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IN THIS ISSUE

MAY 2005
VOL. 27, NO. 5 • (pages 49-60)

The lesson of the Terri Schiavo case: Living wills no panacea for end of life

Dispute was aberrant but it offers lessons for risk managers

In the final days of the dispute over whether Terri Schiavo, the 41-year-old, severely brain-damaged woman in Florida, should be allowed to die by removing her feeding tube, news commentators repeatedly cited the need for patients to have living wills. If only Schiavo had signed a living will before her injury, all of this turmoil could have been avoided, they said.

But that's just not true. Risk managers know better than most people that, while living wills can be useful in some circumstances, they do not guarantee that end-of-life decisions will be simple or uncontested. The Schiavo case proves that point well, says **Carl E. Schneider**, MD, JD, the Chauncey Stillman Professor of Law at the University of Michigan (UM) Law School and professor of internal medicine at UM in Ann Arbor. Schneider has studied living wills extensively with researcher **Angela Fagerlin**, PhD, a research scientist with the UM Medical School and Veterans Affairs Ann Arbor Healthcare System. **(See p. 52 for more on their research.)**

Schiavo did not have a living will, but the two researchers say the document would not have helped quell the vicious debate among family members.

"I don't think a living will would have changed things one iota," says Schneider. "You have a family that is embroiled in such mutual animosity that they are prepared to do anything they can to strike out at the other side. If you really feel that way and have the resources to do it, you can cause unending trouble for the people you're dealing with, and that is clearly what has happened here."

Any document can be contested

So if she had a living will, even one that was unusually specific in detailing that she did not want nutrition and hydration after a prolonged period in a vegetative state, Schiavo's parents still would have contested

it, he says. It is very hard to write living wills that accurately reflect a person's desires, he says, and even the best living will can be picked apart by a good lawyer.

"The living will depends not just on the language you use, but on the clarity of the medical circumstances," Schneider explains. "Here, there would have been ambiguity even if the living will said she did not want to live in a persistent vegetative state. They would just keep arguing that she was not in a persistent vegetative state and they would find doctor after doctor who would say that for them. That's exactly what they did, and a living will would not have deterred them."

No matter how ironclad the living will may appear, any opposing party with enough motivation can keep picking at it, word by word, until they find a court that will agree it is not so ironclad after all.

"Every day I go teach a class of law students; I teach people how to do that," Schneider says. "Then you have to hope they won't do it in an irresponsible way. But lawyers are trained to identify ambiguity and to build arguments based on even the smallest opening."

Don't push for more living wills

Fagerlin cautions risk managers not to jump on the living will bandwagon just because everyone else seems to be recommending them in the wake of the Schiavo case. **(For more of her advice on that issue, see p. 52.)**

To have *any* effect on calming the debate, Schiavo's living will would have had to be extremely specific, describing exactly the situation she was in 15 years after the incident that left her brain damaged. The problem, Fagerlin explains, is that no one can anticipate precisely what situation they will be in when the living will is invoked. Schiavo was just 26 when her heart stopped because of a chemical imbalance believed to have been brought on by an eating disorder, leaving her severely brain-damaged. How many healthy 26-year-olds can imagine being in the condition Schiavo was in after 15 years of brain damage and make an informed decision about what should be done at that point?

Very few, Fagerlin says. The result is that even when someone with the best intentions creates a living will, it is rarely specific enough to avoid the kind of intrafamilial dispute that occurred with Schiavo. If one member of the family, especially someone with substantial standing like the parents, disagrees with the living will or the whether it is time to invoke it, the document usually is not strong enough to withstand the challenge, Schneider says.

In most situations, the patient is better served by assigning a durable power of attorney to a trusted relative or friend who can then make all health care decisions on his or her behalf, Fagerlin

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.

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says. That arrangement is far more practical and reliable than a living will. But in the Schiavo case, even a durable power of attorney would not have made much difference, she adds.

A durable power of attorney grants legal standing for one person to make decisions for another; but in the Schiavo case, the courts repeatedly confirmed that the patient's husband had that authority. As far as the courts were concerned, the husband was responsible for determining her fate and a durable power of attorney would not have added to that authority in any way.

So how could the patient, the hospice, and the family end up in a situation in which such legal documents have no bearing? Schneider says the Schiavo case is "a truly disastrous example" of what can happen when opposing parties are motivated to contest end-of-life decisions no matter what. That is not what happens in most cases.

"Very few of these cases even go to the hospital's ethics board, much less going to 25 different court rooms in search of a decision," Fagerlin says. "I think it would be a terrible reaction to use this case for any policy changes or legislative initiatives because it is so very unusual."

Watch for legislative action

One bad outcome from the Schiavo case could be a growing emphasis on living wills and proof of a vegetative state.

"If I were a risk manager, I would be worried that in reaction to this case legislatures will pass laws requiring that you always err on the side of life and prevent you from withdrawing treatment unless you provide all sorts of really clear evidence," Schneider says. "The other thing I would worry about is any effort to promote living wills even more than they already are. Apparently, there are some efforts under way in Washington as a result of this case to make us all have living wills. I can only imagine how hospitals are going to get the burden of that requirement."

If there is any good news for risk managers in the wake of the Schiavo controversy, it is this: You're very unlikely to have a similar case at your own facility. Even in the Schiavo case, the health care providers were essentially bystanders waiting to be given instructions, he notes.

"No one would want to be the provider with all these lawsuits swirling around you, but this is so completely atypical. It is the most unusual decision to end treatment in the history of the United States," Schneider says. "It is not a good example of anything at all in a legal sense. It is dangerous to try to draw conclusions on anything based on this case, because it such a freakish case."

Schneider does suggest that risk managers look at the Schiavo case as the nightmare scenario for how badly end-of-life decisions can go off the rails. You're unlikely to find yourself in the same degree of controversy, he says, but memories of the Schiavo case may prompt risk managers to intervene earlier when families are not in agreement about a patient's death.

"It seems there were so many points at which they might have compromised, but once they got locked into this mutual hatred there was no hope of discussing the case reasonably," he says. "That's where the risk manager might play a role, by helping the family come together through mediation before the animosity goes past that point of no return."

Encourage mediation early in disputes

Schneider's research shows that most end-of-life decisions are made over the course of 24-72 hours, and the family ends up feeling they did the right thing. What can set off a dispute, he says, is not the substance of the decision. Instead, disputes are prompted by the way people are treated in the midst of such sad circumstances.

"It comes down to very small human misbehavior that irritates the family, like someone saying he

is the spokesman for the family and everything must go through him," he says. "That infuriates people. What upsets people about the hospital is not being given information. It's the pathetic woman who won't leave her husband's bedside to go to the bathroom because she's afraid she'll miss the doctor and not be able to talk to him for another day."

Risk managers can help by making sure family members are properly attended during this time, he suggests. For instance, they should have a place to rest and wait other than the patient's room. Too often, he says, family members report feeling lost and out of place in the hospital, left to stand in the hallway.

"If you want to avoid trouble with the family, there are some straightforward things you can do that are good for everybody. Make sure they have all the information they need, and attend to their basic human needs in this tragic time for them," Schneider says. "Those are better than any legal solutions, and it's also just a good thing to do for people." ■

Brace for more living wills, encourage deeper thought

Many agencies and nonprofit organizations that tout living wills are reporting a sharp increase in people seeking the documents because of the Schiavo case, so you can expect more patients to show up with questions about them or clutching a living will that they downloaded off the Internet.

That's not good news for a risk manager, says researcher **Angela Fagerlin**, PhD, a research scientist with the University of Michigan Medical School and Veterans Affairs Ann Arbor Healthcare System. The recent flurry of advice about living wills will result in people signing the documents without the necessary reflection, she cautions.

"People are saying these documents are the solution the problems in the Schiavo case, which is not true, and so they're finding a standard living will form somewhere and signing it," Fagerlin says. "They're doing it without putting enough thought into these very, very important decisions. If they say they don't want mechanical ventilation, have they considered that they might get pneumonia and need a ventilator for just a couple of days?

"Are they saying they would rather die than do that?"

Health care providers are obligated under the federal Patient Self-Determination Act to tell patients about living wills and other advance directives, but Fagerlin says risk managers should make sure that patients are informed about the limitations of living wills and the other options, such as a durable power of attorney.

Patients may get the impression that a living will is necessary to avoid prolonged life support, having no idea that a surrogate can be designated to make decisions at that time instead of trying to specify preferences now. See questions about a living will as an opening for a more thorough discussion of options, Fagerlin suggests.

"Encourage people to consider the situation more thoroughly, because they may not have even read the living will they downloaded off the Internet," she says. "Remind people that this is a very serious decision they're making and they need to fully consider all the ramifications. Make sure they know that there may be a better way to have their wishes carried out, a better way than this one document they've heard so much about." ■

Research questions living wills and sees a better way

Living wills just aren't worth the paper they're printed on, say two experts who have looked at how the documents are really used. The documents may lull risk managers into a false sense they have avoided potential difficulties by encouraging patients to address them up front, they say.

Those conclusions stem from a comprehensive review of hundreds of studies of living wills, end-of-life decisions, and the psychology of making choices by **Angela Fagerlin**, PhD, a research scientist with the University of Michigan (UM) Medical School and Veterans Affairs Ann Arbor Healthcare System, and **Carl E. Schneider**, MD, JD, the Chauncey Stillman Professor of Law at the UM Law School and professor of internal medicine at UM in Ann Arbor.

Schneider and Fagerlin recently released a study in which they analyzed how living wills were actually used and how much they reduced the end-of-life debates they were intended to address.[1] Their basic conclusion was that a living will is "a nice idea, but it doesn't work," Schneider says.

The living will, Fagerlin notes, was designed by bioethicists who wanted to give patients a chance to spell out what treatment they would want and what treatment they would reject if they became unconscious or unable to make their own decisions for some other reason. The idea of the living will is to allow people to maintain control even at the end of life but they have proven to be impractical, he says.

Fagerlin says there is no evidence that living wills work, yet health care providers spend thousands of dollars every year promoting them to patients, partly because the law requires them to and partly because there is a strong belief that living wills are "the right thing to do."

Schneider urges risk managers to reconsider how living wills are promoted in their institutions because he says they are, at best, a waste of time. But he goes a step further and suggests that you are doing your patients a disservice by encouraging them to sign something that ultimately will not be useful.

"I do think it is a kind of malpractice to be pretending to patients that these documents are really going to have an effect," he says. "People are making these really serious decisions based on little information, seeing it as just one more form to fill out. And you're telling them that they have addressed a very serious matter when in fact they have not."

It is unlikely that patients could find a successful way to sue the provider when a living will does not fulfill its promise, but Schneider says risk managers are fooling themselves if they think that living wills will help them avoid thorny situations like the Schiavo case.

Reference

1. Fagerlin A, Schneider CE. Enough: The failure of the living will. *Hastings Center Report* 2004; 34:30-42. ■

MN hospital creates a culture of full disclosure

To make full disclosure work, you first have to remember that it is not a "program" or an "effort," or a "policy," says a leader at one hospital that has undergone a major change in way adverse events are discussed with patients and families. Full disclosure is more of a philosophy and an overall way of working with people, says **Julie Morath**, RN, MS, chief operating officer and vice president of care delivery at Children's Hospitals and Clinics of Minnesota in Minneapolis.

"If you want to be patient and family-centered, that requires a foundation of trust," she says. "If our patients and families can't trust us to be honest with them and tell the truth, to disclose when there has been an error, an accident, a failure in their care, I don't think we can enter a true therapeutic relationship."

Implementing such a philosophy takes time. Children's spent more than a year carefully crafting policies and procedures and even choosing the right words to use. Some semantic differences proved important. For instance, Children's asks "What happened?" instead of "Who did it?" after an adverse event.

The hospital also created an Office of Patient Safety that analyzes patient safety data and acts on reports from physicians and staff.

"It was important that they see that something happened to the information they took the time to report," Morath explains. "We work from the premise that everyone comes to work to do a good job and do no harm, so we wanted to create an environment that values people who step forward to let us know about failure points or where they personally got tripped up."

Disclosure policy prompts bigger change

Morath explains that the change began when the Children's board of directors endorsed a policy of full disclosure to families as part of its overall patient safety agenda. The policy states that "Children's Hospitals and Clinics works with its professional staff to achieve complete, prompt, and truthful disclosure of information and counseling to patients and their parents or legal guardians regarding situations in which a medical accident occurred 1) when there is clear or potential clinical significance; or 2) when some unintended act or substance reaches the patient."

The policy is designed to achieve these goals:

- Improve patient and staff safety by decreasing system vulnerability to future accidents.
- Evaluate and improve care provided.
- Reduce the chances for patient morbidity and mortality.
- Restore patient, family, employee, provider, and community confidence that systems are in place to assure future accidents are not likely to recur.

• Emotionally, professionally, and legally support staff who have been involved in events.

• Ensure disclosure of the accident, near miss, or sentinel event to the family, as well as ongoing communication of system improvements to family and caregivers involved in the accident.

When an event occurs, Children's conducts a full analysis to understand the multicausal components that produced the conditions allowing the event to occur. Morath says that immediately following an accident or near miss, a "sequence-of-event" analysis is conducted.

"This is followed by a causal analysis study with all key stakeholders to seek to learn what contributing variables existed, and steps to take to eliminate system vulnerabilities and latent error that could realign to produce a future accident," she says. "Formal procedures and resources are used to guard against blame, attribution, and hindsight bias — all of which are human tendencies in conditions of a devastating event."

While maintaining confidentiality of the patient and providers involved, a case study is created to inform others about the risks so actions are taken to prevent such an event from happening again. That analysis is designed with these goals in mind:

- Understand what happened.
- Identify opportunities for improvement.
- Support caregivers, patients, and their families.
- Incorporate this learning into our daily work.

Disclosure not just a confessional

Morath says that in the disclosure process, a presumption of truth-telling guides all discussions. Generally the physician managing communication should presume that all information that describes the specific event affecting a patient can and should be disclosed, with the exception of identifying the specific staff members involved in the accident, if unknown to the family.

The disclosure is a thoughtful, well-defined process meant to re-establish confidence and maintain a therapeutic relationship, Morath says. **(See p. 55 for more details on how Children's conducts the disclosure process.)**

A key to the Children's philosophy is that "disclosure is not a confessional," Morath says. "This not just an opportunity to get it off your chest so you can feel better. It is a professional activity. It has to be approached with the same knowledge base, skill, and discipline as any other intervention. Disclosure isn't just an outpouring of one's soul."

The disclosure begins with an apology, possibly the most important part of the discussion, she says. From there, Children's offers the patient and family as much information as possible and the assurance that more will be forthcoming as the investigation proceeds.

Physicians and staff are trained in how to disclose, and senior staff such as Morath are available to either accompany others during disclosure or to conduct the disclosure if the other person is either too uncomfortable or unwilling.

"We don't name names in the disclosure process by pointing the finger at someone like the nurse who just happened to be last person in a long line of system failures that made the accident possible," she says. "We indicate what has happened, what the consequences to the patient are as we know them today, that an analytic review will take place, that the family will know the results of that review, and what changes will be made to reduce the probability that this will ever happen again."

No punishment for reporting errors

Another important part of the disclosure philosophy at Children's is the blameless reporting system. Simply promising employees that will not be punished for reporting accidents is not enough, Morath says. They must see over time that you mean what you say.

Under the reporting policy at Children's, staff members who promptly and appropriately report accidents to a patient's immediate care giver, manager or Children's safety office "will not be subject to retaliation and will receive the administrative support of Children's in all matters relating to the accident. This does not require Children's to protect staff members who engage in intentional acts of malfeasance which compromises patient safety."

The hospital devoted a lot of time and resources to educating staff about adverse events and the new system for reporting events and concerns. Targeted learning packets about patient safety were provided to leadership and clinical staff, and different packets for patients and families.

For staff, the safety guides reiterate the importance of moving from a culture of blame and secrecy to one of open communication and analysis of systems, Morath says. For families, the packets are intended to help them understand their role as partners in care, encouraging them to ask questions and participate in ongoing communication with caregivers.

Modeling its reporting system on the type used in the airline industry, Children's adopted a new incident report the form of a "safety learning report" that is mostly text, rather than a series of questions or boxes to check off.

"You mostly learn about systems through the stories, what happened, what the conditions were at the time, and what you think could have prevented this," she says. "One thing we learned was that near misses or vulnerabilities that are not dealt with can reconfigure at another time in a way that actually harms the patient. So we started asking 'Have you ever seen this before?' to help us become aware of recurrent problems."

Morath notes that forms asking a person to check off boxes are good for data management, but not so much for learning. It's a different kind of data analysis that is needed for improving patient safety, she adds.

"We have reading groups that do content analysis and abstract the patterns," Morath says. "Once we land on an issue and create an improvement project, then we measure the data and analyze it. But the narrative description in the original reports is what shows the need for improvement."

One example is how Children's discovered that the lab was getting too many unlabeled specimens. Leaders were first alerted by the narrative reports in which staff explained that specimens were arriving without proper patient identification, and that prompted an investigation. The root cause turned out to be far upstream in the first line patient identification, which led to an improvement project regarding the reliable identification of every patient, every time, with two identifiers.

"We've completely eliminated mislabeled specimens because the lab won't accept them any more," Morath says. "The system depends on staff first alerting someone that something is wrong or could be improved."

Commit to real culture change

Morath suggests that risk managers interested in embracing full disclosure more thoroughly "look far upstream." The changes at Children's required a wholesale revamping of philosophy at the hospital, not just the implementation of a new policy handed down by risk management.

The new approach is a culture change, along with some very practical skills training and tools for disclosure, Morath says. Staff and hospital leaders must be prepared for significant changes in their roles, she says.

Children's found that a very traditional risk management, a legal approach focused mainly on limiting the liability of the organization, did not fit well with the new philosophy of full disclosure. That old-school approach did not promote a good relationship with the patient and family, at a time when they need your support.

"We really reconceptualized our risk management program here," she says. "Protecting the assets of the organization certainly is critical, but even more important is protecting those we care for. We determined that we want legal counsel to advise us of our risk, but the malpractice risk and legal concerns do not form the philosophy or define the relationship with those who depend on us for care." ■

Disclosure process starts with an apology, then info

Disclosure is a complex process, not simply an opportunity to sit at the patient's bed side and say you're sorry, says **Julie Morath**, RN, MS, chief operating officer and vice president of care delivery at Children's Hospitals and Clinics of Minnesota in Minneapolis. Her hospital has developed an extensive protocol for how to disclose adverse events, which starts with an apology but moves on to providing all the information that the patient or family will want.

During initial and follow-up discussion, Morath says the following subjects may be discussed, although discussion of each subject on this list is not required, nor is discussion limited to these topics:

- that Children's and its staff regret and apologize that an accident has occurred;
- the nature of the accident;
- the time, place, and circumstances of the accident;
- the proximal cause of the accident, if known;
- the known, definite consequences of the accident for the patient and potential or anticipated consequences;
- actions taken to treat or ameliorate the consequences of the accident;
- who will manage ongoing care of the patient;
- planned investigation or review of the accident;
- who else has been informed of the accident

(in the hospital, review agencies, etc.);

• actions taken, if any, to identify system issues which may have contributed to the accident and to prevent the same or similar accidents from occurring;

• who will manage ongoing communication with the family;

• the names and phone numbers of individuals in the hospital to whom the parents may address complaints or concerns about the process around the accident;

• the names and phone numbers of agencies to whom the family could communicate about the accident;

• how to obtain support and counseling regarding the accident and its consequences both within Children's and from outside of Children's;

• that charges and expenses directly related to the accident will be removed from the patient's account;

• that Children's will assist the family in referral to resources to help them obtain compensation if actual damages warrant. ■

CPOE leads to other errors if implemented improperly

While computerized physician order entry (CPOE) is expected to significantly reduce medication errors, systems must be implemented thoughtfully to avoid facilitating certain types of errors, according to a recent study.

The study, supported by the Agency for Healthcare Research and Quality (AHRQ), looks at clinicians' experience in using one CPOE system at a major urban teaching hospital. Though the findings may seem critical of CPOE, AHRQ Director **Carolyn M. Clancy**, MD, says that is not necessarily the case. She says the findings are typical for products early in their implementation.

"New health care information technology products usually go through an ongoing process of refinement and improvement as health care workers identify problems," she says. "Ideally, principles of human factors research, usability testing, and work flow impact should all be considered before products are released into the workplace."

Clancy says that while the findings are important, the study focuses on the experience of one hospital and one product and may not be easily applied to industry at large.

"It means these products are in their early implementation period, and there will be a learning period to improve both these systems and make CPOE function at its best," she says.

Clancy says implementation problems would be minimized through testing before products are marketed, and through adaptation to meet the needs of individual clinical settings.

CPOE proven to reduce errors

The use of health information technology to reduce medical errors and improve patient safety has been extensively documented and supported in peer-reviewed literature, Clancy notes.

Last year, President Bush called for the widespread adoption and use of electronic medical records within the next 10 years and established the Office of the National Coordinator for Health Information Technology, headed by **David Brailer**, MD, PhD.

"The findings from this study show that the particular way that computerized physician order entry products are developed and implemented makes all the difference in whether quality is improved," Brailer says. "This study emphasizes the important need for health information technology products to talk to one another so that patient information can be shared."

The study identified 22 situations in which the CPOE system increased the probability of medication errors.[1] According to the study, these situations fell into two categories: information errors generated by fragmentation of data and hospitals' many information systems; and interface problems between humans and machines, where the computer's requirements are different than the way clinical work is organized.

Common CPOE errors cited

Some of the flaws identified by the study include:

• Medical staff may look to the CPOE system to determine minimal effective or usual dosage for infrequently used medications. However, the CPOE system may only reflect dosage sizes available at the pharmacy, which may differ from the minimal or usual dosage that should be prescribed. The flaw represents an inappropriate use of the data available on the CPOE system and could result in prescribing incorrect dosage.

• Clinicians might select the wrong patient file because names and drugs can be hard to read, computer mice are often imprecise, and patients' names do not appear on all screens.

• A patient's medication information is seldom synthesized on a single screen. Up to 20 screens might be needed to see all of a patient's medications, increasing the likelihood of selecting a wrong medication.

• Because of the patient load and multiple tasks, nurses are often unable to enter timely information on the computer about the administration of drugs. The delayed information may affect later medication and clinical decisions.

• Computer downtime, whether for maintenance or in the event of crashes, can result in delays in medications reaching patients.

The study was based on interviews with medical staff, focus groups, shadowing staff as they worked, and a survey of interns and residents at a major urban teaching hospital with a widely used CPOE system.

Reference

1. Koppel R, Metlay JP, Cohen A, et al. Role of computerized physician order entry systems in facilitating medication errors. *JAMA* 2005; 293(10):1,197-1,203. ■

Mandatory error reporting worries hospital leaders

A survey of hospital leaders indicates that many have serious reservations about a mandatory error reporting system, including that it would discourage event reporting and increase the risk of lawsuits, according to a recent study.

The Institute of Medicine has recommended establishing both mandatory and voluntary reporting systems for health care institutions such as hospitals and nursing homes. The purpose of reporting is to collect data on a broad range of events to detect systemic problems that can be altered to reduce the risk of patient harm. As of October 2003, 21 states had mandatory event reporting systems for hospitals, although policies varied.

Joel S. Weissman, PhD, a researcher with the Institute for Health Policy at Massachusetts General Hospital in Boston, and colleagues conducted a study to elicit the views of hospital executives with regard to mandatory state reporting systems and closely related issues of patient safety.[1] The researchers surveyed chief executive and chief operating officers (CEOs/COOs) from randomly selected hospitals in two states with mandatory reporting and public disclosure, two states with mandatory reporting without public disclosure, and two states without mandatory systems in 2002-03.

Responses were received from 203 of 320 hospitals (a response rate of 63%). The researchers found that most CEOs/COOs thought that a mandatory, nonconfidential system would discourage reporting of patient safety incidents to their hospital's own internal reporting system (69%) and encourage lawsuits (79%) while having no effect or a negative effect on patient safety (73%). More than 80% felt that the names of both the hospital and the involved professionals should be kept confidential, although respondents from states with mandatory public disclosure systems were more willing than respondents from the other states to release the hospital name (22% vs. 4% to 6%).

State standards have influence

When presented with hypothetical clinical vignettes, more than 90% of hospital leaders said their hospital would report incidents involving serious injury to the state, but far fewer would report moderate or minor injuries, even when the incident was of sufficient consequence that they would tell the affected patient or family.

"In the hospital setting, executive leaders influence institutional policy and foster norms for their employees," the authors wrote. "These individuals believe that existing state reporting standards fail in some cases to provide clear guidance on what should be reported and that mandatory reporting systems with public disclosure may actually discourage internal reporting, lead to lawsuits, and impart little benefit to patient safety. Hospital leaders, of course, have their own institutional biases, and there is some evidence that hospitals that become accustomed to transparency may eventually grow to be more accepting of it. However, if hospital leaders continue to harbor negative views of reporting, it is unlikely that state mandatory reporting systems will be highly successful in the long run."

Reference

1. Weissman JS, Annas CL, Epstein AM, et al. Error reporting and disclosure systems: Views from hospital leaders. *JAMA* 2005; 293(11):1,359-361,366. ■

Coordinating care doesn't have to increase liability

Conventional wisdom is wrong: Primary care doctors who coordinate the care of their patients by specialists may actually have lower liability risk than primary care doctors who do not attempt care coordination.

That is the advice from **Mark Hall**, JD, professor of law and public health sciences at Wake Forest University in Winston-Salem, NC. But many doctors believe otherwise, he says.

A representative national sample of 1,238 practicing physicians found that 49% listed legal liability as one of the two main barriers to care coordination, Hall reports. In fact, he and his colleagues found that care coordination by physicians does not increase the threat of lawsuits or result in higher malpractice insurance premiums.

Care coordination involves establishing and monitoring a comprehensive treatment plan encompassing the recommendations of all specialists and resolving conflicts among specialists regarding medication, treatment, or patient behaviors, Hall explains.

These primary care doctors review the overall management of the patient's multiple conditions, encouraging compliance with recommendations of the specialists and taking steps to prevent future problems. But many primary care doctors don't try to coordinate care beyond recommending that their patients see specialists, Hall says.

"Persons with multiple chronic conditions often encounter a complex and inefficient system of care as a result of inadequate care coordination," Hall says. "Care coordination currently isn't being done very well."

These patients account for more than half of all medical spending, he notes.

"They endure higher rates of avoidable complications and hospitalizations," Hall says. "Improving care coordination can substantially improve health outcomes and lower costs."

Weighing the liability of care

Coordinating care also can reduce medical errors, so Hall says it is important to remove any perceived barriers to better care coordination by physicians. Physicians worry about liability because coordinating care creates a broader responsibility for patients with complex conditions who have a greater chance of poor outcomes, he explains.

"Based on the collective experience and judgment of experts in medical liability, however, there does not appear to be any basis for physicians who perform care coordination to have serious concerns about liability," Hall says. Patients with chronic illness are not more likely to sue. Also, courts will not hold primary care physicians automatically responsible for mistakes made by specialists just because the primary care physician is coordinating the patient's care.

"Courts hold doctors responsible only for what the doctor does, and not what other doctors might do wrong," he says. ■

Reader Question

When alerting to urgent care copay, beware of risk

Question: We have a freestanding urgent care clinic affiliated with our hospital; but one insurer won't recognize it as an urgent care center, pand those insured patients must pay an emergency department copay instead of an urgent care copay. We've had incidents in which patients became irate after treatment when they were informed that they had to pay the higher copay, so we'd like to place a sign up front explaining the situation. But would that violate EMTALA by discussing financial information before screening the patient? What can we say on the sign without discouraging patients from seeking treatment? (And in general, when and how does EMTALA apply to urgent care clinics?)

Answer: You may be risking more trouble with EMTALA than the original problem is worth, warns **Kerrin Slattery**, JD, a partner in the Chicago office of McDermott, Will & Emery LLP. She says that, while she sympathizes with the desire to alert patients to the unexpected copay amount, a sign in the entrance area may create a bigger problem by creating misunderstandings that could prompt an EMTALA investigation.

First, Slattery explains that EMTALA usually applies to urgent care clinics. Urgent care clinics

are subject to EMTALA if they are a department of the hospital and they meet the definition of a "dedicated emergency department," she says. A dedicated emergency department is defined as meeting any of these three criteria: It is licensed as an emergency department, or it is held out to the public as providing urgent care without scheduled appointments, or at least a third of the clinic's patients come in without a scheduled appointment. Typically, an urgent care clinic qualifies under the second or third criteria.

So assuming the urgent care clinic is covered by EMTALA, the question is whether you would violate the law with a sign that warns patients of a particular insurer's requirement that the emergency copay applies instead of the lower copay for urgent care. The law allows providers to perform any reasonable admission procedures, but it prohibits any action that would unduly discourage an individual from staying to receive treatment.

"Does signage warning that the patient will have to pay more money here unduly discourage?" Slattery asks. "In a perfect world, EMTALA was not intended to restrict good patient service, which is what you're trying to do here. You're trying to help the patient avoid a nasty surprise later with the copay. But the reality of what happens might be different."

Slattery says trouble could arise from even a generally worded sign like "This is not a licensed emergency department; however your insurer may consider services rendered here as emergency services." Patients reading that sign are likely to ask questions of your admissions staff such as "Does *my* insurer charge more if I'm treated here?"

"I think the sign could elicit questions, and then you're really starting to jeopardize EMTALA compliance," Slattery explains. "It all depends on how the staff answers those questions, which might never have been asked but for the sign you put up. It's not necessarily the sign itself that poses the risk but the conversation that is prompted by the sign."

Any statement by the staff that is construed as discouraging the patient from staying for treatment could be seen as an EMTALA violation. And the risk is high even if your staff are very careful about how the copay information is relayed. Consider this scenario:

The staff may explain the facts and encourage the patient to stay for treatment, but the patient may respond that "If I have to pay the $100 emergency copay, I might as well be in an ED." At the ED, the patient mentions that the urgent care clinic staff said he would have to pay a $100 copay, so he came to the ED instead. After hearing that a few times, the ED staff wonders if that is an EMTALA violation they are obligated to report. To cover themselves and avoid charges that they did not report a violation, they pass their concerns on.

The next thing you know, regulators at your door investigating whether you are steering patients away from your urgent care clinic.

No one wants that. Slattery suggests that the problem you're trying to fix — the occasional patient who becomes irate upon learning of the higher copay — is not worth the risk of the EMTALA violation.

"You might be better off by dealing with it at the billing desk after treatment. Explain it to them there, and if you have someone upset about it, deal with them individually," she says. "Otherwise, you get on a slippery slope by trying to address everyone up front." ■

COMING IN FUTURE MONTHS

- The growing risk of e-mail communication
- Info you should have on hand for emergencies
- Risk of falls in young patients often is overlooked
- The top malpractice trends and what you can do about them

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 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. ■

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. Why does Carl E. Schneider, MD, JD, say a living will would not have had much impact in the case of Terri Schiavo?
A. The parents would have contested the specific wording and other elements of the living will.
B. The state of Florida recognizes living wills only in very limited circumstances.
C. A living will would have expired in the 15 years since her initial injury.
D. Living wills do not apply to removal of nutrition and hydration.

18. As a general rule, what do Angela Fagerlin, PhD, and Carl E. Schneider, MD, JD, recommend patients rely on living wills instead?
A. Durable power of attorney
B. A personal letter to the primary physician
C. A lengthy discussion with the risk manager
D. A note inserted in the patient's chart

19. What does Julie Morath, RN, MS, recommend regarding full disclosure after adverse events?
A. It should include an expression of regret and an apology for the incident.
B. To reduce liability exposure; it never should include any expression of regret or an apology for the incident.
C. An apology or expression of regret may be offered only after all investigations are complete and all questions have been answered.
D. An apology or expression of regret only may be offered if the patient or family's attorney specifically requests it.

20. According to Kerrin Slattery, JD, which of the following is true of urgent care centers and EMTALA?
A. EMTALA never applies to urgent care centers.
B. EMTALA applies only to urgent care centers located within the main hospital property.
C. EMTALA applies only when life-saving care is provided in an urgent care center.
D. EMTALA applies to most, but not all, urgent care centers under the government's definition of a "dedicated emergency department."

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

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

Failure to diagnose perforated bowel results in a $670,000 settlement

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

News: A woman presented to the ED of a hospital. When told there would be a two-hour wait to be seen, she tried to drive to another hospital but had to stop and call for emergency medical assistance. She was taken by ambulance back to the first hospital where, several hours she later, she was diagnosed with a perforated bowel. Rather than immediately perform the required emergency surgery, she agreed to be transferred to another hospital. She died shortly after arriving at the receiving facility.

Her husband and parents brought a wrongful death action against the hospital, treating physicians, and ambulance service. Prior to trial, all parties confidentially settled for $670,000.

Background: The woman presented to the ED with complaints of severe abdominal pain. After an initial evaluation by the triage nurse, she was told it would be at least two hours before the physicians would examine her. She elected to leave the hospital with her husband and drive to another hospital about 45 minutes away.

En route to the second hospital, her pain and discomfort became so severe that she and her husband stopped at friend's house and called a rescue squad. Paramedics arrived and transported her to the closest facility, the hospital where she had been triaged earlier.

She arrived at the ED for the second time at 1:50 a.m. Vital signs revealed her to be febrile, with pulse of 88 and blood pressure at 100/60. This was the only recorded set of vital signs throughout the admission. She was placed on a gurney in a hallway and an IV was unsuccessful.

At 3:15 a.m., the ED physician evaluated her. Lab and radiology studies were performed. Flat and upright abdominal films showed a high-grade small bowel obstruction. Lab assessments revealed an elevated white blood cell count of 20,300.

According to her husband, the ED physician told him his wife had a bowel obstruction and asked where she would like to have the surgery performed. The husband said neither the ED physician nor the on-call surgeon offered or suggested the surgery be performed immediately at that hospital.

Since the patient had had prior gastric bypass surgery performed at another facility, she and her husband requested the surgery be performed there. Meanwhile, her condition deteriorated. The ED staff was unable to obtain blood pressure readings and, after several unsuccessful attempts to establish an IV line, the on-call surgeon was asked to establish a central line. The central venous access was finally established at 5:30 a.m. and an arterial blood gas was taken at 5:40 a.m. This test showed the patient was in a metabolic acidosis state.

Her care was turned over to an ambulance service for transport to the other facility at

6:30 a.m. — almost five hours after her second arrival at the ED.

During transport, no oxygen, intravenous fluids, or medications were administered and, with the exception of cardiac monitoring, her vital signs went unmonitored. The patient was awake throughout the trip until her arrival at the receiving facility, where she turned to her right side, took one gasp of breath, and arrested. Full cardiopulmonary resuscitation measures were immediately employed but, despite all efforts, she was pronounced dead at 7:43 a.m.

The decedent's spouse and parents brought action against the providers for wrongful death. The plaintiff alleged the ED physician violated the standard of care by failing to appropriately assess and stabilize the patient prior to transport to another facility.

The plaintiff further alleged the ED staff violated the standard of care by allowing her to be transported. Similarly, the plaintiff claimed the ambulance service should not have transported a patient that was clearly not properly stabilized and that it did not provide sufficient monitoring of her condition while in transit.

The cause of death became an issue. On autopsy, a large, benign adrenal carcinoma known as a pheochromocytoma was found. The defense alleged the death was caused by a "pheo crisis" or "storm" and it further alleged that the medical chart provided by the ED physicians and others was appropriate under the circumstances.

This action resulted in a settlement among all of the defendants of $670,000.

What this means to you: EDs are mandated by EMTALA to provide triage and to stabilize a patient that presents with an emergency medical condition or is in labor.

"By virtue of this federal statute, there is an established standard of care regarding the management of any patient that presents to an emergency department. This is the prevailing issue regarding this case," notes **Cheryl Whiteman**, RN, MSN, HCRM, clinical risk manager at BayCare Health System in Clearwater, FL.

In her first ED visit, the patient made a decision to leave after being told by the triage nurse that she would not be seen for at least two hours, despite the chief complaint of severe abdominal pain.

"It could be argued that if conditions truly prevented an examination by a physician," says Whiteman, "it may have been prudent for the nurse to share findings with the physician. Rather than allowing the patient to leave without being evaluated by a physician, perhaps verbal orders could have been given for preliminary blood work and/or X-rays to at least begin a diagnostic work-up.

"When the patient was returned to the emergency department by ambulance, as a result of worsening symptoms, a first and only set of vital signs were recorded, making it difficult to determine if she exhibited signs of deterioration and certainly eliminating a defense argument that she was being monitored. It took approximately 1½ hours to obtain test results. That perhaps could have been obtained when she first presented, probably two to three hours earlier," she adds.

Communication in the health arena is critical and seems to have been lacking in this instance.

"Based on the radiology studies, the physician was working with a diagnosis of a small bowel obstruction, apparently corroborated by the on-call surgeon. It seems unlikely that the patient and her husband were appropriately

apprised of the risks in attempting transfer to another facility for surgery. Despite having had previous surgery at that facility, risks for the transfer of a patient with a bowel obstruction and a delay in surgery are significant, and it appears that neither the patient nor her husband had a clue as to the serious nature of her condition," says Whiteman.

"As if the communication breakdown was not enough, another delay in treatment occurred in administering fluids as the staff was unable to establish an IV line. Fluid administration did not begin for approximately two hours after a diagnosis was made. Despite arterial blood gases clearly indicating metabolic acidosis, this patient was placed into an ambulance for transport an hour later. As the metabolic acidosis was not addressed, this patient was clearly not stable for transport, thus breaching EMTALA requirements and the standard of care. Likewise, there is no defense for transporting a patient in extremis without monitoring vital signs, administering oxygen, fluids, and appropriate medication," adds Whiteman.

"An autopsy determined that this patient had pheochromocytoma. While abdominal pain is a symptom of such an adrenal tumor, there was no mention of a history of more common symptoms, including hypertension, headache, rapid heart rate and palpitations. In fact, in the absence of documented vital signs throughout her ordeal, it is impossible to determine if this patient displayed extreme symptoms of pheochromocytoma, which can include acute hypertension, ventricular fibrillation, myocardial infarction, and cerebrovascular accident. Regardless of her presentation, had the surgeon proceeded with abdominal surgery for the diagnosed small bowel obstruction, there may have been the possibility of discovering the tumor and perhaps the patient would have had an increased chance of survival. Despite the preoperative diagnosis, multiple delays in diagnosis apnd treatment, failure to stabilize, and transporting an unstable patient leaves little defense for this case," she explains.

"A thorough root-cause analysis is warranted to address serious issues. Staffing needs to be reviewed to determine why there were so many delays in care and treatment. Basic management of the emergency department patient with an acute abdomen as well as the patient in acidosis needs to be taught or reviewed, along with the basics of vital signs. Documentation needs to be addressed urgently. Extensive education in regard to following EMTALA regulations and providing informed consent in regard to transfer is required. The risk manager would also be prudent to initiate an ongoing monitoring system with the emergency department to evaluate the effectiveness of the education and to ensure that the desired improvements are achieved and maintained," concludes Whiteman. ■

Perforation found during surgery causes settlement

News: A woman underwent surgery to remove her gallbladder. During the procedure, the surgeon noticed a hole in the patient's intestine, which he immediately repaired. However, he completed the surgery without examining the rest of the intestine.

After the procedure, the woman exhibited symptoms of an abdominal infection. Doctors reopened the woman's abdomen and discovered a second perforation that had caused intestinal contents to leak into her abdominal cavity. Although they attempted to repair the hole, the delay had irreversibly exacerbated the woman's condition and she died.

Upon filing a lawsuit for medical malpractice, the patient's estate settled with the surgeon for $1.75 million and with the hospital for $350,000.

Background: The 67-year-old woman with a history of abdominal surgery required a cholecystectomy to remove her gallbladder. The attending surgeon decided to perform a laparoscopic cholecystectomy, a newer technique using several small incisions and a small, thin tube with a scope on its tip to see inside the patient.

During the surgery, however, the surgeon experienced difficulty. He altered the surgical method to the traditional open cholecystectomy, whereby he removed the woman's gallbladder through a 5-inch to 8-inch long incision in her abdomen, stretching from below her ribs to just below her waist. During the procedure, the surgeon happened noticed a hole in the patient's intestine, which he immediately repaired.

After the cholecystectomy, the patient was septic and hypotensive. Doctors scheduled a second surgery to examine the woman's abdominal

cavity. This second procedure, performed 36 hours after the cholecystectomy, revealed another hole in the patient's intestine, through which intestinal contents had leaked into her abdomen, causing massive contamination. Although the doctors attempted to repair the second perforation, she died soon afterward from abdominal infection.

After the patient's estate filed suit alleging negligence against the surgeon, the surgeon's professional association, and the hospital, the parties reached a settlement agreement. The surgeon agreed to pay the plaintiff $1.75 million, and the hospital contributed an additional $350,000.

What this means to you: "There are several risk concerns to consider in this case. Given the patient's previous history of abdominal surgery, she had an increased risk for tissue scarring and adhesions. Laparoscopic procedure may not have been the optimal method for this patient, which placed her at increased risk for injury that unfortunately occurred. This is of course a physician judgment call and hopefully the surgeon discussed this with the patient during the informed consent process. As each patient is individual, so are the surgical risks. It's not one size fits all. What may not be a risk for one patient may be a significant risk for another. Risk managers should include this as part of their education on informed consent," notes **Patti L. Ellis**, RN, BSN, LHRM, CPHRM, corporate risk manager at Pediatrix-Obstetrix in Sunrise, FL.

"Perforation is a well-recognized risk of laparoscopic surgery and the most likely cause of this patient's intestinal injuries. Unfortunately, had the surgeon taken the time to fully examine the entire intestine, the complications that ensued including the need to take the patient back to surgery to repair the other hole may have been avoided and changed the outcome for this patient," she states.

"What we don't know from the facts of the case provided are the reasons for the 36-hour delay in returning the patient to surgery, and so we don't know whether it was related to patient monitoring, surgeon availability, or operating room availability. However, given allocation of damages, it is more likely than not that the hospital was somewhat at fault. Patient monitoring and delays in care and treatment are common causes of malpractice litigation and should be part of your risk management education. Case study presentations and evidence based risk assessments are very effective ways to educate and communicate this to your hospital and medical staff," explains Ellis.

"While we don't know whether there was a claim for negligent credentialing, the risk manager plays a valuable role in reducing these types of risks to their organization by ensuring that there are established written policies and procedures for the credentialing process. Part of that includes delineation of privileges, which identifies the surgeon's qualifications and competence in performing specific types of procedures and should be reviewed at the time of medical staff appointment and reappointment," she notes.

"This case sounds like Murphy's Law. Everything that could go wrong did go wrong. While liability rested mainly with the surgeon, it was prudent to settle this case rather than run the risk of a more costly jury verdict," notes Ellis. ■

HIPAA Regulatory Alert

Supplement to Healthcare Risk Management and Hospital Access Management

Privacy and security rules affect development of care management and outcomes improvement programs

Take all reasonable steps to comply with federal law, expert says

Many managed care organizations use care management programs to improve care to members while also saving money. To effectively manage patients' care, providers need the most information possible, says **John Jones**, an attorney in the Philadelphia office of Pepper Hamilton LLP.

The question becomes, under HIPAA, whether managed care organizations can disclose patient information to all providers for any reason.

Jones tells *HIPAA Regulatory Alert* provider disclosures usually are electronic because providers attempt to access the care management programs through their computer systems.

"If you are going to a cardiologist, the doctor will want to know everything about you that is in the system," he says. "We advise care management vendors to develop software that will restrict or exclude information. What we hope will remain is the basic health care information, such as a history, that can arguably be disclosed without patient consent for treatment purposes."

According to Jones, there is a HIPAA exception for health care operations that includes information for care management. But he says state law doesn't always consider the applicability of the information. Pennsylvania law, for instance, allows managed care organizations to disclose information for care management upon patient consent. To the extent possible, the patient is to remain anonymous.

Jones adds that depending on the jurisdiction, protected information may be delivered as part of marketing materials. Those disclosing information should note they are doing it to provide a higher quality of care, he says. If a jurisdiction requires consent but doesn't specify the type, an opt-out form might be acceptable for implied consent.

"If the jurisdiction in which a provider is working requires express consent, you need to get the consent up front, even for treatment," Jones says. "States seem to take the privacy of health information very seriously."

There are privacy concerns any time a virtual electronic medical record is created. This may be particularly true if a National Health Information Infrastructure is developed, a move being pushed by federal officials interested in care management and the sharing of provider and patient information to improve public health. The thought behind a National Health Information Infrastructure is that it would be a secure, interconnected reporting of data from which providers and other health-care professionals could learn about their patients and make sound health care-related decisions.

"We continue to see clients pushing and the law catching up," Jones says. "If you can demonstrate that care management improves health care and take all reasonable steps to comply with the federal law, you're going to be pretty safe, even if you're at risk under some state laws. If you need to be cautious at the state level, you should not make highly sensitive information available such as HIV, mental health, or substance abuse information."

[Contact John Jones at (215) 981-4706.] ■

Process for administrative simplification complaints

In the March 25 *Federal Register,* the Centers for Medicare & Medicaid Services (CMS) published procedures for nonprivacy administrative simplification complaints under HIPAA, along with a description of the procedures the Department of Health and Human Services will follow in reviewing such complaints.

According to CMS, individuals who believe that a covered entity — a health plan, health care clearinghouse, health care provider conducting specified transactions electronically, or prescription drug card sponsor — is not complying with the HIPAA administrative simplification provisions may file a complaint with the agency. Complaints must:

1. be filed in writing on paper or electronically;
2. describe the acts or omissions believed to be violating the administrative simplification provisions;
3. provide contact information for the complainant and the covered entity;
4. be filed within 180 days of when the complainant knew or should have known the act or omission occurred.

Once CMS receives a complaint, it will make a preliminary review to determine whether to accept it for processing. If the complaint is complete and appears to allege a failure to comply with an administrative simplification provision, CMS will notify the complainant that the complaint is accepted for processing and further review. This does not represent a determination that a compliance failure has occurred. If additional information is required to make the preliminary determination, the agency will ask the complainant for the additional information and will wait a reasonable time to receive it.

Complaints that are accepted for processing and review will be investigated by CMS. If the agency finds that a compliance failure may have occurred, it will advise the covered entity that a complaint has been filed and inform the covered entity of the alleged compliance failure.

"CMS will work with covered entities to obtain voluntary compliance," the notice stated. CMS will ask the covered entity to respond to the complaint by submitting in writing one of the following:

- a statement demonstrating compliance;
- a statement setting forth with particularity the basis for its disagreement with the allegations;
- a corrective action plan.

Covered entities that dispute allegations made in a complaint are to document:

- compliance;
- in what respect they believe the allegations to be factually incorrect or incomplete;
- why they disagree that their alleged actions or failures to act constitute a failure to comply.

Once it has received that information, CMS may ask for an opportunity to interview knowledgeable people within the covered entity or review additional documents or materials. The agency also may seek additional information from the complainant.

If a corrective action plan is accepted, CMS said it will actively monitor the plan and require the covered entity to periodically report its progress toward compliance. If the covered entity comes into voluntary compliance, CMS will notify the complainant, and the parties will be notified when a complaint is closed. The agency said it will make "reasonable efforts" to secure a timely response from a covered entity that is the subject of a complaint. If the entity fails or refuses to provide the information sought, an investigational subpoena may be issued to require the attendance and testimony of witnesses and/or production of any other evidence sought in furtherance of the investigation.

After finding that a violation exists, the notice said, the secretary of Health and Human Services will pursue other options such as, but not limited to, civil money penalties. ■

Many are unprepared for April 20 security deadline

Many small physician practices had gaps in three key areas as they attempted to meet the April 20 deadline for HIPAA security standards, according to Dallas-based MedSynergies. Many small practices use older practice management software systems that have not been upgraded to comply with HIPAA, says **Judi McClain**, who supervises HIPAA compliance for MedSynergies.

The three key problems the company has seen in working with physicians in 23 states are:

1. **Lack of data backup plan**.

In many practices, medical data are backed up on a tape drive connected to the main computer. In some cases, tapes are stored at the provider's office. The HIPAA security standards call for providers to be able to access data in case of an emergency so operations can continue. Continuing to store backup tapes at the provider's office is not an option, McClain says. In the ideal situation, providers would back up data at a secure, remote facility.

2. **Lack of access controls**.

The HIPAA standards require all users of medical information systems at a medical office to have a two-step log-in. Each user must have a unique user ID and secure password. This is similar to the

two-step process required for most on-line financial transactions. However, many older practice management systems don't require a password or allow users to log in with a common shared user name and password.

3. No audit controls.

The new standards require that the office's practice management software system keep a detailed record of who has logged on to the system and what data they have accessed or changed. This is necessary in case confidential medical data accidentally is transmitted to the wrong address or inappropriately modified.

[For information, contact Christopher Tammen at (972) 791-1206, ext. 1206, or go on-line at www.medsynergies.com.] ■

HHS publishes paper on HIPAA physical safeguards

The Department of Health and Human Services (HHS) has published the third in a series of seven papers designed to provide guidance on the HIPAA security standards. (Go to www.cms.hhs.gov/hipaa/hipaa2.) This paper deals with requirements for physical safeguards for information systems and related equipment and facilities.

The HIPAA Security Rule defines physical safeguards as "physical measures, policies, and procedures to protect a covered entity's electronic information systems and related buildings and equipment from natural and environmental hazards and unauthorized intrusion."

The department says that when covered entities evaluate and implement the standards, they must consider all physical access to electronic protected health information (EPHI), noting this may extend outside of an actual office and could include work force members' homes or other physical locations where they access EPHI.

Physical standards include facility access controls, workstation use, workstation security, and device and media controls. For each of the standards, the paper includes definitions, questions for covered entities to consider, and implementation specifications. Previous papers presented an overview of the rule and guidance on administrative safeguards. Upcoming papers will cover technical safeguards; policies, procedures, and documentation; risk analysis and risk management; and implementation for small providers. ■

Group wants changes to privacy rule requirement

The Confidentiality Coalition, a group of hospitals, health plans, drug companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, employers, medical teaching colleges, and others, is asking Health and Human Services Secretary **Mike Leavitt** to use his authority to change the HIPAA privacy rule's accounting of disclosures requirement.

Under the privacy rule, the group said, all covered entities must track and account for disclosure of patient health information, with certain exceptions, and maintain records on all patients in such a way that the records can be used to furnish accounting of disclosures on demand, even when such disclosures are required by law, regulation, or request of a regulatory agency. The rule permits individuals to request an accounting of disclosures made over a six-year period.

"This regulation has been extremely burdensome and costly," the coalition wrote to Leavitt. "In fact, one hospital estimated that compliance with this requirement meant the hiring of two full-time employees whose sole job consists of HIPAA-related paperwork. While only a small percentage of patients will ask for a list of disclosure accountings after their care, the hospital must maintain a specific record of each disclosure in case a former patient should happen to request an accounting of disclosures."

The coalition also noted that state insurance departments routinely require health plans to turn over thousands of records every year for claim verification and auditing functions. And health plans and providers sometimes are required to report immunization, birth, death, and other records to state authorities. "Tracking millions of records every year because of government requests is extremely costly," the letter explained. "In addition to the cost of tracking, there is an enormous storage cost as health plans and providers must secure gigabytes and terabytes of computer storage for this very significant level of records."

The coalition said it had noted with interest a September 2004 report from the Government Accountability Office recommending a reduction in the administrative burden created by the accountability of disclosures requirement. The group recommended HHS modify the rule to exempt mandatory disclosures to public health

authorities from those that must be reported under the accounting of disclosures requirement.

The Government Accountability Office report expressed serious concern that the rule's requirements regarding accounting of mandatory disclosures to public health authorities do not support the rule's goal of ensuring effective patient privacy protections without imposing unnecessary costs or barriers, the coalition said.

It added that while it supports the recommended change regarding disclosure to public health authorities, it is important to clarify that the exemption also includes disclosures to other government entities such as state insurance departments. "In our view, this should not be limited to mandatory disclosures, but should be expanded to cover routine disclosures to government entities. Further, the burdens associated with the accounting of disclosures provision grow more complex when considered in the context of a national health information infrastructure and interoperable electronic health records — an important goal of President Bush. It will be extremely costly and administratively complex to maintain these records, thereby discouraging entities from participating in a regional information exchange."

Given that the act gives the HHS secretary the ability to modify requirements as deemed appropriate, but not more than once every 12 months, and the last modifications of the HIPAA privacy rule were incorporated into the final rule published Aug. 14, 2002, the group said additional modifications would be allowed at any time and thus urged Leavitt to take immediate steps to modify the requirements for all mandatory and routine disclosures to government entities, since such a change is consistent with the law's goal and would provide important cost savings. ■

HIPAA's 'chilling effect' on biomedical research

An editorial in the February issue of the *Annals of Epidemiology* expresses concern that HIPAA's efforts to enhance patient confidentiality by restricting access to medical records is slowing the progress of critical biomedical research.

University of Pittsburgh Graduate School of Public Health professor **Roberta Ness** reports a significant "chilling effect" of the regulations after documenting trends in recruitment of research subjects to the Prenatal Exposures and Preeclampsia Program Project, an ongoing prospective study of women followed throughout pregnancy at Magee-Womens Hospital of the University of Pittsburgh Medical Center, for which she is a co-investigator.

The ultimate aim of the study is to determine the cause of preeclampsia, a complication that affects up to 7% of first pregnancies and can be fatal to mother and baby.

The first phase of the study took place from 1997 to 2001, before HIPAA implementation, with an average of 12.4 women recruited each week, he says. But after HIPAA, due to restrictions on researchers' ability to identify potentially eligible subjects, recruitment fell to an average of 2.5 to 5.7 women a week.

Inconsistencies among academic institutions concerning interpretation of HIPAA regulations remains a potent threat to a wide range of clinical and biomedical research studies, Ness adds. The University of Pittsburgh's Institutional Review Board first disallowed waivers of the rule, she says. Investigators may seek a waiver to allow them easier access to protected health information, but waiver criteria vary among universities. At Pitt, a waiver was granted in 2003 and rescinded in 2004.

"Recruitment with a HIPAA waiver decreased by half, and recruitment without a HIPAA waiver fell by half again," Ness explains. Internal university efforts continue to resolve these kinds of conflicts for researchers, she says, but modifications to the rule itself would go a long way toward standardizing the way institutions view it.

"The post-HIPAA era brought an unwillingness on the part of the University of California system to continue its 16-year-long rapid cancer case reporting relationship with the California State Cancer Registry," Ness adds.

"For well over a year, researchers were barred from access to large numbers of recently diagnosed cancer patients in a case that also briefly engaged the state's court system. Fortunately, the University of California reversed its stance," she notes.

The American College of Epidemiology has called on Health and Human Services (HHS) to address the issue. "An HHS advisory committee has proposed HIPAA modifications that include harmonizing HIPAA with the common rule that determines other Institutional Review Board activities, among others," Ness says. "We can only hope that the new secretary of Health and Human Services will adopts these modifications." ■