule of 6 on its way out

• After consulting safety experts, JCAHO reaffirmed the requirement that pediatric hospitals and

services which currently use the "Rule of 6" convert to standardized concentrations, as required by National Patient Safety Goal 3b, no later than Dec. 31, 2008.

The Rule of 6 is a methodology used in pediatrics to simplify intravenous preparation of weight-based drugs. JCAHO notes that a significant number of pediatric hospitals have requested permission to continue to use the Rule of 6 as an alternative approach to the requirement during some or all of the interim period.

Requests for alternative approaches to National Patient Safety Goal 3b "will continue to be considered and will require ongoing evidence of progress toward full implementation by Dec. 31, 2008, of the use of standardized drug concentrations," JCAHO reports. To be considered for the exceptions process, JCAHO requires a provider to meet these criteria:

— The exception applies only to neonatal or pediatric acute care services.

— All (emergent and nonemergent) admixtures are prepared only by pharmacy staff in a sterile environment.

— Calculations of the drug solutions are validated during the preparation.

— The labeling of solution concentration and drug per milliliter are clear to all caregivers, and the solution concentration (amount of drug per unit volume of solution) is clearly indicated on the label.

— If the Rule of 6 is used in a pediatric setting, but standardized drug concentrations are used in other parts of the hospital, guidance aids are made available to caregivers who may not be familiar with one of these systems.

— If the organization has a Neonatal Intensive Care Unit, the pharmacy is open 24 hours a day to support the admixture service.

— The facility uses smart pumps designed to recognize prescription errors, dose misinterpretations and keypad programming errors.

Free-flow protection now scored

• The Sentinel Event Advisory Group has begun the process of identifying potential 2006 National Patient Safety Goals and the group recently provided advice on current goals.

With regard to "free-flow" protection for infusion pumps, the group confirmed that all organizations should be scored for compliance beginning Jan. 1, 2005. Also, the interpretive guideline on the JCAHO web site will clarify that, in relation to intravenous administration sets used with infusion pumps, it will be acceptable to have "preassembled" free-flow protective mechanisms instead of "intrinsic" free-flow protection.

Concerning the requirement to report critical test results "directly" to physicians, the group advised that for 2006, the word "directly" should be deleted from Requirement 2d for laboratories. Beginning Jan. 1, 2005, JCAHO changed the interpretive guidelines for Requirement 2d for laboratories to say that "directly" reporting critical test results can include reporting to an authorized agent of the responsible licensed caregiver.

The Sentinel Event Advisory Group also recommended these topics for field review as potential 2006 Patient Safety Goals: culture of safety; patient involvement in safety; multidose medication vials; wrong-line connections; health care worker fatigue; delays in treatment; anticoagulant, insulin and narcotic use; and decubitus ulcers.

Must measure quality of organ procurement

• JCAHO also revised a requirement concerning organ procurement. Effective July 2005, standard PI.1.10 will require hospitals and critical access hospitals to "measure the effectiveness of their organ procurement efforts: The conversion rate data are collected and analyzed and, when possible, steps are taken to improve the rate. The conversion rate is the number of actual organ donors over the number of eligible donors as defined by the organ procurement organization. The intent of the requirement is to optimize the conversion of potential donors to become actual donors." ■

Reader Question

It's risky to allow patients to leave by the back door

Question: We have a physical therapy clinic that has an exit leading directly from the treatment area to the patient parking lot. Since most patients don't need to check out at the front desk before leaving, the therapists often direct them to this rear exit for convenience. But I'm concerned that patients are leaving through a door not

specifically intended for the general public to use. Am I right to be concerned or am I overreacting?

Answer: You're not overreacting. To the contrary, you're being a good risk manager, says **Fred Roll**, president of the International Association for Healthcare Security and Safety in Glendale Heights, IL.

A "back door" or any door not within sight of your staff and intended for the public to use, always poses a risk, he states. When people are allowed to come and go through that door, you raise the risk of theft for starters. If the door is unlocked and anyone can slip in unnoticed, you're going to find some laptops missing before long. And even if the door is locked from the outside, it's easy enough for someone to slip in when a patient comes out, Roll adds.

"Not only do they get in to do the theft, but then they get right back out that same door no one is watching. There's no one to ask why they're carrying your computer away," he says. "It's the same reason we don't let environmental service people park in the loading dock of a hospital after hours. They can just walk out the door and throw something in the truck and take off."

Of course, theft is not the worst result. The same person could enter to assault an employee or patient, and then the risk manager is going to have to explain why a rapist so easily slipped into the facility.

Allowing patients to use more than one main exit door also stretches your security resources. In many cases, your security resources are simply the front desk staff. They're expected to keep an eye on the lobby and notice if something is wrong.

"But they can't watch the other doors, too, and I'm guessing your physical therapists are involved with patients so they're not watching the back door," Roll says. "If you have limited security resources, you structure things so that they can keep their attention on one area."

Roll says it is proactive to recognize the risk of letting patients leave from multiple exits. It is not necessary to have patients check out at the front desk, but he suggests funneling them back through the same door they entered.

"It might be something that poses a small inconvenience, but you're preventing something much worse," he says. ■

Prepare for a flu season that has not hit its peak

It's not over yet!

This year is a wild card, and anything still could happen. First, we had a dangerous shortage of influenza vaccine, followed by many high-risk people who couldn't get or decided to forgo immunization. Fortunately, this has been a mild flu season — so far.

But February and March are the historical peak months for influenza activity, and the large numbers of high-risk, unprotected people make this a potential recipe for disaster. Influenza vaccine shortages and delays are a recurring problem,

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

- Does EMTALA obligation apply when a patient leaves ED during treatment?
- Board report formats — what are your colleagues doing?
- Hospital reduces some medical errors by 70%
- Work better with housekeeping to prevent falls

and at some point, we inevitably will face another influenza pandemic.

Are you and your hospital prepared if we run out of luck? Do you know where to turn for guidance and help? Do you know how to prevent the spread of this infectious disease? Or how to handle major staff shortages due to record absenteeism?

Thomson American Health Consultants has developed an influenza sourcebook to ensure you and your hospital are prepared for what could happen this flu season — or the next flu season.

Hospital Influenza Crisis Management provides the information you need to deal with ED overcrowding, potential liability risks, staff shortages, and infection control implications for staff and patients. This sourcebook addresses the real threat of a potential pandemic and the proposed response and preparedness efforts that should be taken in case of such an event. Major guidelines and recommendations for influenza immunization and treatment are included, along with recommendations for health care worker vaccination and the efficacy of and criteria for using the live attenuated influenza vaccine.

Hospital Influenza Crisis Management will offer readers continuing education credits. For information or to reserve your copy at the price of $199, call (800) 688-2421. Please reference code **64462**. ■

CE objectives/questions

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 managers in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **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.
- **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.

5. According to Kathy Rapala, JD, RN, what is the main requirement for people wishing to join Clarian's Safe Passage Safety Council?

A. They must be staff level employees.
B. They must be managers.
C. They must be senior administrators.
D. They must have at least five years' experience within the institution.

6. What effect did the Safe Passage initiatives have on occurrence reporting at Clarian?

A. No effect
B. Occurrence reporting decreased 57% in 2003
C. Occurrent reporting increased 134% in 2003
D. Occurrence reporting remained at the same level as in previous years

7. According to Jay Wolfson, DrPH, JD, in what way does the Sarbanes-Oxley law pose a risk for not-for-profit hospitals?

A. It requires greater accountability and disclosure from not-for-profit organizations, and it can create a way for federal regulators to find a cause of action.
B. It requires more lenient billing and collections practices.
C. It sets a cap on the amount indigent patients may be charged for some services.
D. It makes overly aggressive collections practices a federal crime.

8. According to a recent warning from JCAHO, where do most "PCA by proxy" adverse events occur?

A. Home care
B. Outpatient care
C. Long-term care
D. Hospitals

Answers: 5. A; 6. C; 7. A; 8. D.

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

Improper prescribing leads to toxicity and death: $2.2 million settlement in Missouri

By **Jan J. Gorrie**, Esq., and B**lake J. Delaney**, Summer Associate
Buchanan Ingersoll Professional Group
Tampa, FL

News: An elderly man diagnosed with rheumatoid arthritis was prescribed methotrexate by his doctor. Although he immediately began to experience symptoms of methotrexate toxicity, the doctor failed to take his patient's complaints seriously and refilled the prescription for another month. The man continued to experience the same symptoms and, two weeks later, he was rushed to an emergency department (ED) for treatment. The ED physicians, however, were unable to prevent the man's death, which they attributed to methotrexate toxicity. After the man's widow filed suit against the doctor and the pharmacy, the parties settled for $2.2 million.

Background: An 80-year-old man experiencing pain in his joints visited his doctor for treatment. The doctor diagnosed the man's condition as rheumatoid arthritis, an abnormality in his immune system that caused inflammation of the lining in his joints and internal organs. The doctor prescribed methotrexate. The patient filled the prescription at a regional pharmacy and he took daily doses as prescribed. After a few days, the man developed inflammation in his mouth and trouble swallowing.

After his prescription ran out, the patient revisited his doctor to complain of the symptoms. The physician told him not to worry and prescribed a refill of methotrexate. The man continued to take the drug. Two weeks later, the inflammation of his mouth and his difficulty in swallowing became too severe for him to bear and he went to a hospital emergency department. The ED's physician team recognized the man's symptoms to be indicative of methotrexate toxicity and gave him folic acid as an antidote. The man's condition began to improve, but it was too late and he died shortly thereafter.

The decedent's widow filed a wrongful death action against the prescribing physician and the regional pharmacy for their prescription of methotrexate. One of the plaintiff's experts said the doctor never should have prescribed methotrexate because the decedent did not have rheumatoid arthritis. A second expert witness testified that the drug, which had immunosuppressant effects, should have been administered in a single large dose on a weekly basis rather than in a series of small daily doses to give the man's body time to recover from the side effects. The second witness also concluded that the pharmacy had acted negligently because the doctor's prescriptions exceeded the maximum recommended daily dosage.

In his defense, the doctor argued that the drug did not cause any injuries to the man. He claimed that the patient's age and pre-existing health condition were the principal contributing factors to the death. The pharmacy, on the other hand, maintained that it acted properly for two reasons. First, the prescription did not exceed the maximum recommended dosage that could be taken on a weekly basis. Second, because the pharmacist was not permitted to substitute his or her judgment for that

of the physician, the pharmacy should not be held accountable for the treating physician's negligence.

Before the matter proceeded to trial, the two defendants settled with the plaintiff for $2.2 million.

What this means to you: "Several readily available medication safety tools were apparently not used in this case leading to the tragic death of this elderly man," notes **Marva West Tan**, RN, ARM, FASHRM, health care consultant in Marietta, GA. "Clinicians unfamiliar with the correct dosing or possible side effects of methotrexate can easily consult print or on-line drug guides, pharmacists should have a policy and procedure for contacting physicians regarding any medication orders that raise questions and physicians should both instruct patients about potential medication side effects as well as listen carefully to patients' complaints. Using any one of these safe practices might have prevented this fatal error.

"Current medication error research and reporting systems have identified certain groups of drugs more likely to be involved in serious medication errors," says Tan. "Physicians, whether prescribing in an office or inpatient setting, should take special care in prescribing high-alert medications, those drugs that the Institute for Safe Medication Practices (ISMP.org) have found carry a 'heightened risk of causing significant patient harm when they are used in error.' The ISMP lists oral and parenteral chemotherapeutic agents as a high-alert class of medications and oral methotrexate, used in nononcologic treatment, as a specific high-alert drug," adds Tan.

"Fatality related to incorrect methotrexate dosing as identified in this claim is not an isolated problem," states Tan. "The ISMP notes dozens of reported fatalities in patients receiving oral methotrexate. Common errors include incorrect prescribing by physicians, incorrect transcription of correct orders, and patient misunderstanding of correct dosing and labeling. In most of these errors, the patient took the medication daily rather than weekly as recommended. The ISMP further points out that methotrexate's once-a-week dosing schedule is used in relatively few medications, which could be a contributing cause of error on the part of physicians and patients more familiar with daily dosing of medications.

"Confusion about the correct dosing schedule for oral methotrexate presents a large pool for potential medication errors, due to the large numbers of patients with rheumatoid arthritis, asthma, psoriasis, inflammatory bowel disease, myasthenia gravis and inflammatory myositis who may be prescribed methotrexate for immune modulation or suppression. The Arthritis Foundation (www.arthritis.org) estimates that 2.1 million Americans now have rheumatoid arthritis, a disease that is more common in women in their 40s or 50s although it can strike either gender at any age. Although methotrexate used to be reserved for patients in the latter stages of rheumatoid arthritis, the current therapeutic approach favors early use of methotrexate or one of the other disease-modifying antirheu-matic drugs (DMARDS) to retard progression of rheumatoid arthritis before joint destruction and disability occur. Other DMARDS include intramuscular and oral gold, hydroxychloroquine, sulfasalazine and azathioprine with new drugs emerging in this group. Methotrexate is one of the most frequently used DMARDS and often is combined with hydroxychloroquine and one of the nonsteroidal anti-inflammatory drugs, e.g., ibuprofen or naproxen, in multidrug therapy," continues Tan.

"The usual dose of methotrexate is 7.5 to 20 mg, given orally as a single dose weekly," she reminds. "Because methotrexate use can be associated with liver damage, baseline liver function tests should be performed before methotrexate is started and periodically, usually monthly, while treatment continues. Red cell, white cell, and platelet production may also be monitored.

Physicians should remind patients that monthly blood tests will be needed for ongoing monitoring, schedule the next laboratory test date at each office visit and enter the patient's name into an office tickler system for callback if laboratory test dates are missed. Folic acid is often prescribed along with methotrexate and alcohol use should be minimal to prevent liver damage. Patients should also be informed that they are at risk for opportunistic infections while on methotrexate and should call the physician if any infections, mouth ulcers or stomach problems develop while they are taking the medication. The physician may recommend that methotrexate use temporarily be suspended until the patient recovers from the infection. Long term methotrexate use may increase a patient's risks of certain types of cancer but this risk must be balanced against the risks of prednisone, a powerful alternative with many serious side effects. Since rheumatoid arthritis is a chronic disease currently requiring lifelong treatment, patients should be encouraged to get involved in self-management, which may reduce errors as well as improve outcomes," notes Tan.

"Pharmacists and nurses daily provide a marvelous safety net to catch problematic drug orders before any medication error occurs," states Tan. "Physicians should welcome pharmacists and nurses' questions about their drug orders because catching incorrect orders early benefits both the patient and the physician from the devastation of a medication error, poor outcome, and possible malpractice claim. Pharmacists and nurses have an independent professional responsibility for correct medication use and must contact a physician if they have questions or concerns about an order. Fear of an angry response from a physician is no excuse to avoid a call. Patient safety must come first. Inappropriate physician responses can be reported later up the chain of command. Hopefully in the new culture of safety, there will be less hesitation to question unsafe orders. As part of the organizational patient safety program, clinicians in many health care settings are making an effort to report 'saves' or 'near misses' as well as actual medication errors. Capturing and recording near misses in order to be able to analyze potential root causes currently is an elusive task as no easy process has been identified. One approach is to discuss daily "saves" at shift change."

In conclusion, Tan notes that one of the ISMP's Medication Safety Alerts contains a list of safe practice recommendations for methotrexate prescribing. "These safe practices include general recommendations applicable to all medications, such as use of electronic prescribing systems with built in alerts," says Tan, "as well as methotrexate-specific recommendations such as naming a specific day of the week on the label instructions to reinforce the weekly dosing schedule. ISMP further recommends that 'Monday' not be selected as the dose day as a patient might confuse it with 'morning.' Fatal medication errors with high-alert medications such as methotrexate can be prevented if physicians, pharmacists and patients all take responsibility to inform themselves about the medications they prescribe, dispense and use, and to ask questions if they have concerns." ■

Reference

• *Estate of Anonymous v. Anonymous Doctor & Anonymous Pharmacy,* St. Louis City (MO) Circuit Court. ■

Failure to obtain informed consent: $400,000 verdict

News: A patient successfully underwent aortic value replacement surgery; however, it had the adverse side effects of causing her to lose her sight and sustain a hand injury. Two years later, the surgery was unsuccessfully repeated and the patient died. The family brought suit against the hospital and doctors alleging malpractice and the failure to obtain informed consent. The jury found in favor of the physicians, but awarded the plaintiffs $400,000 against the hospital for failure to obtain informed consent from the patient prior to undergoing the first procedure.

Background: A 56-year-old certified nurse's aide was admitted to the hospital to undergo a Ross procedure, which is a form of aortic value replacement surgery. The plaintiffs claimed that as a result of the procedure, the patient went blind and sustained a debilitating hand injury. The plaintiffs also alleged that the procedure was incorrectly performed and resulted in a prolapsed aortic value two years later, which necessitated repeat surgery from which the patient did not survive.

The plaintiffs alleged medical negligence on the part of the physicians, violations of informed consent procedures by the hospital, and wrongful death against both the hospital and physicians. All of the defendants maintained they committed no

negligence in the care of this patient and asserted they met applicable standards of care in their diagnoses, care, and treatment of the patient. The defendants also claimed that the patient was fully informed of all material risks, available alternatives, and benefits of the initial aortic value replacement procedure, as well as the risks and benefits expressly associated with the Ross procedure.

The jury returned a verdict awarding the plaintiffs $400,000 against the hospital for the failure to obtain informed consent and defense verdict in favor of the treating physicians.

What this means to you: Informed consent is a process of effective communication or exchange of information between the physician and patient regarding the intended procedure, risks, benefits, alternative treatment, expected outcome, and consequences for refusal of treatment.

"The physician has the ultimate duty to obtain informed consent from the patient or legally authorized representative; however, the hospital may, as this case demonstrates, still find itself liable if something goes wrong," says **Patti L. Ellis**, RN, BSN, LHRM, corporate risk manager, Pediatrix-Obstetrix Medical Group of Sunrise, FL.

"The patient's signature or that of a legally authorized representative does not constitute informed consent. The written consent form serves only to prove that informed consent took place. While the hospital and it nurses are not responsible for obtaining informed consent, the hospital usually through its nurses does have the duty to ensure that informed consent has been properly obtained and documented. Proof of informed consent is evidenced by a properly executed consent form placed in the patient's medical record. Many states, such as Florida, have specific laws on informed consent. Every risk manager should be well versed on their state's requirements governing informed consent and include it as part of their risk management education," she adds.

While the circumstances in this particular case are not known, "in the scenario where a hospital fails to have the patient/legally authorized representative sign a written consent form prior to surgery when dictated by hospital policy, where it can be proven that the patient was under the effects of sedation or duress when signing the form, when the signed form is in a language other than the patient's and where the failure of the hospital staff/ nurse to intervene on the patient's behalf and the patient sustains injury, one can understand how the jury might find the hospital liable for failure to obtain informed consent," notes Ellis.

"While unforeseen conditions can occur during the course of surgery that may require an additional procedure; it is obviously the surgeon's responsibility to address this with the patient during the informed consent process. In addition, this should be included on the consent form itself," she says.

"Every risk manager should have the overall responsibility for policy and procedure development for informed consent with direct involvement from the medical staff and nursing. Physician and nursing education is most important for avoiding litigation related to failure to obtain informed consent. As part of the your facility's quality improvement program, consider periodic chart audits to monitor consent form compliance, for as this facility found — even though obtaining informed consent is the physician's responsibility, if the hospital is unable to show that informed consent was documented they may be liable," concludes Ellis.

Reference

• King County (WA) Superior Court, Case No. 98-2-28165-1. ■

HIPAA Regulatory Alert

Supplement to Healthcare Risk Management and Hospital Access Management

Two HIPAA privacy provisions 'unnecessarily burdensome'

GAO report gauges provider reaction to privacy rule

A survey of providers, health plans, patient representatives, and others conducted by Congress' General Accounting Office (GAO) found providers and health plans believe that implementation of the HIPAA privacy rule went more smoothly than expected in its first year, but that two provisions of the rule are unnecessarily burdensome.

The providers and health plans raised issues about the requirements to account for certain information disclosures and to develop agreements with business associates that extend privacy protection downstream.

Consumer and provider representatives said the general public is not well informed about rights under the privacy rule, and more structured educational efforts are needed.

The GAO contended some evidence of patients' lack of understanding of the rule's scope and provisions may be reflected in the 5,648 complaints filed with the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) in the first year after the privacy rule became effective. Of the roughly 2,700 complaint cases OCR closed as of April 13, 2004, GAO said, nearly two-thirds fell outside the privacy rule's scope because they involved either accusations of actions not prohibited by the regulation, entities that are not covered under the regulation, or actions that occurred before covered entities were required to be compliant. Of the cases that were covered by the rule, OCR found that in 50%, no violation had occurred.

According to the GAO, provider groups stated that some physicians and hospitals remain unclear about what type of information may be disclosed for law enforcement purposes. Also, health plan representatives reported ongoing difficulties associated with knowing what state laws take precedence over the privacy rule.

The GAO said most provider and health plan organizations interviewed identified the requirement to account for certain disclosures as unnecessarily burdensome. The organizations reported that significant time and resources are needed to establish and maintain systems to track disclosures.

For example, various hospital departments keep patient information in separate systems not necessarily linked electronically. According to the Health Care Compliance Association, hospitals have had to review systems to establish electronic links or have had to create manual-tracking mechanisms. Similarly, health plan representatives reported many plans or insurers generally keep information related to one patient in multiple systems, making it difficult to track all information disclosures for that patient.

Provider and health plan representatives also expressed concern about the volume of disclosures that must be tracked, commenting that frequent, diverse disclosures required by law add significantly to the volume of information that must be tracked continually.

Many organizations GAO interviewed questioned whether the privacy rule accounting provision generates much benefit for patients. These organizations reported that their members have received few or no requests from patients for an accounting of the disclosures of their protected health information.

To somewhat reduce the burden of the requirement to account for disclosures, several organizations suggested that OCR modify the rule to require covered entities to inform patients in the privacy practices notice that when required by law, their information will be disclosed to public health organizations and law enforcement agencies.

The GAO said provider and health plan representatives reported that significant resources also have been required to implement business associate agreements. The organizations said that some

of the burden associated with implementing the provision stemmed from confusion and variation in determining which relationships with downstream entities require agreements.

Although the privacy rule provided for phased-in implementation of business associate agreement requirements to accommodate existing contracts, provider and health plan groups still viewed the business associate agreement provision as very burdensome, the GAO said.

Some organizations representing providers and health plans suggested that OCR provide more guidance to covered entities about when and how to enter into a business associate agreement. The organizations said OCR's existing guidance is not specific enough to assist providers and health plans with their agreements.

Patient advocates reported facing new obstacles when seeking access to protected health information on behalf of patients due to excessive paperwork, misunderstanding of the rule, and reluctance by providers and health plans to share information with legal aid attorneys, state ombudsmen, and others when the rule permits discretion.

Many organizations said patients are not aware of their rights under the privacy rule, either because they don't understand the notice of privacy practices or because they have not focused attention on privacy issues when notices are presented to them. In its conclusion, the GAO recommended that the secretary of HHS:

- modify the privacy rule to require that patients be informed in the notice of privacy practices that their information will be disclosed to public health authorities when required by law and exempt such public health disclosures from the accounting for disclosures provision;
- conduct a public information campaign to improve awareness of patients' rights under the privacy rule.

In written comments, the GAO said, the department agreed with the finding that implementation went more smoothly than expected and privacy procedures have become routine practice for many staffs.

In commenting on a recommendation that it conduct a public information campaign to improve awareness of patients' rights under the privacy rule, the agency agreed notices of privacy practices may appear too long and complicated and consumers may not be reading the notices closely. HHS said that the complaint data received by OCR may not indicate consumers are unaware of their rights under the rule, but rather that they don't properly understand their rights. HHS pointed to two new consumer fact sheets posted to its web site last August, a toll-free phone line to respond to questions about the rule, and efforts to encourage covered entities to develop consumer-friendly notices that highlight key information.

The GAO said a more diverse approach to consumer outreach may be necessary to effectively communicate the new privacy rights. Information available on the web site and through a toll-free phone line provide access to a portion of the general public, it added, but may not reach the many consumers who don't know of those sources. "We believe it is important that, in current and future efforts to educate the public, HHS more effectively disseminate information about protections provided under the privacy rule," the GAO said.

(Download the GAO report at www.gao.gov/cgi-bin/getrpt?GAO-04-965.) ■

Requirements on copying cost charges confusing

What costs are considered reasonable?

What used to be a fairly routine occurrence for many health care providers — supplying copies of patient medical records on request — is becoming a major issue under HIPAA because of questions about how much can be charged for a copy of the record and the service under the HIPAA privacy rule and various state laws.

Copies of medical records are requested routinely by patients changing providers, providers in connection with giving treatment to patients, and attorneys for use in legal cases. Under the privacy rule, covered entities (health plans, clearinghouses, and providers that transmit health information in electronic form in connection with a HIPAA covered transaction) are to inform individuals of their right of access to inspect and obtain a copy of their protected health information in the records maintained by or for the covered entity.

Rebekah A.Z. Monson, an attorney with Pepper Hamilton's Philadelphia office, tells *HIPAA Regulatory Alert* the privacy rule permits covered entities to charge "reasonable cost-based fees" for providing copies of protected health information to individuals or their personal representatives. Under the privacy rule, she says, fees for copies of medical records only can cover costs of:

1. **copying**, including costs for supplies and labor;
2. **postage** if the individual has requested that the information be mailed;
3. **preparing an explanation or summary** of the information, but only if agreed to by an individual who has requested such a summary or explanation rather than the complete record.

The problem, Monson says, is in the preamble to the privacy rule, the Department of Health and Human Services wrote that while fees for copying and postage costs under state law are presumed to be reasonable, per-page costs that include costs excluded under the privacy rule, such as processing, retrieving, and handling charges, are not acceptable. As a result, she says, state-mandated fees for copying charges, or a portion of those fees, may be preempted by HIPAA and the privacy rule.

"Many state-mandated copying fees are higher than the costs involved in copying the information, and therefore, these fees may be pre-empted by the lower 'reasonable' cost standard," Monson says. "In connection with providing copies to individuals or their personal representatives, covered entities will need to carefully review the state-mandated fees and determine whether they meet the privacy rule reasonableness standard."

The department has not tried to give specific allowable cost figures because costs vary depending upon the size of the covered entity and the form of the copy, she adds.

Another area of confusion involves the fee charged individual patients, contrasted with the fee that can be charged for other requests or permitted disclosures, such as disclosures to a third-party pursuant to a patient authorization, which appear to fall outside of the scope of the privacy rule copy charge requirements.

"The department, in its comments on the privacy rule, intended to assure that a right of access would be available to all individuals and not only to those who can afford a copying fee," Monson says. "But there is a question of how an appropriate fee should be determined if, for example, an attorney is requesting the records as part of litigation. We've been hearing of some very high fees charged third parties when the copying is done in states that have limited or no controls over fees to be charged."

In general, under the privacy rule, the authority of patients' personal representatives to act on behalf of individuals stems from the representatives' authority to make health care decisions for the individual, such as through a health care power of attorney. That typically is not the case when attorneys are representing patients in lawsuits.

Also, the preamble to the privacy rule clarified that the department's intent was to enable individuals to have access to their protected health information. "We do not intend to affect the fees that covered entities charge for providing protected health information to anyone other than the individual," it said.

Monson says there have been reports of some malpractice plaintiffs attorneys asking their clients to request the information and have it sent to them for future delivery to their attorney, thus hoping to keep the cost of copying at the individual level.

She says there is confusion about the scope of HIPAA's copy charge requirements, particularly with respect to how they intersect with state law requirements, and would expect continued attention and possible litigation on these issues.

[Contact Ms. Monson at (215) 981-4031 or e-mail her at monsonr@pepperlaw.com.] ■

CMS issues first of seven security guidance papers

Paper provides security rule overview

The Centers for Medicare & Medicaid Services (CMS) has issued the first in a projected series of seven papers to provide guidance for covered entities. *Security 101* is an overview of the HIPAA security rule requirements and implementation and a preview of the remaining six papers.

The Security Series papers are designed to give HIPAA-covered entities insight into the security rule and assistance with implementation of the security standards, CMS said. "While there is no one approach that will guarantee successful implementation of all the security standards, this series aims to explain specific requirements, the thought process behind those requirements, and possible ways to address the provisions."

All HIPAA-covered entities must comply with the security rule. Compliance deadlines are April 20, 2005, except for small health plans, which have until April 20, 2006.

In explaining the rationale for the security rule, CMS noted that before HIPAA, there was no generally accepted set of security standards or general requirements for protecting health information. At the same time, new technologies were evolving,

and the health care industry was beginning to move away from paper processes and rely more heavily on the use of computers to pay claims, answer eligibility questions, provide health information, and conduct many other administrative and clinically based functions.

The security rule differs from the privacy rule in that the privacy rule sets standards for, among other things, who may have access to protected health information, while the security rule sets the standards for ensuring that only those who should have access to electronic protected health information actually will have access. CMS said that with the passing of deadlines for both the privacy and electronic transactions and code set standards, many covered entities now are turning their attention to the security requirements.

An "implementation specification" in the security rule is a detailed instruction for implementing a particular standard. Each set of safeguards is comprised of a number of standards that, in turn, generally are comprised of a number of implementation specifications that are either required or addressable.

For required implementation specifications, covered entities must implement policies and/or procedures that meet what the implementation specification requires. For those that are addressable, covered entities must assess whether they are reasonable and appropriate safeguards in the entity's environment. That involves analyzing the specification in reference to the likelihood of protecting the entity's electronic protected health information from reasonably anticipated threats and hazards. Covered entities that choose not to implement an addressable specification must document the reasons and implement an equivalent alternative measure if that measure would be reasonable and appropriate. CMS said decisions on which security measures to implement to address the standards and implementation specifications will depend on a variety of factors, including the entity's risk analysis, security analysis, and financial analysis.

At a minimum, the process for complying with the security rule should involve assessing current security, risks, and gaps; developing an implementation plan; implementing solutions; documenting decisions; and reassessing periodically, the agency said. The security requirements were designed to be technology-neutral and scalable from the very largest of health plans to the very smallest of provider practices. CMS said covered entities will find that compliance with the security rule will require an evaluation of what security measures currently are in place, an accurate and thorough risk analysis, and a series of documented solutions from a number of complex factors unique to each organization.

"HHS recognizes that each covered entity is unique and varies in size and resources, and that there is no totally secure system," it added. "Therefore, the security standards were designed to provide guidelines to all types of covered entities, while affording them flexibility regarding how to implement the standards. Covered entities may use appropriate security measures that enable them to reasonably implement a standard. In deciding which security measures to use, a covered entity should take into account its size, capabilities, the costs of the specific security measures, and the operational impact. For example, covered entities will be expected to balance the risks of inappropriate use or disclosure of electronic protected health information against the impact of various protective measures. This means that smaller and less sophisticated practices may not be able to implement security in the same manner and at the same cost as large, complex entities. However, cost alone is not an acceptable reason to not implement a procedure or measure."

Security standards are divided into administrative, physical, and technical safeguards. Generally, administrative safeguards are the administrative functions that should be implemented to meet security standards, including assignment or delegation of security responsibility to an individual and security training requirements. Physical safeguards are those mechanisms required to protect electronic systems and equipment and the data they hold from threats, environmental hazards, and unauthorized intrusion, including restricting access to electronic protected health information and retaining off-site computer backups. Technical safeguards primarily are the automated processes used to protect data and control access to data, including using authentication controls to verify that the person signing onto a computer is authorized to access the electronic protected health information or encrypting and decrypting data as they are being stored and/or transmitted.

Other papers in the series will cover administrative safeguards, physical safeguards, technical safeguards, organizational policies and procedures, and documentation requirements.

(For information and copies of Security Series papers, go on-line to www.cms.hhs.gov/hipaa/hipaa2.) ■