CPR refusal highlights risk of overly strict policies

Don't create unethical conflicts and potential liability with corporate rules

Recent media coverage showed a dramatic 911 call between an emergency dispatcher and a nurse at a retirement home who refused to perform cardiopulmonary resuscitation (CPR) on an elderly woman who was unresponsive. Now some healthcare leaders and attorneys are wondering if similar dilemmas could arise at other facilities. The real issue, they say, concerns overly restrictive policies rather than the particular type of setting where that event occurred.

The incident happened at the Glenwood Gardens Retirement Facility in Bakersfield, CA. A recording from the 911 call center, played repeatedly by the news media in the days afterward, included a nurse refusing the 911 dispatcher's instructions to give CPR to a dying resident of the facility. The nurse told the dispatcher that the 87-year-old woman was barely breathing. In response to the dispatcher's instructions to begin CPR, the nurse says "Yeah, we can't do CPR at this facility." *(For more of the exchange between the dispatcher and the caller, see the story on p. 52.)*
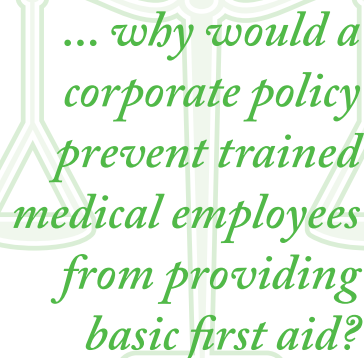
... why would a corporate policy prevent trained medical employees from providing basic first aid?

Lorraine Bayless died by the time paramedics arrived, and the ensuing media attention was highly critical of the retirement facility. How could the nurse be so callous? And why would a corporate policy prevent trained medical employees from providing basic first aid?

For healthcare risk managers, the issues are more complex and more far-ranging than what was portrayed in the news media, says **Eve Green Koopersmith**, JD, a partner with the law firm of Garfunkel Wild in Great Neck, NY. The fact that the death occurred in a retirement home, rather than an acute care center or similar setting, muddies the waters regarding what is expected of staff, Koopersmith says. But that setting does not necessarily mean the employee's actions or the corporate policy were proper, she says.

"The lesson is that the industry needs to help the public understand the difference between an assisted living facility, an independent living facility, and a nursing home. The

AHC Media

www.ahcmedia.com

lines between these types of facilities have blurred tremendously," she says. "If you are a resident in the independent living facility, a nurse from the nursing home building is not going to come over and help you when you fall. That's not what they do. Someone is going to call 911, but if these incidents are not handled well, this is the type of reaction you get."

The assisted living issue is only one part of the story, however. Concerns raised by this case can affect all healthcare providers, Koopersmith explains. That same potential overreach, the too-broad or ambiguous corporate policy, could create conflicts with medical care in other settings, she says.

Nurse criticized by company

The woman lived in the independent living building at the retirement facility, which does not offer medical care as part of its agreement with residents. The retirement facility's corporate owner stated publicly that its policy was not to provide any medical care at the building, including CPR. The executive director of Glenwood Gardens, **Jeffrey Toomer**,

Executive Summary

The death of a woman at a California senior living home highlights the unintended consequences of some corporate policies. Risk managers should review their policies to ensure they do not create ethical dilemmas for caregivers or put the organization at risk.

✦ The woman's death resulted in widespread media attention and several investigations after a nurse at the facility refused to perform cardiopulmonary resuscitation (CPR) and cited the organization's internal policy.

✦ Issues raised by the incident go beyond senior living facilities and CPR policies to affect all types of healthcare providers.

✦ An administrative policy should never prevent a clinician from using his or her own best medical judgment.

defended the nurse in a written statement and said saying she followed the facility's policy.

"In the event of a health emergency at this independent living community, our practice is to immediately call emergency medical personnel for assistance and to wait with the individual needing attention until such personnel arrives," Toomer said. "That is the protocol we followed."

A few days later, after growing criticism, the company issued a new statement. The employee had misinterpreted the company's guidelines, the company said, and the nurse was on voluntary leave while the case is investigated. "This incident resulted from a complete misunderstanding of our practice with regards to emergency medical care for our residents," the new statement said. The company did not offer further clarification on what its policy states or how she misunderstood it.

The woman's family also issued a statement, saying she and they were fully aware that the retirement facility did not offer medical care. She did not have a do-not-resuscitate order but would not have wanted to be revived,

AHC Media

Editorial Questions
Questions or comments?
Call **Greg Freeman**, (770) 998-8455.

the family said.

Even though the nurse was not employed as a caregiver in the facility, she had a duty to provide at least the basic first aid she was qualified to give, including CPR, says **Tanvir Hussain**, MD, a cardiologist and a former adjunct professor of bioethics of the Pepperdine University School of Law in Malibu, CA, now practicing at Johns Hopkins Medicine in Baltimore, MD.

"The nurse did not keep up with her ethical and moral duties as a healthcare practitioner to provide care to a dying patient and should have her licensure reviewed by the state nursing board," Hussain says. *(For more on the nurse's potential ethical conflict, see the story on p. 52.)*

Should a nurse provide CPR?

Support for that view comes from **Joel Blass**, MD, medical director at the Workmen's Circle MultiCare Center, a 524-bed short-term, long-term, and sub-acute rehabilitation and nursing facility in Bronx, NY. Barring any advance directives to the contrary, a nurse should provide CPR, and there should not be a policy that discourages her from doing so, Blass says. The fact that the facility does not provide medical care should not discourage someone who has the necessary skills from providing first aid in the same way they would if they encountered the woman on the street or in a restaurant, he says.

"If they know CPR, ethically speaking they should initiate CPR, in pretty much any environment," Blass says. "In the end, it turned out that this elderly woman did not want to be resuscitated, but no one knew that at the time. The right thing happened in the end, but it happened by accident."

Koopersmith suggests that the nurse making the 911 call might have been confused by a confluence of factors: She was a nurse but not employed in a care-giving position, the incident was happening in the retirement building where residents know that medical care is not provided, and the company policy might

have been unclear. "Unlike a nursing home, independent living communities, such as the one reported in this case, are not generally legally required to provide health services, including emergency services. Instead, these types of facilities offer assistance in contacting emergency first responders in the event of an emergency," she says. "While a nurse may be allowed to step in to help in an emergency as a good Samaritan, he or she may be reluctant to do so due to concerns about providing care beyond the scope of his or her practice."

Probes following the incident

In further evidence of how even if the policy was legal and correct, it still can cause nightmares for risk managers, consider how Bayless' death prompted investigations in several arenas: The Bakersfield police department sought to determine if any crime was committed in refusing to perform CPR; the Kern County Aging and Adult Services Department is investigating possible elder abuse; and the California state legislature's Aging and Long-term Care Committee is studying whether changes in the law are necessary.

In addition, the Assisted Living Federation of America is urging its members to review policies that could lead to potential ethical conflicts. Senior Vice President **Maribeth Bersani** issued a statement saying that even if a facility does not provide medical care as part of its services, employees should cooperate when a 911 dispatcher instructs them to provide first aid. The California Board of Registered Nursing stated that it is investigating why the nurse would not hand the phone to someone else who was willing to help, even if she felt restricted by her employer's policy.

"That's what has caused so much of the outrage," Koopersmith says. "It's certainly appropriate for an assisted living facility to say they don't provide medical services and make that very clear, but the flip side of that policy, saying 'and our staff are prohibited from helping or following the directions of an operator,'

that's a policy question that probably can't be supported."

Having a nurse on staff but in a non-nursing position, such as residency director for an independent living center, can create an ethical and legal quandary, says **Larry Abrams**, director of administration at the Workmen's Circle MultiCare Center in Bronx, NY. People might ask why you bothered to employ a nurse if that person is not allowed to provide even the most basic first aid to residents.

Having such employees on staff might — intentionally or not — give the impression that your employees are qualified and ready to respond to an emergency, even if you explicitly state that you do not provide medical care, Abrams notes.

"Having employees who have an RN after their names may give some credibility, but it also might allow family members to avoid having that difficult conversation about what their loved one wants and expects in an emergency," he says. "And I could easily see that leading to a lawsuit if it doesn't turn out the way people want."

Blass says he learned one very important risk management lesson from the incident.

"I know I will never say, when the press asks me why we did something, 'Oh, it's our policy,'" Blass says. "That just sounds like you're hiding behind your policy."

SOURCES

• Larry Abrams, Director of Administration, Workmen's Circle MultiCare Center, Bronx, NY. Telephone: (718) 379-8100, Ext. 447.

• Joel Blass, MD, Medical Director, Workmen's Circle MultiCare Center, Bronx, NY. Telephone: (718) 379-8100, Ext. 474.

• Tanvir Hussain, MD, Levine Group at Green Spring Station, Lutherville, MD. Telephone: (410) 583-2926. Email: tanvir75@gmail.com.

• Eve Green Koopersmith, JD, Partner, Garfunkel Wild, Great Neck, NY. Telephone: (516) 393-2282. Email: ekoopersmith@garfunkelwild.com. ✦

Details of 911 call when nurse refused to give resident CPR

The 911 call from the Glenwood Gardens Retirement Facility in Bakersfield, CA, is chilling, not because the person is emotional or panicking, but because she is oddly calm and straightforward.

After the caller, who identified herself as a nurse employed at the facility as a resident services director, refused instructions to start cardiopulmonary resuscitation (CPR), the obviously frustrated 911 dispatcher tells the nurse to hand the phone to a passerby, "any citizens," so she can guide them in providing CPR. The nurse says no one is available.

"Anybody there can do CPR. Give them the phone, please," the dispatcher pleaded. "This woman's not breathing enough. She's going to die if we don't get this started."

The dispatcher continues trying to convince the nurse on the line to help. "I don't understand why you're not willing to help this patient. Is there anybody that works there that's willing to do it?"

"We can't do that," the nurse says. "That's what I'm trying to say." When the dispatcher asks if the nurse is going to just let the woman die, the caller replies, "Well, that's why we're calling 911."

"Is there a gardener? Any staff, anyone who doesn't work for you? Anywhere?" the dispatcher pleads. "Can we flag someone down in the street and get them to help this lady? Can we flag a stranger down? I bet a stranger would help her."

At one point in the conversation lasting 7 minutes and 11 seconds, the caller can be heard complaining to someone else in the room. "She's yelling at me and saying we have to have one of our residents perform CPR. I'm feeling stressed, and I'm not going to make that call." ✦
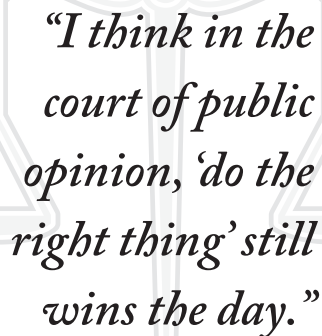
Policy or no policy, bioethicist says nurse betrayed her duties

The nurse who refused to give cardiopulmonary resuscitation (CPR) to a dying resident of an assisted living home "failed in her moral and ethical responsibilities," says **Tanvir Hussain**, MD, a cardiologist and a former adjunct professor of bioethics of the Pepperdine University School of Law in Malibu, CA, now practicing at Johns Hopkins Medicine in Baltimore, MD.

"Moral, because of what we would hope anyone would do for us if we were in Lorraine Bayless' position, and ethical because of our deeply held belief that nurses and doctors should intervene on the part of the distressed or dying under any or most circumstances, even over their own self-interest," Hussain explains. "From accounts, there was no immediate indication the resident did not want resuscitation, nor did anyone make mention of this during the 911 call."

Hussain notes that the nurse's inaction, and what many perceived as a blasé attitude in the face of a dying woman, prompted a visceral response from many people. "Our deeply held belief is that a nurse or a doctor, whatever the situation, should intervene on behalf of someone in medical distress. Otherwise, why call out

for a doctor or nurse in a restaurant or on the plane?" Hussain says. "Secondly, there is something deeply troubling

"I think in the court of public opinion, 'do the right thing' still wins the day."

about trained medical personnel actively withholding their skills in a time of need, especially when someone's life is at stake. It feels inherently wrong, even if it is not legally wrong under certain circumstances."

Further fanning the fires of public outrage, Hussain says, was the appearance that the nurse was withholding treatment out of self-interest. She specifically stated that the company's policy was not to intervene, mentioned that her boss was present, and spoke with her

boss during the 911 conversation. All of those statements implied she would face repercussions for administering CPR, he says. "If this was the case, it not only is troubling to the average listener, but is deeply disappointing and sets a dangerous precedent," he says.

Hussain also is troubled by the way the company first supported the nurse and then, as the public outcry increased, reversed course and said she misinterpreted its policy. "Clearly the company gave a face-value impression that they were willing to throw their employee under the bus, as it were," he says. "Had her immediate supervisor not spoken up in her defense, I wonder if she would still be under their employment."

As for handling future incidents, Hussain says it seems only to a facility's benefit that they should allow workers or any trained medical staff to at least attempt assistance if a resident is clearly dying or otherwise in medical distress. Most importantly, time is of the essence in cases such as these, and not intervening out of fear of a lawsuit could bring lawsuits of another kind, he says.

"One could easily imagine a different family under different circumstances or beliefs bringing a suit against the facility

and parent company. And clearly they would have full public support, and the company would have gotten hammered in the media," Hussain says. "I think in the court of public opinion, 'do the right thing' still wins the day." ✦
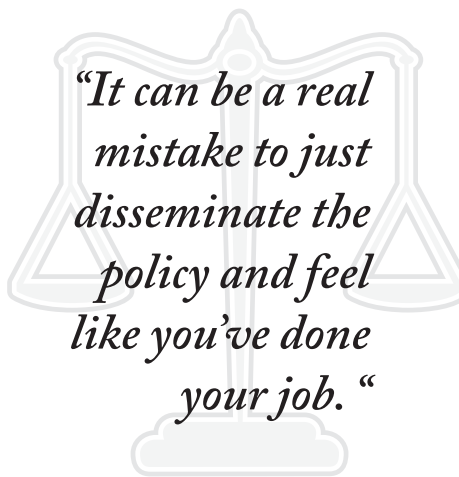
Review policies for unintended consequences

The fallout from the refusal to perform cardiopulmonary resuscitation (CPR) at an assisted living home in Bakersfield, CA, is a good reason for healthcare providers to review any policies for unintended consequences, says **Abby Pendleton**, JD, a founding partner with The Health Law Partners in New York City.

In particular, she says, risk managers should watch for any policies that could put a licensed caregiver in conflict with his or her own clinical judgment or ethical duties. "That means making sure policies aren't written in such a way that they can be misinterpreted by employees," Pendleton says. "We have to keep in mind that what may seem like a straightforward statement of policy to you and me can create a dilemma when someone is trying to do the right thing but also doesn't want to lose their job."

Any policy that restricts the actions of an employee in an emergency situation must be carefully crafted, says **Eve Green Koopersmith**, JD, a partner with the law firm of Garfunkel Wild in Great Neck, NY. Stating that the facility does not provide a particular type of care should not prevent employees from acting as any private citizen would when facing a person in need of basic first aid, including CPR, she says. That distinction will require education, however.

This assisted living incident could have been the result of an overly cautious interpretation of the facility's policy by the employee on the phone, says **Jessica Gustafson**, JD, a founding partner with The Health Law Partners in Southfield, MI.

"It can be a real mistake to just disseminate the policy and feel like you've done your job."

"This is a good example of how you need to have continuing education to help employees understand what you really expect from these policies," Gustafson says. "It can be a real mistake to just disseminate the policy and feel like you've done your job. You need to educate people on what it means and let them ask those questions that you never thought of. Let them ask what this policy means in their day-to-day life, and listen to some of their interpretations. You might be concerned by what you hear."

SOURCES

- **Jessica Gustafson**, JD, Founding Partner, The Health Law Partners, Southfield, MI. Telephone: (248) 996-8510.
- **Abby Pendleton**, JD, Founding Partner, The Health Law Partners, New York City. Telephone: (212) 734-0128. Email: apendleton@thehlp.com. ✦

Be aware of false claims exposure with root cause analysis

Protecting the contents of a root cause analysis (RCA) requires much more than slapping a "peer review" label on the file and assuming that label means it is off limits to prying eyes. Peer review privilege might not protect your RCA at all, but there are other ways to limit the potential downside from someone reading about all your shortcomings.

The potential discovery of RCA contents has always been a concern, and that concern is a primary reason healthcare risk managers sometimes don't get as much out of the process as they could, says **George B. Breen**, JD, an attorney with the law firm of Epstein Becker Green in New York City. Breen works closely with risk managers who use RCA to address adverse events and other issues in their facilities, but he is sometimes disappointed that they did not achieve the end result: effectively determining the foundation of how and why an event came to pass.

In some cases, the RCA has conflict-

Executive Summary

The material in a root cause analysis could be discoverable and used against a facility in a medical malpractice case or a federal false claims allegation. Specific steps should be taken to protect the information as much as possible.
✦ State laws vary, but more courts are determining that RCA content is not protected by peer review.
✦ False claim investigators will be interested in any RCA material that shows knowledge of fraudulent billing.
✦ Having an RCA conducted under the direction of legal counsel can offer some protection.
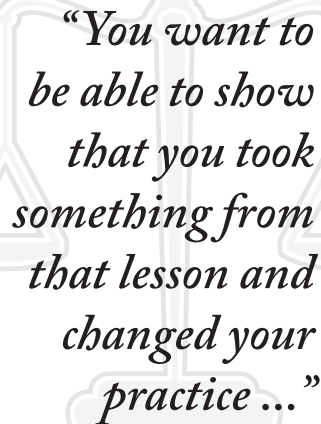
ing interests from the start, Breen says. On one hand, the risk manager wants to determine what unknown or unforeseen factors affected an event and how to keep that event from happening in the future. But at the same time, the risk manager might be concerned with protecting the practitioner and the institution from liability. As such, the risk manager wants to avoid creating "bad paper" that could be subject to discovery and used by a plaintiff's attorney.

"Those interests don't always coalesce," Breen says. "Courts are increasingly looking at some of this material developed in a root cause analysis and saying that it is discoverable. It's going to be state law-specific, but there are more and more courts being asked to address challenges to claims that these materials are protected by peer review. Some courts are allowing the discovery of this information."

The government is increasingly focused on cases involving medical necessity and quality of care, and on the federal level there is no peer review protection, he notes. That situation creates the risk of a false claim allegation based on a paper trail created during an RCA. "There is a different exposure in the false claims context," Breen says. "The reality is that if you are billing the federal government for a service that is not medically necessary and appropriate, then the government is going to come back and ask for that money back and potentially treble damages and interest."

The RCA can come into play when the government investigates what the institution knew about a practitioner or entity who filed false claims, Breen says. "They will want to know what the institution knew, when they knew it, and whether they took notice and made any attempt to address the problem," he explains. "So there is sometimes a greater risk of exposure from false claims allegations when it comes to root

> *"You want to be able to show that you took something from that lesson and changed your practice ..."*

cause analyses and the paper trail it creates, than from the medical malpractice claims that most people worry about with regard to the root cause analysis."

One way to protect your RCA from prying eyes is to follow a set of clearly defined procedures conducting the analysis, Breen says. The goal is to establish in your policies and procedures, as clearly as possible, that you intend this process as a "true self-look at what it is we are or are not doing," Breen says. The policies and procedures also should

ensure that the organization follows through on the findings of an RCA by addressing problems and confirming that they have been resolved.

"It's fine to say that your analysis revealed this problem, but you want to have auditing and follow-ups to ensure that the lesson you just learned was not held in isolation," Breen says. "You want to be able to show that you took something from that lesson and changed your practice so that you can avoid that exposure in the future."

Involving legal counsel can provide some measure of protection, Breen says. Since it is dicey to rely on saying the RCA is protected by peer review, you are better protected if you can show that the materials were prepared at the direction of legal counsel, which can help protect the confidentiality of the records.

"I don't think that the False Claims Act exposure here is on the radar of most risk managers," Breen says. "The issue of peer review might be more known by them, depending on their state, but the false claims exposure has the potential for being much more damaging. That's why you need to have a well thought-out plan for how you conduct an analysis and a plan for protecting it that goes beyond just calling it peer review."

SOURCE

• **George B. Breen**, JD, Epstein Becker Green, New York City. Telephone: (202) 861-1823. Email: GBreen@ebglaw.com. ✦

Hospital achieves 50% reduction in falls with huddles, better rounding

A hospital in Fargo, ND, focused on preventable falls in its cardiac telemetry unit and is seeing admirable results. After a year of effort, falls were reduced by 25% at the end of 2012, and then the hospital hit a 50% reduction barely a month later.

The reductions are the result of a comprehensive effort to address many of the issues most directly related to preventable falls, says **Tina Kraft**, BSN, house supervisor at Essentia Health — Fargo. Cardiac telemetry was selected for the project because it had the highest rate of falls in the hospital. The fall reduction team started by reviewing records and surveying staff members in that unit to determine who was falling and where.

"People were complaining that there weren't enough staff on weekends and nights, and that people were falling the most at those times," Kraft says. "But our information actually showed the complete opposite. The falls were happening

with people who were alert and oriented, with the majority happening during the day.”

The team implemented more hourly rounding with a purpose, that is, specifically checking on patients to see if they might need to get up for the bathroom or for any other reason and to ask if they had all the personal belongings they might want. The goal was to keep the patients from getting out of bed on their own, Kraft says.

Two of the key strategies are training the patient on the use of the call light and conducting post-fall huddles. In addition, the fall risk level is systematically recorded and written with colored markers on white boards in the unit and included in every shift report. Below that, the nurse writes any known problems such as a missing or malfunctioning bed alarm that could affect the fall risk.

Unit managers keep track of how well the nurses conduct their hourly rounding, and those with 80% or more for confirmed hourly checks get their names placed on a high-achievers board in the unit that is decorated. But there also is a board for those whose hourly rounding is not up to par, and the staff members are encouraged to move from the bad board

Executive Summary

One hospital has reduced preventable falls in a unit by 50%. The program targeted some of the most common root causes of falls.
✦ Staff now round hourly in an effort to spot and reduce fall risks.
✦ Huddles are conducted each morning and after any fall.
✦ The hospital holds staff accountable for their efforts, or lack thereof, to reduce falls.

to the good board.

“We’ve found that holding people accountable is an important part of this,” Kraft says. “Everyone will nod their head and agree with what you want to do, but you have to hold them accountable for what they really achieve on a day-to-day basis.”

Kraft also implemented a morning huddle for three minutes to go over each patient’s diagnosis and condition, but especially how mobile the patient is and the fall risk. There also are post-fall huddles to discuss what happened and to try to narrow down the root cause. In many cases it has turned out to be that the bed alarm was not re-applied after the patient got up for some reason.

As a result of these efforts, from January to September 2012, the unit’s fall rate decreased from seven falls per 1,000

patient days to 2.4 per 1,000 patient days, Kraft says.

“We also hung a sign in the main entrance area that says ‘X number of days without a patient fall,’ and people really respond to that. It’s very visible there all the time, and people want to keep that number going,” Kraft says. “The first time we had to back up and set it to zero, it was pretty traumatic for that nurse. But we assured her it wasn’t meant as any kind of punishment. The sign holds us accountable, and it’s had a big impact.” *(See information about toolkit to address patient falls, below.)*

SOURCE

• **Tina Kraft**, BSN, House Supervisor, Essentia Health — Fargo, Fargo, ND. Telephone: (701) 364-4354. Email: tina. kraft@essentiahealth.org. ✦

AHRQ toolkit can help prevent patient falls in hospitals

The Agency for Healthcare Research and Quality (AHRQ) is offering an online toolkit titled “Preventing Falls in Hospitals: A Toolkit for Improving Quality of Care” that focuses on reducing falls that occur during a patient’s hospital stay.

Nearly one million patients fall in

U.S. hospitals each year, the AHRQ notes. The toolkit is organized under six major areas that address hospital readiness, program management, selection of fall prevention practices, implementation, measurement, and sustainability.

“Fall prevention programs require

an interdisciplinary approach to care in order to manage a patient’s underlying fall risk factors, such as problems with walking and transfers, medication side effects, confusion, and frequent toileting needs,” the AHRQ says.

The toolkit is available online at http://1.usa.gov/XVSvW8. ✦

Nurses with higher education decrease patient deaths

When hospitals hire more nurses with four-year degrees, patient deaths following common surgeries decrease, according to new research

by the Center for Health Outcomes and Policy Research at the University of Pennsylvania School of Nursing in Philadelphia.
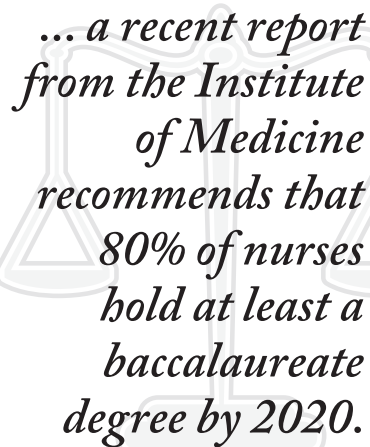
Reported in the policy journal *Health Affairs*, the study says less than half the nation’s nurses (45%) have baccalaureate degrees, according to

the most recent data available (2008).

If all 134 Pennsylvania hospitals involved in the study had increased the percentage of their nurses with four-year degrees by 10 percentage points, the lives of about 500 patients who had undergone general, vascular, or orthopedic surgery might have been saved, the researchers said in their article.

Consider the example of a 10-percentage point increase, from 30% to 40%, in the overall percentage of BSN-prepared nurses in the hospitals studied between 1999 to 2006. Statistically, that increase would have saved about two lives for each 1,000 patients treated on average, according to lead author Penn Nursing professor **Ann Kutney-Lee**, PhD, RN, who is also a senior fellow at the Leonard Davis Institute of Health Economics. The researchers surveyed 42,000 registered nurses in Pennsylvania in 1999 and 25,000 in 20006.

RNs have obtained a four-year (baccalaureate degree), a two-year (associate's) degree, or graduated from a hospital-based diploma

... a recent report from the Institute of Medicine recommends that 80% of nurses hold at least a baccalaureate degree by 2020.

school. Licensed practical nurses (LPNs) also practice at the bedside with a one-year degree.

"This adds to the importance of public policies to help direct a substantial shift toward the production of nurses with baccalaureates in nursing," said Kutney-Lee. She noted that a recent report from the Institute of Medicine recommends that 80% of nurses hold at least a baccalaureate degree by 2020. "Nursing is both high-touch and high-tech, requiring honed critical thinking skills in

our complicated healthcare system," Kutney-Lee said.

While the authors of the study did not pinpoint why more patients survive surgeries, previous work at the center found that better-prepared nurses offer higher levels of surveillance of patients. The better-prepared nurses notice subtle shifts in their patients' conditions that can lead to death from complications while there was still time to intervene.

"As part of their practice, nurses are responsible for the continual assessment and monitoring of a patient's condition, identifying changes that could indicate clinical deterioration, and initiating interventions when necessary," noted Kutney-Lee in the journal article. "The findings provide support for efforts to increase the production and employment of baccalaureate nurses."

(Note from the editor: An abstract of the journal article is available online at http://tinyurl.com/nurseeducation. The full text of the study requires a membership or one-time purchase of $12.95.) ✦

22 strategies called most effective for patient safety

After analyzing 41 patient safety practices, an international panel of patient safety experts has identified 22 strategies that should be adopted right away. Enough evidence exists that health systems and institutions can move forward in implementing these strategies to improve the safety and quality of health care, the panel says.

A report from the Agency for Healthcare Quality and Research (AHRQ) summarizes the research and findings of the panel. "Making health care safer II: an updated critical analysis of the evidence for patient safety practices" (AHRQ Evidence Report No. 211) updates the agency's 2001 report on the same topic. The 2001 report analyzed the strength of

evidence for patient safety practices in use at that time. The 2013 report analyzed a growing body of patient safety research to determine the level of evidence regarding the outcomes, as well as implementation, adoption, and the context in which safety strategies have been used.

Of the 22 strategies identified in "Making Health Care Safer II," these 10 are "strongly encouraged" for adoption based on the strength and quality of evidence:

• preoperative checklists and anesthesia checklists to prevent operative and postoperative events;

• bundles that include checklists to prevent central line-associated bloodstream infections (CLABSIs);

• interventions to reduce uri-

nary catheter use, including catheter reminders, stop orders, or nurse-initiated removal protocols;

• bundles that include head-of-bed elevation, sedation vacations, oral care with chlorhexidine, and subglottic-suctioning endotracheal tubes to prevent ventilator-associated pneumonia;

• hand hygiene;

• "do-not-use" list for hazardous abbreviations;

• multicomponent interventions to reduce pressure ulcers;

• barrier precautions to prevent healthcare-associated infections;

• use of real-time ultrasound for central line placement;

• interventions to improve prophylaxis for venous thromboembolisms.

"Making Health Care Safer II" also

identifies these 12 patient safety strategies that are "encouraged" for adoption based on the strength and quality of evidence:

• multicomponent interventions to reduce falls;

• use of clinical pharmacists to reduce adverse drug events;

• documentation of patient preferences for life-sustaining treatment;

• use of informed consent to improve patients' understanding of the potential risks of procedures.

• team training;

• medication reconciliation;

• practices to reduce radiation exposure from fluoroscopy and computed tomography (CT) scans;

• use of surgical outcome measurements and report cards, such as the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP);

• rapid response systems;

• utilization of complementary methods for detecting adverse events/medical errors to monitor for patient safety problems;

• computerized provider order entry (CPOE);

• use of simulation exercises in patient safety efforts.

To access "Making Health Care Safer II" (AHRQ Evidence Report No. 211), go to http://tinyurl.com/safetystrategies. ✦

Cesarean section rates vary widely among hospitals, changes are suggested
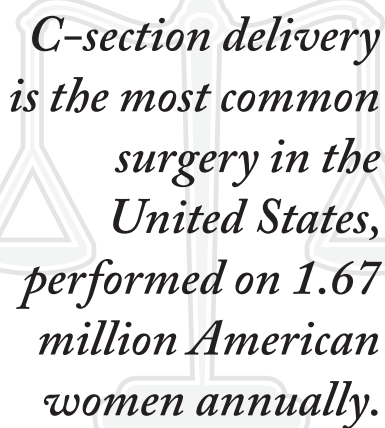
The rate of cesarean (c-section) deliveries varies significantly among hospitals across the country, according to a recent study, ranging from 7% of all births at the hospital with the lowest share of cesarean deliveries to 70% at the hospital with the highest rate.

C-section delivery is the most common surgery in the United States, performed on 1.67 million American women annually. The research from the University of Minnesota's School of Public Health in Minneapolis was published recently in the journal *Health Affairs*. To arrive at their results, School of Public Health researchers examined hospital discharge data from a representative sample of 593 hospitals with at least 100 births in 2009.

Cesarean delivery is an important, potentially lifesaving, medical procedure, and some variance in hospital rates would be expected based on differences in patient characteristics, explains lead author **Katy B. Kozhimannil**, PhD, assistant professor in the School of Public Health. To address this issue, researchers also examined cesarean rates among a subgroup of lower-risk patients: mothers whose pregnancies were not preterm, breech, or multiple gestation, and who had no history of cesarean delivery.

Among this group of women with lower-risk pregnancies, in which more limited variation might be expected, hospital cesarean rates varied fifteenfold, from 2.4% to 36.5%. "We were

C-section delivery is the most common surgery in the United States, performed on 1.67 million American women annually.

surprised to find greater variation in hospital cesarean rates among lower-risk women. The variations we uncovered were striking in their magnitude and were not explained by hospital size, geographic location, or teaching status," Kozhimannil says. "The scale of this variation signals potential quality issues that should be quite alarming to women, clinicians, hospitals, and policymakers."

Childbirth is the most common and most costly reason for hospitalization in the United States. Cesarean births are more expensive than vaginal deliveries, and cesarean rates have increased from 20.7% in 1996 to 32.8% in 2011. Nearly half of all U.S. births are financed by state Medicaid programs. In 2009 alone, public insurance programs paid out more than $3 billion for cesarean deliveries.

"Cesarean deliveries save lives, and every woman who needs one should have one," Kozhimannil says. "The scope of variation in the use of this procedure, especially among low-risk women, is concerning, as its use also carries known risks compared to vaginal delivery such as higher rates of infection and re-hospitalization, more painful recovery, breastfeeding challenges, and complications in future pregnancies."

The authors offer four major policy recommendations to reduce these variations:

• **First, women need to be offered the right care for their own pregnancies.** Evidence from earlier studies shows women with healthy pregnancies benefit from care provided by midwives, support from trained doulas, and access to care in licensed birth centers. Women with low-risk pregnancies should have access to care options that might benefit them, with strong referral systems and specialized care for complications that might arise.

• **More and better data on the quality of maternity care are needed**

to support the rapidly advancing clinical evidence base in obstetrics. Clinicians and hospitals cannot improve maternity care, and insurers cannot pay for such improvements, without clear and consistent measures of quality.

• **Tying Medicaid payment policies to quality improvement programs may influence hospital** policies and practices and provide incentives and reward hospitals and clinicians for providing consistent, evidence-based care.

• **Finally, information about cesarean rates and maternity care should be more readily available to pregnant women, who have time, motivation, and interest to research their options.** However, they lack access to unbiased, publicly reported information about cesarean delivery rates and other aspects of maternity care.

An abstract of the journal article is available at http://tinyurl.com/ratesvary. The full text requires a membership or one-time purchase of $12.95. *(For more on unnecessary c-sections, see* "Healthcare Risk Management," *April 2013, pp. 37-41.)* ✦

Minnesota adverse events hold steady despite safety efforts

Minnesota hospitals and ambulatory surgery centers reported the same number of adverse events last year as in the previous one, despite intense efforts to improve patient safety. And even more worrying, a recent report from the state says more patients were injured or dead as a result of those adverse incidents.

The Minnesota Department of Health's ninth annual public accounting of adverse health events shows that the state's surgical facilities reported 314 adverse events between October 2011 and October 2012, a figure unchanged from the previous 12 months. That included 14 patient deaths (up from five) and 89 serious injuries (up from 83).

Falls accounted for almost 90% of the patient injuries or deaths. The 79 reported falls, which resulted in six deaths, were not as high as the 95 falls in 2008 with 10 deaths. However, the 79 reported falls were an increase over 71 falls with three deaths in 2011.

The report notes that in 2003, Minnesota became the first state in the nation to pass a law requiring all hospitals, and later ambulatory surgical centers, to report whenever a serious adverse health event occurs and to conduct a thorough analysis of the reasons for the event. In 2012, the ninth year of reporting, the total number of events reported under the law was 314, essentially unchanged from the previous year.

"A closer look at the overall profile of reported events shows an increase in falls, wrong body part surgical/procedural events, and patient protection events (suicides/elopements), while showing a decrease in medication errors, retained foreign objects, and pressure ulcers," the report says.

"While the number of total reported events is similar to last year, and the number of cases of harm increased, this masks improvement in several key areas."

The report cites these examples of improvement in 2012:

• The number of pressure ulcers declined by 8%. This is the first decline of this magnitude in the nine years of reporting. This year's total of 130 is down from an all-time high of 141 last year.

• Retained foreign objects declined by 16%. This is the first decline in this category in five years.

• Medication errors dropped by 75% from the previous year and were at the lowest level in all nine years of reporting.

The full report is available to readers online at http://tinyurl.com/minnesotareport. ✦

Obese patients more likely to suffer adverse event

Extremely obese patients are more likely than a patient in the general adverse event population to experience a harmful adverse event, according to information released recently by the Pennsylvania Patient Safety Authority (PPSA) in Harrisburg.

The PPSA analyzed 1,774 events submitted by Pennsylvania healthcare facilities over a five-year period in which class III obese patients were involved in a serious event (an event that caused harm to the patient). Serious events accounted for 24% of the total number of reports submitted involving a class III obese patient. In comparison, the general adverse event patient population experiences a serious event less than 4% of the time, explains **Lea Anne Gardner**, PhD,

RN, senior patient safety analyst for the authority.

"Class III obese patients require special equipment that is big enough and strong enough to support them safely while they are in the care of others," Gardner says. "Our analysis shows these patients experience equipment failures, treatment delays, and an overall higher risk of harm in the health-

care setting."

A further review of the Pennsylvania healthcare events identified 180 (10%) equipment-use event reports involving class III obese patients. In comparison, the general adverse event patient population equipment-related reports accounted for 0.8% of all adverse event reports in 2011. In July 2012, the PPSA completed a statewide survey of Pennsylvania hospitals to determine how prepared they were to care for the class III obese patient population.

"Results from the authority survey showed that 36% of respondents said that their hospital does not have an evacuation plan in place for moving class III obese patients to a safe location during an emergency," Gardner says. "We also found that more hospitals rent versus own equipment specifically made for class III obese patients. This may explain why, in some of the reports, patients had delays in treatment or equipment was not available."

Class III obese patients are identified as having a body mass index (BMI) greater than 40 or weighing at least 100 pounds more than their ideal body weight. From 2000 to 2005, the prevalence of individuals reporting a BMI greater than 40 increased by 50% and the prevalence of individuals reporting a BMI greater than 50 increased by 75%.

"Our analysis shows these patients experience equipment failures, treatment delays, and an overall higher risk of harm in the healthcare setting."

"Not all obese patients require special care and equipment, but class III obese patients have different needs," Gardner says. "Healthcare facilities need to be prepared to provide safe general medical care to class III obese patients whose size surpasses the capacity of present equipment. Class III obese patients should also know what kind of equipment a facility has available to meet their healthcare needs"

The PPSA offers facilities guidance as to how they can provide safe care for class III obese patients that includes addressing patient equipment needs, staff education and sensitivity training, and structural considerations.

"There are several steps healthcare facilities can take to increase the safety of obese patients and staff caring for them," Gardner says. "Some of these steps are as simple as making sure class III obese patients have identification wristbands that are long enough to fit properly. Others may require more thought, such as where to place these patients if they need to be transferred to another unit quickly, but as the numbers of class III obese patients increase, the issue of delivering safe care to this patient population must be addressed."

For more information about the class III obesity preparedness survey, go to http://tinyurl.com/obesepatients. ✦

COMING IN FUTURE MONTHS

✦ Safety protocol decreases risk of a fire

✦ How to pick the right insurance broker

✦ Improved career prospects for risk managers

✦ Fleet safety: An overlooked liability risk?

CNE OBJECTIVES

Upon completion of this educational activity, participants should be able to:
• describe the legal, clinical, financial and managerial issues pertinent to risk management;
• explain the impact of risk management issues on patients, physicians, nurses, legal counsel and management;
• identify solutions to risk management problems in healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.

CNE INSTRUCTIONS

Nurses participate in this CNE program and earn credit for this activity by following these instructions.
1. Read and study the activity, using the provided references for further research.
2. Log on to **www.cmecity.com** to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ✦

CNE QUESTIONS

1. In the incident at the Glenwood Gardens Retirement Facility, in which a nurse refused to perform cardiopulmonary resuscitation (CPR), which of the following is true?
   A. The employer initially supported the nurse but then said she misinterpreted corporate policy.
   B. The employer immediately condemned the nurse's refusal to follow the dispatcher's directions and fired her.
   C. The employer initially fired the nurse for her actions but then reinstated her.

2. According to Eve Green Koopersmith, JD, a partner with the law firm of Garfunkel Wild, which is true regarding the Glenwood Gardens CPR policy?
   A. It is always improper to have a policy saying the facility does not provide medical services.
   B. It is acceptable to have a policy saying the facility does not provide medical services, and it is equally acceptable to have employees refuse to follow the directions of a 911 dispatcher.
   C. It is acceptable to have a policy saying the facility does not provide medical services, but it is difficult to justify having employees refuse to follow the directions of a 911 dispatcher.

3. Which of the following is true of root cause analysis (RCA) content, according to George B. Breen, JD, an attorney with the law firm of Epstein Becker Green?
   A. It is always protected by peer review privilege.
   B. It's going to be state law-specific, but there are more and more courts being asked to address challenges to claims that these materials are protected by peer review. Some courts are allowing the discovery of this information.
   C. It is never protected by peer review privilege.

4. What was the range of rates of cesarean births in hospitals across the United States, according to recent research from the Minnesota School of Public Health?
   A. The rate varies significantly among hospitals across the country, ranging from 7% of all births at the hospital with the lowest share of caesarean deliveries to 70%.
   B. The rate is consistently low, ranging only from 4% to 12%.
   C. The rate is consistently high, ranging from 65% to 79%.

Are you in the cloud? Time to scrutinize agreements

Omnibus rule clarifies definition of cloud providers as business associates

Although healthcare organizations have been slower to adopt cloud-computing services than other industries,[1] a recent study shows that 62% are using cloud services for some activities.[2] However, 47% of respondents relying on the cloud are not confident that information is secure, and 23% are only somewhat confident.

The Health Insurance Portability and Accountability Act (HIPAA) omnibus rule addresses security concerns with expanded and clarified definitions of business associates (BAs) to include vendors who may transmit only data, a task performed by cloud service providers.

"Throughout the past two years of review and comment on the rule, cloud vendors insisted they be treated as a conduit of information and not as a business associate with access to data," explains **Cynthia J. Larose**, Esq., an attorney and member of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo in Boston.

The actual conduit exception defined in the final rule is limited to companies such as wireless carriers, telephone companies, or delivery services such as FedEx, she explains. "Even if a cloud services provider is not contracted to work with the data of a client, the point is that the vendor has to have access to provide maintenance, upgrade service, or perform other operations."

Identification of cloud service providers as business associates is not new, points out **Anna L. Spencer**, JD, an attorney with Sidley Austin in Washington, DC. "Even prior to HITECH [Health Information Technology for Economic and Clinical Health], the FAQ guidance on business associates indicated that companies that provided hosting or software services were considered business associates," she explains. This fact was highlighted with the fine levied against Phoenix Cardiac Surgery for using a publicly accessible Internet calendar to schedule appointments and surgeries. One of the findings by the Office of Civil Rights (OCR) was that the practice "failed to obtain business associate agreements with Internet-based email and calendar services where the provision of the service

included storage of and access to its ePHI."[3]

The good news for hospitals and health systems is a "crystal clear" definition of cloud providers as business associates. The bad news is a critical need to review existing agreements with cloud providers to ensure they are held to the same standards as all business associates. "Covered entities must revisit all cloud vendor agreements," recommends Larose. "Even if a cloud provider claims to be HITECH-compliant, the covered entity must ask for proof." This proof includes documentation of a third-party assessment report certifying existence of privacy and security controls within the organization, a Statement on Standards for Attestation Engagements (SSAE) No. 16, she suggests.

While the SSAE provides proof of an assessment, it is not healthcare-specific, so require other documentation as well, suggests **Andrew Hicks**, MBA, CISA, CCM, CRISC, director and healthcare practice lead at Coalfire, a Louisville, CO-based independent IT governance, risk, and compliance firm. "The best proof is a HITRUST [Health Information Trust Alliance] certification," he says. "It is specific to healthcare and covers privacy and security concerns." Third-party reports should include documentation of penetration testing as well as vulnerability assessments, and all documentation should be

---

EXECUTIVE SUMMARY

While cloud service vendors have argued that they are not business associates (BAs) because they do not "handle" the data as more traditional BAs such as billing services do, the HIPAA omnibus rule clearly defines cloud service providers as BAs.

• Healthcare organizations should revise agreements with cloud service providers to meet BA requirements.

• Ask for documentation of third-party audits to prove compliance with security requirements.

• Understand how and where data is stored and protected.

• Make sure the cloud service provider has BA agreements with all downstream subcontractors.

requested annually, he adds. "The covered entity must hold the cloud service provider responsible for data."

While all of this documentation should be in place at the start of any new contract, a covered entity should specify a timeframe in which existing vendors must prove compliance to continue the business arrangement, he recommends. *(See story on this page for specific questions about security to ask a new vendor.)*

Know downstream vendors

The omnibus rule also points out the business associate's responsibility for downstream vendors, says Spencer.

"This is critical for healthcare organizations working with cloud providers because many companies presenting themselves as cloud vendors are offering services that run on other cloud platforms such as Google or Microsoft," she says.

While the vendor with whom the hospital contracts has privacy and security controls in place, the actual platform provider might not, she explains. For this reason, make sure the cloud provider is asking for the same proof of compliance from its own vendors.

"Encryption is an interesting wrinkle in this conversation about cloud provider responsibilities," says Spencer. "Theoretically, the cloud service provider's access to data is not an issue if the healthcare organization transmits only encrypted data." At this point, there is no guidance as to whether this type of encryption eliminates the business associate responsibility for the cloud provider, she adds.

"Encryption minimizes risk but doesn't eliminate it, so don't select a cloud provider who can't produce the documentation you require, even if you plan to only transmit and store encrypted data," says Spencer. If you are already working with a cloud services vendor who won't produce the documentation you require, be ready to move to a new vendor. "This is not always easy to do," she admits.

Although business associates are required to return or destroy data after termination, a hospital's current contract might not identify the vendor as a business associate, and language in the contract might not address status of the data upon early termination. "Operationally, it may not be easy to switch to another vendor, but even if it is, be sure you know what happens to your data with the previous vendor," she adds.

Ensuring compliance with security requirements might take time and effort, but the risks are great, Spencer points out. "It's not just

about OCR penalties. If a cloud service provider can't meet security requirements, and a hospital continues to do business with the vendor, the hospital is financially responsible for all the costs of a breach, which can be sizable when a cloud services provider is involved." *(For more on the HIPAA omnibus rule, see "Final HIPAA rule increases penalties, liability for associates," Healthcare Risk Management, March 2013, p. 25.)*

REFERENCES

1. CDW. Silver linings and surprises: CDW's 2013 state of the cloud report. 2013. Accessed at http://webobjects.cdw.com/webobjects/media/pdf/CDW-2013-State-Cloud-Report.pdf.
2. Ponemon Institute. Third Annual Benchmark Study on Patient Privacy & Data Security. December 2012. Accessed at http://www2.idexpertscorp.com/assets/uploads/ponemon2012/Third_Annual_Study_on_Patient_Privacy_FINAL.pdf.
3. Department of Health and Human Services. HHS settles case with Phoenix Cardiac Surgery for lack of HIPAA safeguards. Press release. April 17, 2012. Accessed at http://www.hhs.gov/news/press/2012pres/04/20120417a.html.

Is the cloud safe for healthcare?

Ask these questions to determine data security

The benefits of using cloud service providers include improved operating efficiencies as well as reduced costs related to infrastructure, when compared to more traditional, physical

environments.

Ensuring data security, however, is more complex than traditional data storage systems, says **David S. Linthicum**, founder and chief technology officer of Blue Mountain Labs, information technology advisors in St. Louis, MO. As times go on and more healthcare organizations rely on cloud computing, regulations such as the omnibus rule will provide guidance on how health entities can ensure they are choosing a cloud service provider that is compliant with privacy and security regulations, Linthicum explains. "Until then, it is up to the healthcare organization to be skeptical and ask cloud providers to prove their ability to meet security requirements," he says.

One of the first steps is to understand what service you are purchasing, suggests Linthicum. The cost-savings of cloud computing are related to the multi-tenant structure of the service. The cost benefit of cloud computing are related to multiple customers sharing the costs of transmitting and storing data. The multi-tenancy is something healthcare organizations need to understand. Some of the key questions to ask potential cloud service providers include:

• **How are clients segmented?**

Andrew Hicks, MBA, CISA, CCM, CRISC, director and healthcare practice lead at Coalfire, a Louisville, CO-based independent IT governance, risk, and compliance firm, says, "If it is one system with multiple tenants, there are firewalls between data, but healthcare organizations should ask how the cloud service provider ensures data is never mixed."

Another key issue to address is how the cloud service provider can identify what data is involved if a breach occurs. Although the provider is not working directly with the data, it should be able to identify which client's data was breached and the extent of the breach.

• **Where is data stored?**

Cynthia J. Larose, Esq., an attorney and member of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo in Boston, says, "Another significant concern that must be addressed in any agreement with a cloud service provider is the location of the data."

Data with a cloud service provider is always moving from server farm to server farm, depending on demand for access and space on servers, Larose explains. "Many providers use server farms outside the U.S., where data security is not as regulated," she says. "For this reason, healthcare organizations should specify that their data is never to be stored anywhere outside the U.S."

• **Do you work with healthcare or financial institutions?**

It is helpful to work with a cloud service provider that understands healthcare privacy and security requirements, but a provider who handles financial transactions, such as credit cards, is accustomed to high levels of security, Hicks points out. "They also have systems in place to track location of data and correctly identify what information was affected by a breach," he says.

Ask specifically about other healthcare clients, suggests Linthicum. "Request permission to contact their largest and most active healthcare clients for a reference," he advises.

• **What are your physical security protections?**

Don't just focus on data security while in storage or transmission, suggests Hicks. "Ask about controls that limit physical access to servers as well as employee access to data," he says. Just as a hospital tries to ensure employees don't carry unencrypted personal health information home on a laptop that can easily be lost, a cloud service provider should have physical safeguards as well as policies to protect your data.

• **What are your disaster recovery procedures?**

When asking about security protections, ask about disaster recovery plans as well, says Hicks. "Understand what their disaster recovery plans include such as location of data and how easily accessible it is to you," he says. In addition to making sure your data is secure in the event of a disaster, you also want to make sure continuity of your service is not affected, he adds.

While use of cloud computing can be a safe, cost-effective business solution for many healthcare organizations, it might not be right for everyone, admits Linthicum. "Each organization should evaluate their needs, costs of cloud versus other computing solutions, and their organization's readiness to change," he says.

If an organization enters into an agreement with a cloud services provider, be sure to define specific penalties and responsibilities for the provider, suggests Linthicum. "Healthcare is very wary of cloud computing, but there are benefits," he says. "Each organization needs to weigh the risks and benefits to make the right choice based on individual need." ∎

Free resources help with risk assessments

If consultant is needed, follow these suggestions

New provisions and clarifications in the Health Insurance Portability and Accountability Act (HIPAA) omnibus rule might have

some hospitals scrambling to determine their compliance level, but it might not be a situation that requires outside help.

"Organizations should always return to a risk assessment when there are questions about compliance or changes in regulations," says **Judi Hofman**, CHP, CHSS, CAP, privacy and security officer at St. Charles Health System in Portland, OR. "A high level assessment can help you quickly identify gaps that you can address in more detail."

Although some organizations might find it beneficial to hire an outside consultant to help with the assessment, there are free resources that might meet your needs, says Hofman. The American Health Information Management Association (AHIMA) is a national health information management professional association that offers free resources, she says. *(Go to http://www.ahima. org and select "resources," and then choose "Privacy, Security and Confidentiality.")* "And state chapters of AHIMA are also producing best practices to share among members," she says. A list of AHIMA state chapters can be found at http://www.ahima.org/about/csa.aspx. Another free source of guidance includes the Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) at http://www.healthit.gov. *(Select "For Providers & Professionals.")*

State hospital associations often have an information technology committee actively working on guidance as well, says Hofman. "There is free guidance if a hospital doesn't have the financial resources for outside help," she says.

If the decision is made to hire an outside consultant, Hofman recommends the following:

• **Decide what services you need before talking with consultants.**

"Do you want a full risk assessment but not a mitigation work plan, or do you want both?" Hofman asks. "It's important to know exactly what you want before interviewing consultants because you want to determine the scope of the project, not ask the consultant to do so."

• **Use a committee to evaluate consultants.**

Invite everyone who will be affected by results of a risk assessment to help evaluate a consultant's skill, experience, and approach, says Hofman. "Obviously, the privacy and security officers should be included, but also include the information technology managers and other key hospital leaders." Their involvement at the start of the project will ensure continuity as gaps are identified and mitigation plans developed, she explains.

• **Remember consultant's perspective.**

"Don't be surprised to receive a list of gaps in your compliance plan," says Hofman. "Consultants are paid to find risks, so they will give you a comprehensive list to justify their fees." The key is to evaluate the risks identified by the consultant carefully, she says. "Ask yourself if the deficiencies are correctable or if they are not a priority at this time."

• **Ask state associations and other hospitals for recommendations.**

"It is best to have recommendations for consultants from people you trust," says Hofman. By turning to other healthcare organizations in your area, you can be sure to find someone who knows healthcare and has the skill and experience to handle your risk assessment, she adds.

While the potential cost is prohibitive to some organizations, the benefits of an outside consultant include a subjective, third party assessment, Hofman points out. "Consultants usually arrive with a team of people to focus only on the assessment, which frees you up to do your work," she says. "This is helpful because it is hard to conduct a thorough risk assessment and stay current with day-to-day responsibilities at the same time." ∎

Breaches affect more than 21 million

The importance of encryption is emphasized with most of the recent major breaches added to the Department of Health and Human Services' (HHS') list of breaches. Seven of the breaches involved laptops, while the other two involved paper records.

Other recent breaches were caused by a hacking incident and unauthorized access. The largest number of individuals affected by a single breach was 109,000. The incident involved Crescent Healthcare, a Walgreens company that provides pharmacy and nursing solutions. Theft of a desktop computer resulted in the breach.

The HHS list includes 556 breaches affecting 21.7 million individuals. More than half of the breaches are related to lost or stolen unencrypted computers or mobile devices. The list contains breaches that affect 500 or more individuals and tracks incidents that have occurred since September 2009 when the breach notification rule came into effect.

For a complete list of breaches, go to http://www.hhs.gov/ocr/office/index.html. Select "Health Information Privacy" on top navigation bar, then select "HIPAA Administrative Simplification Statute and Rules." On the left navigation bar, choose "Breach Notification Rule," and then on the right side of the page, under "View Breaches Affecting 500 or More Individuals," select "View a list of these breaches." ∎

$25 million malpractice verdict against hospital, cardiologist to be reduced to $2 million pursuant to state caps

By **Jonathan D. Rubin**, Esq.
Partner
Kaufman Borgeest & Ryan
New York, NY

Elizabeth V. Janovic, Esq.
Associate
Kaufman Borgeest & Ryan
New York, NY

Barbara K. Reding, RN,
LHCRM, PLNC
Clinical Risk Manager
Central Florida Health Alliance
Leesburg, FL

News: A jury awarded $25 million to a 41-year-old man who experienced a severe heart attack only a few months after being given ibuprofen to treat his heart condition.

According to the law firm that represented the man, it is the largest ever medical malpractice verdict in the state of Virginia and the largest personal injury verdict ever handed down in the county. Pursuant to state law, it is expected the award will be reduced to less than a tenth of the original amount because of a state law that caps medical malpractice damages in the state at a maximum of $2 million.

Background: In January 2010, the plaintiff, then 37 years old,

Plaintiff claimed that prior to the heart attack he ran his own lawn care business, was athletic, and coached his kids in sports.

experienced a sudden onset of chest pain that radiated to his jaw and left arm. Plaintiff was treated at two hospitals before the defendant cardiologist examined the results of tests to determine whether arteries near plaintiff's heart might be blocked. The defendant cardiologist diagnosed plaintiff with a mild infection of his heart that could be effectively treated with over-the-counter medication. The defendant cardiologist also stated that plaintiff's coronary arteries were normal and clear of any disease.

A mere three months later,

plaintiff suffered a massive heart attack. After the heart attack, another cardiologist, working in the same practice with the defendant cardiologist, reviewed plaintiff's initial visit records from January 2010. Plaintiff claimed that the second cardiologist disagreed with the defendant cardiologist's original diagnosis.

Plaintiff sued the defendant cardiologist and the hospital where the cardiologist treated him, and he alleged negligence and medical malpractice. Plaintiff claimed that prior to the heart attack he ran his own lawn care business, was athletic, and coached his kids in sports. Following the heart attack, plaintiff stated he could not run to first base without getting severely winded. He also claimed to be at a severe loss for breath after a long conversation or a walk up two flights of stairs.

At trial, plaintiff's lawyers claimed that he will likely require a heart transplant within five years. They also claimed there is only a 50% chance plaintiff will survive 10 years after a heart transplant, thereby setting plaintiff's possible life expectancy between 52 to 56 years of age. Plaintiff's experts con-

tended the January tests showed severe blockages in his arteries that should have required a stent to open the arteries. The defense experts, however, contended the blockages seen in January were far less severe and did not necessitate drastic action.
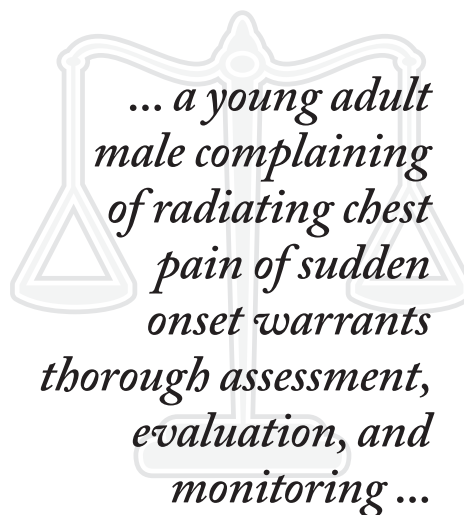
The jury deliberated for three and a half hours before reaching their verdict. The jury found the defendant cardiologist and defendant hospital negligent and awarded plaintiff $25 million. *(Editor's note: Information on how the award was split was unavailable.)* According to the law firm that represented the man, it is the largest ever medical malpractice verdict in the state of Virginia and the largest personal injury verdict ever handed down in the county. Pursuant to state law, it is expected the award will be reduced to less than a tenth of the original amount because of a state law that caps medical malpractice damages in the state at $2 million.

What this means to you: While the monetary award in this case might be reduced pursuant to Virginia law to a cap of less than 10% of the original verdict award, such a reduction does not diminish the punitive effect the initial $25 million jury finding for plaintiff demonstrates. Based on evidence presented at trial, the jury determined plaintiff was entitled to recover damages suffered as the result of negligent action. The $25 million verdict indicates not only compensatory damages were to be restored, but substantial punitive damages were awarded as well.

In reviewing the arguments as provided in the case background, several significant factors are noted. First and foremost, the presentation to two hospitals of a young adult male complaining of radiating chest pain of sudden onset warrants thorough assess-

ment, evaluation, and monitoring to ensure a positive outcome for the patient and diminish the risk of misdiagnosis and/or inappropriate treatment. A young adult male presenting with sudden cardiac symptoms requires risk containment. Initial evaluation and treatment at one hospital prior to transfer to the second hospital, where the defendant cardiologist examined coronary artery test results, supports the need for careful cardiac evaluation, monitoring, and treatment services for this type of patient.

The cardiologist then determined based on test results that

> *... a young adult male complaining of radiating chest pain of sudden onset warrants thorough assessment, evaluation, and monitoring ...*

plaintiff's coronary arteries were within normal limits with no signs of an active disease process. An over-the-counter medication is recommended for what is thought to be a mild heart infection. This is an interesting pharmacologic therapy approach for a heart infection. At trial, the testimony of a partner in the defendant cardiologist's practice states the partner later reviewed the initial records following the patient's myocardial infarction event and disagreed with the defendant cardiologist's original diagnosis. This presents an interesting twist with regard to expert witness testimony. The utilization of the testimony of a doctor who is in the same practice as

the defendant might or might not enhance expert witness credibility based on whether the partner is in agreement or disagreement with the defendant practitioner. One can only surmise such a diagnosis disagreement between the two partners in this case had an impact on the jury with respect to proving negligence on the part of the defendant cardiologist; i.e., if your own partner disagrees with you, then your initial diagnosis must be presumed to have been in error. This could serve as proof the defendant deviated from the standard practice of competent fellow professionals.

In addition, experts for the defense testified "blockages seen in January," at the time of the initial diagnosis, were "far less severe and did not necessitate drastic action". Blockages? The defendant cardiologist previously informed the patient his coronary arteries were normal. There was no mention by the cardiologist to the patient of any blockage at that time; an over-the-counter medication was the only treatment prescribed for the single diagnosis of a mild heart infection. Score yet another point for the plaintiff's attorneys in proving a breach of the duty to care and the subsequent injury of a massive heart attack three months later in a 37-year-old claimed to be caused by a departure from the standard of care.

As for proving injury, which might include but is not limited to loss of income, physical harm, pain, and suffering, plaintiff claimed a change in lifestyle and loss of physical capability and endurance following his heart attack. It was also claimed his life expectancy is now greatly diminished as a result of the massive heart attack and subsequent heart damage. A 37-year-old father facing a potential heart transplant within five years, followed by a

potential 10-year post transplant survival rate of 50%, understandably evokes sympathy in members of a jury. A sympathetic jury tends to award significant punitive damages.

At the center of this verdict are plaintiff and his family. Two million dollars or $25 million, legal

cap or no cap, together they will need to adjust to the physical and financial changes in their lives and relationship as a result of the finding of fact regarding negligence. As for defendant practitioners and hospitals, in any case with cap or no cap, whether a verdict for the plaintiff or the defense, positive

patient outcomes and risk management strategies must remain priorities in the practice and delivery of healthcare today.
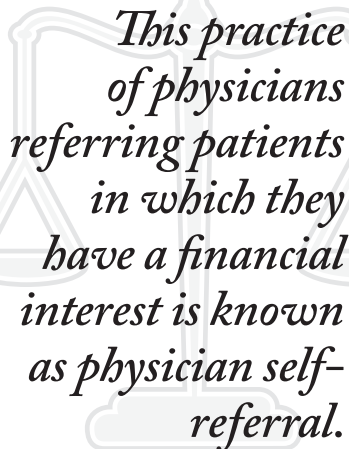
Reference

CL12000094-00, Hampton Circuit Court, Virginia (2013). ✦

Hospital system pays $9.3 million to settle False Claims Act and Stark Law violations

News: In November 2012, a multi-hospital healthcare system settled allegations of improperly compensating physicians from its many clinics for referrals of Medicare and Medicaid patients. It was alleged by the United States Department of Justice Civil Division that these actions were in direct violation of the False Claims Act and Stark Law. The hospital system agreed to pay $9.3 million to settle those allegations.

Background: A multi-hospital healthcare system, consisting of three hospitals, paid $9.3 million to settle allegations that it violated the False Claims Act and Stark Law. The Stark Law limits the referrals of designated health services provided to Medicare and Medicaid patients if the physician making the referral has a financial relationship including compensation arrangements that are based on the volume of referrals, generated revenue of referrals, or investment interests, with that entity. This practice of physicians referring patients in which they have a financial interest is known as physician self-referral. In this case, the financial interest was a compensation agreement based on the amount of patient referrals,

but it might be as conspicuous as an ownership interest. The False

This practice of physicians referring patients in which they have a financial interest is known as physician self-referral.

Claims Act and Stark law exist to protect the integrity of the government-funded health care benefit programs.

The multi-hospital healthcare system allegedly provided improper incentive pay to 70 physicians. This incentive pay program was based on the revenue generated by the physicians' referrals for services provided within the multi-hospital healthcare system. Such services included diagnostic testing. This incentive compensation might have taken into account the value and volume of those physicians' referrals.

The physician compensation

for referral agreements in violation of the False Claims Act and Stark Law was discovered by the multi-hospital healthcare system during an internal review conducted in 2009. The multi-hospital healthcare system self-disclosed these errors to the United States Attorney in its district and claimed the errors were made inadvertently. The hospital system expressed that the complexity of federal guidelines was a major cause of the errors. In 2012, after a lengthy investigation of the disclosures in conjunction with the Federal Bureau of Investigation, the U.S. Attorney's Office for the district, and the Office of Inspector General of the U.S. Department of Health and Human Services, the United States Department of Justice Civil Division alleged that the hospital system knowingly violated the False Claims Act and Stark Law by compensating some of its physicians with incentive compensation.

This is just one example of many since the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative to prevent Medicare and Medicaid financial fraud was announced in 2009. Since January 2009, the United States Department

of Justice has applied the False Claims Act and the Stark Law to recover $10.1 billion in cases involving fraud by doctors and hospitals against federal healthcare programs such as Medicare and Medicaid. This amount is significant considering the fact that the United States Department of Justice has recovered a total of over $13.8 billion in all False Claims Act cases since January 2009.

What this means to you: In today's healthcare world of regulatory compliance, it is not difficult to become lost or distracted in the multiple state and federal regulations and requirements and the interpretation of those rules. The False Claims Act of 1986, the Ethics and Patient Referral Act of 1989, the Omnibus Budget Reconciliation Act of 1989 (effective Jan. 1, 1992, and includes Stark I), and the Omnibus Budget Reconciliation Act of 1993 (includes Stark II) are but a few examples of the regulatory requirements healthcare providers must be knowledgeable of and comply with on a daily basis. Terms such as "kickbacks," "fraud," and "false claims" have become common, negative words familiar to government agencies, healthcare providers, and consumers alike.
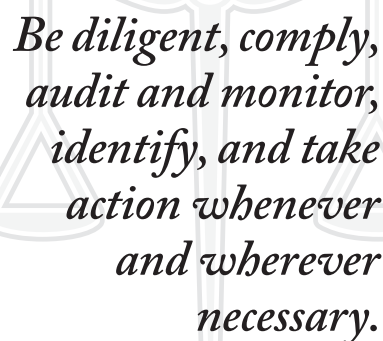
Developing, enacting and maintaining a compliance program are not simple or easy tasks. The "Federal Sentencing Guidelines Manual" recommends seven core elements for an effective compliance program:

leadership and structure (including a compliance officer and a corporate compliance counsel);
written standards;
education and training;
internal lines of communication;
auditing and monitoring;
responding to potential violations;

corrective action procedures.

A compliance program is costly and time-consuming, yet without an effective program in place, the risks of penalties, litigation, and harm rise even higher in both cost and time. It is imperative to be cautious and take regulatory compliance seriously.

In an Office of Inspector General's (OIG) "Open Letter to Health Care Providers" dated March 9, 2000, Inspector June Gibbs Brown stated the following: "The best evidence that a provid-

Be diligent, comply, audit and monitor, identify, and take action whenever and wherever necessary.

er's compliance program is operating effectively occurs when the provider, through its compliance program, identifies problematic conduct, takes appropriate steps to remedy the conduct and prevent it from recurring, and makes a full and timely disclosure of the misconduct to appropriate authorities."

The pitfall in this case was related to incentive compensation. Compensation packages of any type within the healthcare industry require due diligence to ensure compliance with regulations. Reviews by legal counsel, compliance officers, and risk managers are one means of making every effort to avoid perceptions of kickbacks, fraud, or false

claims. Financial disclosure is also necessary to avoid conflict of interest and compensation issues, especially when referrals to system-owned clinics and outpatient services might be involved.

In this case, the multi-hospital healthcare system met several of the core elements as recommended in the "Federal Sentencing Guidelines Manual." They conducted an audit, responded to potential violations, and as per the Office of Inspector General open letter of March 2000, identified problematic conduct and disclosed their findings to the appropriate authorities. Although the health system leaders self-reported their audit findings to the authorities, a lengthy federal investigation was conducted, and the allegations were settled at a cost to the healthcare provider of $9.3 million. Recovery of Medicare and Medicaid funds related to regulatory non-compliance, whether intentional or unintentional, has been and continues to be an active goal of the United States Department of Justice. Since 2009 they have proven to be successful in doing so.

What does this mean to you? Be diligent, comply, audit and monitor, identify, and take action whenever and wherever necessary.

Reference

This case was handled by the United States Department of Justice's Civil Division, the U.S. Attorney's Office for the Western District of Missouri, the Office of Inspector General of the U.S. Department of Health and Human Services, and the Federal Bureau of Investigation. The claims in this case were settled between a government agency and the hospital. No trial or court information is available for purposes of citation. ✦