Healthcare RISK MANAGEMENT

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Wave of settlements with deaf patients raises risk for hospitals

Plaintiffs claimed hospitals did not offer adequate interpreters, other aid

Hospitals and other providers have settled a surprising number of lawsuits recently alleging failure to accommodate patients with hearing disabilities, which puts the spotlight on an obligation and liability risk that can easily slip under the radar. Risk managers should take note and review accommodation programs to makes sure they don't end up with the same financial loss, attorneys warn.

The Department of Justice (DOJ) recently announced the settlement of five more investigations with healthcare providers concerning access to services for persons who are deaf and hard of hearing, bringing the total to seven in the past year. *(See the story on p. 88 for more on those cases.)*

These recent settlements stem from the DOJ's ongoing partnership between the Civil Rights Division and U.S. Attorneys' offices nationwide. This partnership, announced in July 2012, is designed to target enforcement efforts of healthcare facilities to ensure that people with disabilities, especially those who are deaf or hard of hearing, have equal access to medical services. The five newly announced settlements — one with a hospital, two with rehabilitation centers, and two with private specialty practices — highlight the continuing focus on healthcare providers of all sizes and their policies and practices when providing medical information to deaf and hard-of-hearing patients or companions.

The DOJ representatives have made clear that they are quite interested in pursu-

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ing this type of case, says **Melissa L. Taylormoore**, JD, an associate with the law firm of McGuireWoods in Tysons Corner, VA. The common thread among the recently settled cases is that the plaintiffs alleged the hospitals did not provide adequate accommodation to either the patient or the patient's caregivers and relatives, she says.

Two questions arise from the allegations and settlements, Taylormoore says.

"Who is going to provide for the costs? Providers understand they have some obligation to provide a means of communication, but the sticking point often comes down to who is going to be paying for the services," she says. "These settlement agreements contribute to the case law that clearly shows the cost is going to fall to the provider."

The second question is just what is required to provide effective communication. *(See the story on p. 87 for what is required by the Americans with Disabilities Act [ADA].)*

"What may be effective in one situation may not be in another, so that means providers have to have a flexible enough system to be able to have that interactive process with patients and their caregivers," Taylormoore says. "Providers have to be willing to engage in that process before the actual care begins. It is a common theme that these problems arose before the patient even began treatment. It was during intake or when the patient was just trying to arrange treatment."

Executive Summary

Seven providers have settled claims recently in which deaf patients alleged a failure to accommodate their communication needs. The flurry of settlements puts healthcare providers at high risk of similar allegations.

- ✦ Risk managers should immediately review their programs to assist deaf patients.
- ✦ Pay special attention to documenting a patient's refusal of sign language interpretation.
- ✦ Juries tend to sympathize with plaintiffs alleging discrimination due to a hearing disability.

Patients are savvy about the law

Many healthcare providers are not adequately prepared for patients and others with hearing disabilities, says **Nathan A. Kottkamp**, JD, a partner with McGuireWoods in Richmond, VA.

"The time to figure out what duties you owe to these individuals is not when they show up at the door," he says. "It's long, long before that."

People affected by hearing disabilities tend to be "pretty savvy" about the law and required accommodations because they experience the difficulty of hearing loss every day, Kottkamp says. As a rule, this group of people will be quick to realize when a hospital is not meeting its obligations and will have connections with the right advocacy groups and legal

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representatives to take action.

"That's one of the general cautions for providers. This is something they should be proactive about because if you get it wrong, it won't be overlooked," Kottkamp says. "If you fail to meet your obligations, the people affected are going to call you on it, and the DOJ is ready to take action."

Healthcare providers tend not to be as well-prepared for accommodating those with hearing disabilities as they are with language translation services, Taylormoore notes. The bottom line is that providers have to make sure people with hearing disabilities have equal access to the services offered, and that definition is interpreted broadly. "That means from the beginning, from intake all the way through discharge," Taylormoore says. "And people must be put on notice of those resources. There will be a reasonableness standard, so for instance, having an interpreter on staff 24 hours a day may not be reasonable."

But even if the facility does not have an interpreter present at all times, there must be plans to make one available quickly, Taylormoore explains. If the provider is in a community known to have a high percentage of people with hearing disabilities — because a school for the deaf is nearby, for example, or you contract with a physician group that treats hearing loss — that facility will have more obligation to keep an interpreter available at all times.

"It's not unusual for large hospital chains to contract with interpreter services to have people on call at all hours, with specifications that they can get an interpreter to an emergency room within a certain time frame," Taylomoore says. "That tends to be the more practical solution."

Document offer and refusal

Kottkamp points out that in addition to offering interpreters, it is crucial to fully and accurately document the process. Records must show that you asked if any communication aid was necessary and must show the patient or caregiver's response — especially if there is a hearing disability and the offer is declined.

Kottkamp points out that in addition to offering interpreters, it is crucial to fully and accurately document the process.

"A lot of times someone will come in with a spouse or child who can interpret and they will say they prefer using that person instead of your translation services," Kottkamp says. "You want to document that so that there is no doubt about it later on. You want to avoid a situation in which the person claims you didn't offer any translation and so they had to use a child or spouse who was not able to properly translate the information."

That scenario is similar to one of the cases recently settled, in which a patient claimed that the hospital refused to provide an interpreter and left her to rely on her 11-year-old daughter. *(See the story on p. 88 for additional information about some of the settled cases.)*

In addition, the recent settlements make clear that the DOJ expects healthcare providers to offer interpretation to family members as well, whether the patient needs interpretation or not. This would apply in a situation, for example, in which the patient is not hearing-disabled, but a caregiver such as a spouse or parent is.

Failing to adequately accommodate the deaf could result in damages from malpractice cases alleging a lack of informed consent or other harm caused by a lack of communication, Taylormoore explains. If the DOJ becomes involved, civil damages also are possible.

If you are sued for failing to provide accommodations for someone with hearing disabilities, it will not be a case you want to fight to the end, Kottkamp says.

"These tend to be very sympathetic plaintiffs," he explains. "When people say they have been denied adequate healthcare because of a disability, that is not the kind of case you want to take before a jury. The vast majority of these cases settle because of those dynamics."

SOURCES

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ADA requires equal access for deaf patients

The Americans with Disabilities Act (ADA) requires places of public accommodation, including hospitals, doctors' offices, ambulatory surgery centers, and other healthcare providers, to offer people with disabilities equal access to goods, services, and facilities. When applying the ADA requirements to people with hearing disabilities, the main issue is ensuring adequate communication, says **Melissa L. Taylormoore**, JD, an associate with the law firm of McGuireWoods in Tysons Corner, VA.

Under Title III of the ADA, healthcare providers are required to provide qualified sign language interpreters and other auxiliary aids to individuals who are deaf, hard of hearing, or who have speech disabilities, free of charge, in situations in which the medical services involve important, lengthy, or complex oral communications with patients or companions. Healthcare providers must provide these types of auxiliary aids unless doing so poses an undue burden to the healthcare provider or fundamentally alter the nature of the services provided.

The specific type of auxiliary aid required depends on multiple factors including the nature and length of the communication, the patient's or companion's communication skills and knowledge, and the individual's stated need for an auxiliary aid. Examples of auxiliary aids include, but are not limited to, qualified interpreters on site or though video remote interpreting (VRI) services, written materials, exchange of written notes, video text displays, or the use or text telephones (TTYs).

The individual with a disability cannot be charged extra for the cost of an interpreter or other auxiliary aid. ✦

7 hospital settlements in past year related to hearing

The Department of Justice (DOJ) announced recently that, as part of its Barrier-Free Health Care Initiative, over the past year it has reached seven settlements with eight healthcare providers from across the United States to ensure that they are providing effective communication to people who are deaf or have hearing disabilities.

These settlements address the requirements of the Americans with Disabilities Act (ADA) for healthcare providers, such as hospitals, medical clinics, nursing homes, and doctor's offices, to provide effective communication to people who are deaf or have hearing disabilities in the provision of medical services.

The DOJ's Barrier-Free Health Care Initiative is a partnership of the Civil Rights Division and U.S. Attorney's offices across the nation, to target enforcement efforts on a critical area for individuals with disabilities. The initiative, launched on the 22nd anniversary of the ADA in July 2012, includes the participation of more than 40 U.S. Attorney's offices. Six of the seven settlements were obtained by the U.S. Attorney's Offices. The settlement obtained by the department's Civil Rights Division covers two facilities.

The seven settlements from the past year are:

- April 2012 — Richard Noren, MD, Henry Kurzydlowski, MD, and Pain Care Consultants, in the Northern District of Illinois;
- May 2012 — Steven Senica, MD, and Senica Bruneau, in the Northern District of Illinois;
- June 2012 — NorthShore University HealthSystem in the Northern District of Illinois;
- November 2012 — Paul S. Biedenbach, MD, and Northern Ohio Medical Specialists Healthcare in the Northern District of Ohio;
- January 2013 — The Center for Orthopaedics and Sports Medicine in the Eastern District of Virginia;
- March 2013 — Manassas Health and Rehab Center and Gainesville Health and Rehab Center, both in the Eastern District of Virginia;
- March 2013 — Monadnock Community Hospital in the District of New Hampshire.

"Disability-based discrimination in healthcare is illegal under the Americans with Disabilities Act and will not be tolerated," said **Eve L. Hill**, senior counselor to the assistant attorney general for the Civil Rights Division, in announcing the settlements. "All types of healthcare providers — from hospitals to nursing homes, from surgeons to general practitioners all across the country — need to provide equal access to people with disabilities, including people who are deaf. More than 20 years after passage of the ADA, the time for compliance is now."

In addition to the department's settlements, in early March 2013 the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) reached a settlement agreement with Genesis HealthCare, one of the nation's largest providers of senior care with more than 400 facilities, to provide sign language interpreters and other means of effective communication to individuals who are deaf or hard of hearing. ✦

Settlement cases show how disabled patients can be affected

In the recent settlements regarding discrimination against people with hearing disabilities, the Department of Justice (DOJ) found that at each of the eight facilities, a person who is deaf sought to access healthcare services and was denied a needed sign language interpreter.

By not providing a sign language interpreter or otherwise communicating effectively with the individuals who are deaf, the facilities and doctors were compromising the overall health of their patients, the DOJ concluded. The DOJ provides this summary of the alle-

gations in a few of the settled cases:

• In the Monadnock Community Hospital settlement, the complainant went to the emergency department (ED) at the hospital for treatment for an allergic reaction that caused her to have difficulty breathing. Upon entering the hospital, she requested a sign language interpreter by presenting an Emergency Interpreter Referral Card. Despite this request, hospital staff attempted to use the complainant's 11-year-old daughter as an interpreter. The complainant repeatedly asked for an interpreter during her time in the ED, where she was administered medical procedures. She eventually was discharged, and although she was provided with discharge paperwork, she alleged she had no understanding of what was done to her and had no understanding of the discharge document.

• In the Center for Orthopaedics and Sports Medicine settlement, the patient, who is deaf, repeatedly requested an interpreter for multiple medical and physical therapy appointments related to a back injury. The orthopedic practice told the patient it was her responsibility to provide an interpreter and did not provide her with an interpreter at any of her appointments.

• Similarly, in the Northern Ohio Medical Specialists matter, the complainant, who is deaf and communicates using American Sign Language (ASL), sought medical care and requested an interpreter, but Northern Ohio Medical Specialists refused to provide an interpreter for her at her appointment and cited company policy.

• In the NorthShore University HealthSystem matter, R.A., who is deaf, was the primary caretaker of his 80-year-old mother S.A. On three occasions, for an ED visit and two hospitalizations, R.A. and S.A. requested a sign language interpreter so R.A. could communicate with the hospital's medical personnel about his mother's condition. R.A. was told that the hospital does not provide interpreters to family members of patients who are not hearing impaired.

Under each settlement agreement, the healthcare provider agreed to change their policies to provide effective communication, including sign language interpreters, free of charge, and to train all staff on their new policies and procedures and the effective communication requirements of the Americans with Disabilities Act (ADA). Under the terms of the agreements with Monadnock Community Hospital, the Center for Orthopaedics and Sports Medicine, the NorthShore University Health Specialists, Senica Bruneau, and Noren, monetary damages were paid to the complainants.

In the NorthShore University HealthSystem and the Northern Ohio Medical Specialists settlements, the healthcare providers agreed to pay a civil penalty to the United States. Under the ADA, a civil penalty of up to $55,000 may be assessed against a healthcare provider or other entity that violates the ADA. ✦

Real-time video monitoring in OR checks safety compliance

A first-of-its-kind video monitoring system used to measure hand-washing compliance at North Shore University Hospital (NSUH) in Manhasset, NY, is being expanded to include cameras in operating rooms (ORs) at a sister facility, Forest Hills (NY) Hospital.

The new pilot program strengthens patient safety by providing hospitals with real-time feedback in their ORs, and it is the first time in the United States that remote video auditing (RVA) has been used in a surgical setting, explains **John F. Di Capua**, MD, the Peter Walker associate professor and chairman of the Department of Anesthesiology at Hofstra North Shore-LIJ School of Medicine in Hempstead, NY. Di Capua also is chief medical officer of North American Partners in Anesthesia (NAPA) in Melville, NY.

RVA ensures that surgical teams take a "timeout" before they begin a procedure to prevent wrong-site surgeries. The cameras also are being used to alert hospital cleaning crew when a surgery is nearing completion and the preoperative area when a room is ready for the next case, which helps reduce the time it takes to prepare the OR for the next surgery. To reduce the risk of infections, the monitoring system also confirms whether ORs have been cleaned thoroughly and properly, both in between cases and overnight. *(See the story on p. 90 for more on how the video monitoring works.)*

The program was designed and implemented by NAPA, which is North Shore-LIJ's anesthesiology provider, in partnership with Mount Kisco, NY-based Arrowsight, a developer and

Executive Summary

A hospital system is using real-time video monitoring of operating room activities to ensure compliance with patient safety efforts. The monitoring is intended to improve patient safety but not to punish individual staff or physicians.

✦ The monitoring helps ensure that OR teams take a timeout.
✦ Cleaning crews can use the system to know when a procedure is complete.
✦ The program evolved from video monitoring to ensure hand washing compliance.

third-party provider of RVA services and software.

The program was initiated in March 2013 in eight ORs at North Shore-LIJ's Forest Hills Hospital. The initial focus at Forest Hills has been on monitoring for surgical timeout compliance, and within just one week of receiving real-time performance feedback, the operating room teams achieved nearly perfect scores, says **Rita Mercieca**, RN, the hospital's executive director.

Given the success of the program at Forest Hills, Di Capua says the monitoring system was installed in June 2013 in more than 20 ORs at another North Shore-LIJ hospital. "We are very excited to bring this important innovation to additional surgical suites," he said. "We believe that third-party RVA can provide our hospitals with strong, sustainable tools to improve patient safety and perioperative efficiencies."

The introduction of video monitoring in ORs follows its ongoing, successful use in the medical and surgical intensive care units at NSUH. In a 2011 study published in *Clinical Infectious Diseases Medical Journal*, NSUH demonstrated that the use of an RVA system rapidly improved and sustained hand hygiene rates to nearly 90% in fewer than four weeks.[1]

Forest Hills also revised its timeout process to make it more interactive, Mercieca notes. "The anesthesiologist and the circulating nurse are asking questions rather than just going through a checklist off the top of their heads," she explains. "They ask specific questions of the surgeon and the team about the patient, making sure they have the right patient and the right procedure, and that they are prepared for anything that might occur. They make sure everyone is engaged."

The timeout should take a few minutes to complete, Mercieca says. If it takes less than a full minute, the timeout cannot be valid. Since Forest Hills began video monitoring of the time outs, the OR teams have achieved nearly 100% compliance, she says.

The video monitoring does not stop when the procedure is complete. Auditors also use the cameras to ensure that terminal cleaning is performed correctly, checking that certain tasks are included and that the cleaning takes at least one hour.

"We're at 100% compliance on the terminal cleaning as well, and that's a really big deal," Mercieca says. "We believe that will reduce surgical site infections."

The monitoring allows the collection of data on every procedure, not just sampling, and that makes the information much more compelling, Di Capua says. He points out that monitoring alone will not produce significant changes in behavior. Clinicians will be motivated to a limited degree simply by knowing that they are being watched, he says, but that effect is limited and decreases over time. The real change comes from using the monitoring to compile data about compliance and providing that data to staff and department heads.

"When you put the data out, that's when you achieve compliance. Having the cameras present without reporting the information didn't achieve much of anything," Di Capua says. "You have to report the data and let people internalize it. Once people trust the data, they will do what you ask them to do."

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How remote video monitoring of OR activity works

All eight operating rooms (ORs) at Forest Hills (NY) Hospital are equipped with video cameras that enable real-time video monitoring of everything that happens before, during, and after a procedure, says **Rita Mercieca**, RN, the hospital's executive director.

The cameras in the ORs feed images to screens at the desk of the OR director and also at the main OR desk, where the director and others can watch for compliance. The images also can be viewed remotely by parties interested in verifying compliance or timing how long certain tasks take to complete, such as the infection control director or the quality assurance manager.

All activity in the OR is recorded and saved for 24 hours, but then the recordings are erased. In addition, the monitoring equipment is purposefully set to produce low-definition video in which the actions of the OR team can be discerned but no one's identity is clear. "We don't want to compromise a patient in any way," Mercieca says. "The auditor can see the people around the table but the patient cannot be identified at all and the OR team's faces are obscured by their masks and the low definition video."

Potential use by plaintiffs also was a factor in deciding to erase the video, she notes. The hospital wanted to emphasize to staff and physicians that the video monitoring was solely to improve quality and patient safety and not to create a video record that could be used against them in any way. Saving the video would create documentation that could be subpoenaed

in a malpractice case, and even though the record might sometimes prove useful for the defense, the hospital leaders decided the best move was to erase everything, she says.

Staff and physicians initially were skeptical of being videotaped in the OR, but Mercieca says they came on board once they understood that the purpose was to improve patient safety rather than to catch them in an error and punish them. ✦

'Know Your Physician' program improves care, safety

Patients, family members, and even staff sometimes don't recognize physicians or remember who is caring for which patient, and that issue can compromise patient safety. For that reason, Natividad Medical Center in Salinas, CA, developed a program to help everyone get to know the doctors better.

"Know Your Physician" is a communication improvement program developed to ensure that every caregiver on the medical/surgical floor knows the roles and responsibilities of each attending physician and resident at all times as well as their patient assignments and call schedules. The new program includes well-defined physician roles and responsibilities, a master call schedule, and assignment tool.

In addition to hospitalists and other physicians, Natividad has family medicine residents. For that reason, there are a lot of doctors around every day, explains Quality Director **Jane Finney**, CLS, MBA, CPHQ. "We found that the nurses complained of never knowing who the doctor was for the patient," she says. "The first solution was to put a white board in the room with the name of the patient's doctor on it, but the nurses didn't know what doctor's name to write. On any given day, the patient might have the attending, a number of residents, plus the on-call team in the evening hours, so it was very confusing to track."

Some investigation revealed the way the hospital published its call schedule was "extremely antiquated," Finney explains. The schedule was being faxed from the telecommunications department to each nursing unit, where it sat on the fax machine or the desk of the unit clerk rather than being communicated throughout the unit.

Finney also determined that the computer record listed the name of the physician who admitted the patient but was not updated with the name of the doctor who took over after admission. "The result was that our nurses were wasting a lot of time running around asking who to call about a patient, and doctors were getting calls about patients that weren't theirs anymore," she says. "We also found that the lab was trying to call doctors with critical results and not getting through to the right doctor."

The solution was the "Know Your Physician" program, which has several components:

- The roles of attending physicians, hospitalists, and residents were more clearly defined so that nurses would better understand which one should be responsible for certain tasks and information.
- The call schedule was reformatted to make it more user-friendly, and it is now posted on the computer system that is available to all nurses. The nurses use a computer at the bedside to document, and the call schedule is available on that device.
- The resident teams are clearly stated on the call schedule to avoid confusion regarding which residents are involved in the patient's care.
- The hospital's main computer is updated regularly with the name of the patient's attending physician, which ensures the lab knows who to contact with critical results.

The program has produced good results, Finney says. Nurses now know who to contact, patient satisfaction scores have improved 9% on the Hospital Consumer Assessment of Healthcare Providers and Systems Survey, administered by the Agency for Healthcare Research and Quality. The lab also is better able to report results.

"We consider this an important patient safety initiative, because if a nurse needs to get in touch with a doctor to say the patient's status has changed, those can be critical minutes," Finney says. "Critical lab results also are a matter of time and accuracy, so getting to the right physician immediately can be crucial to patient safety."

SOURCE

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Executive Summary

A California hospital has developed a program to help staff, patients, and families know physicians better. The effort is intended to improve patient safety, communication, and patient handoffs.

✦ The hospital had an antiquated method of posting call schedules.
✦ Critical lab results were being delayed while determining the right doctor to call.
✦ Frequent updating of the call schedule and attending physician solved much of the problem.

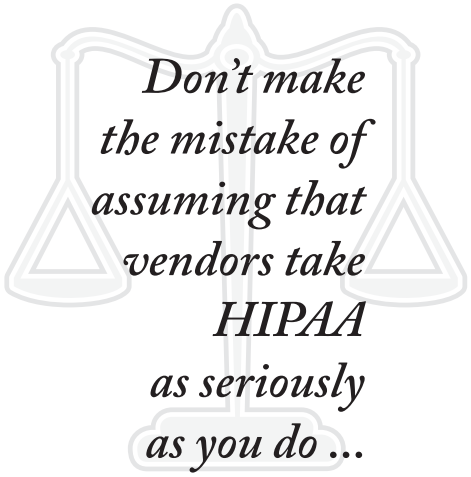
Onus is on you to determine business associates under HIPAA

With more vendors qualifying as business associates under the Health Insurance Portability and Accountability Act (HIPAA), some covered entities are wondering just where the responsibility lies for making that determination and ensuring compliance. The consensus is that the healthcare provider must be responsible, partly to protect yourself.

The final HIPAA rule broadened the definition of business associates to include subcontractors, data transmission companies, personal health record providers, and entities performing patient safety activities that have access to protected health information (PHI). The new definitions will be effective on Sept. 23, 2013. *(For more on the new definitions, see the* HIPAA Regulatory Alert *included in this issue.)*

Providers cannot wait for business associates to make their own determination because an incorrect conclusion leaves the healthcare provider at risk, says **Kimberly Short Kirk**, JD, an attorney with the law firm of Moore & Van Allen in Charlotte, NC. "A party becomes a business associate by definition — their function and what they do — and not what they decide," she explains. "I wouldn't wait for parties to self-identify. You will not be helped later on by saying that the vendor declared themselves not a business associate and so you did not take the steps to make sure they were handling PHI properly."

Don't make the mistake of assuming that vendors take HIPAA as seriously as you do and are acting in good faith to determine if they are business associates, cautions **Eric D. Fader**, JD, an attorney with the law firm of Edwards Wildman Palmer in New York City. Too many vendors have avoided making a valid determination and opted instead to "just stick their heads in the sand and keep saying they're not business associates," Fader says.



"It's a dangerous strategy because if there is a data breach, everybody is going to potentially get in trouble anyway under HIPAA," Fader says. "I advise my healthcare clients to enter into business associate agreements [BAAs] with all of their outside service providers who might have access to protected health information. It's really just cheap insurance so that in the event of a breach you can show the government that you took every step to ensure that you were meeting your obligations."

Fader points out, however, that signing a BAA does not make a vendor a business associate if they're actually not one in the opinion of the Office of Civil Rights (OCR). Signing a BAA even when the vendor might not be a business associate does no harm and could eliminate some worry, Fader says.

Conversely, a vendor who OCR considers a business associate is subject to the privacy rules whether they sign a BAA or not, notes **Robert D. Belfort**, JD, a partner with the law firm of Manatt, Phelps & Phillips in New York City. Avoiding the agreement is not a path to immunity, he says, and risk managers might need to point that out to vendors who are reluctant to sign.

Existing BAAs must be revised to reflect the HIPAA final rule by Sept. 23, 2014, and most amendments will require mutual consent, Belfort says. "Hospitals should have a master list of all their business associates and they should be working to have each of those properly amended by that deadline," he says. "If there are arrangements with data storage companies that were not considered business associates, those will not appear on your master list. That process also should include determining what agreements you had with those vendors and completing their agreements by the deadline."

The provider must take the reins when determining business associates because the OCR will hold it ultimately responsible for failures

Executive Summary

Healthcare providers should not rely on vendors to determine if they are business associates under the Health Insurance Portability and Accountability Act (HIPAA). An incorrect assessment could leave the provider at risk in the event of a data breach.

- ✦ Err on the side of considering vendors business associates.
- ✦ Signing a business associate agreement does not make a vendor an associate if it would not be otherwise.
- ✦ Be cautious with downstream subcontractors that might need more support for compliance.

by a vendor, says **Bob Janacek**, chief technology officer with DataMotion, a secure data delivery provider in Morristown, NJ. "The covered entity can be held liable when a business associate or subcontractor is not compliant, so that means the provider should have visibility all the way down the chain," he says. "There is risk, a long tail of risk, because the protected health information originated with them. The provider should know who is touching that information and how."

Janacek points out that providers might be comfortable with the HIPAA compliance program of the first vendor in the chain, but the subcontractor might have fewer resources or understanding of HIPAA obligations. Each additional subcontractor might be less and less able to protect PHI.

"As those companies get smaller and smaller down the line, they're going to look to the provider for guidance and resources," he says. "They may not even be aware of the need to comply with HIPAA. They may consider themselves in a different business altogether and not even consider that they are obligated to comply with HIPAA."

SOURCES

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AACN issues practice alert to manage clinical alarms

Clinical alarms designed to alert nurses to changes in their patients' conditions have become a continual barrage of noise that poses a significant threat to patient safety, according to the American Association of Critical-Care Nurses (AACN). A new AACN Practice Alert outlines evidence-based protocols to reduce false or non-actionable alarms and improve the effective use of these monitoring aids.

Since 1983, the average number of alarms in an ICU has increased from six to 40, despite the fact that humans have difficulty learning more than six different alarm sounds, the group reports. The sensory overload from sounds emitted by monitors, infusion pumps, ventilators, and other devices, known as alarm fatigue, can cause a person to become desensitized to the alarms. This might result in delayed responses or missed alarms, sometimes contributing to patient deaths, explains AACN Senior Director **Ramón Lavandero**, RN, MA, MSN, FAAN.

"Today's hospital bedsides are filled with devices that support patient care even while sometimes creating unsafe situations," Lavandero says. "Patient care staff are inundated with alarm sounds, many of which are false or don't require action. True alarms can be missed, compromising patient safety."

Based on the latest available evidence, this AACN Practice Alert summarizes expected nursing practice related to alarm management, including the following:

- Provide proper skin preparation for ECG electrodes, which can improve conductivity and decrease the number of false alarms.
- Change ECG electrodes daily.
- Customize alarm parameters and levels on ECG monitors.
- Customize delay settings and threshold settings on oxygen saturation via pulse oximetry (SpO_2) monitors. The combination of appropriate alarm delays and threshold settings optimizes the monitor to its highest potential, and it produces an alarm when action is required.
- Provide initial and ongoing education about devices with alarms.
- Establish interprofessional teams to address issues related to alarms, such as the development of policies and procedures.
- Monitor only those patients with clinical indications for monitoring.

(For more on the risks of alarm fatigue, see Healthcare Risk Management, *June 2013, p. 68. For information on a specific case involving alarm safety, see "Commissioners approve $20 million settlement for boy's brain damage suit against county hospital" in this month's* Legal Review & Commentary *supplement.)* ✦

FDA cautions on devices connected to health care networks

The Food and Drug Administration (FDA) recently warned healthcare providers to build awareness of the vulnerabilities and risks associated with medical devices being increasingly connected to information systems and networks.

The FDA is recommending that medical device manufacturers and healthcare facilities take steps to ensure that appropriate safeguards are in place to reduce the risk of failure due to cyber attack, which could be initiated by the introduction of malware into the medical equipment or unauthorized access

to configuration settings in medical devices and hospital networks.

"Many medical devices contain configurable embedded computer systems that can be vulnerable to cyber security breaches," the FDA statement says. "In addition, as medical devices are increasingly interconnected, via the Internet, hospital networks, other medical device, and smartphones, there is an increased risk of cyber security breaches, which could affect how a medical device operates."

The FDA cites these cyber security vulnerabilities and incidents that could directly impact medical devices or hospital network operations:

• network-connected/configured medical devices infected or disabled by malware;

• the presence of malware on hospital computers, smartphones and tablets, targeting mobile devices using wireless technology to access patient data, monitoring systems, and implanted patient devices;

• uncontrolled distribution of passwords, disabled passwords, and hard-coded passwords for software intended for privileged device access (e.g., to administrative, technical, and maintenance personnel);

• failure to provide timely security software updates and patches to medical devices and networks and to address related vulnerabilities in older medical device models (legacy devices);

• security vulnerabilities in off-the-shelf software designed to prevent unauthorized device or network access, such as plain-text or no authentication, hard-coded passwords, documented service accounts in service manuals, and poor coding.

The full alert from the FDA is available online at http://tinyurl.com/paymv9u. ✦

FTC provides guidance to hospitals on red flags rule

The Federal Trade Commission is providing new guidance to help hospitals and other creditors comply with its Red Flags rule, which was revised in 2012 to reflect a change in the law that more narrowly defined the types of creditors subject to the rule.

Hospitals and others that meet the rule's definition of "creditor" must develop a written identity theft prevention program. The rule generally applies to creditors that "regularly and in the ordinary course of business" engage in certain conduct, such as using or furnishing information to consumer reporting agencies with a credit transaction.

However, the regulatory obligations in the rule are not triggered by isolated conduct.

"What is deemed 'regularly and in the ordinary course of business' is specific to individual companies," the new guidance states. "If you get consumer reports or furnish information to a consumer reporting company regularly and in the ordinary course of your particular business, the rule applies, even if for others in your industry it isn't a regular practice or part of the ordinary course of business."

The guidance is available online at http://tinyurl.com/redflagguide. For more on the rule, go to www.aha.org/redflags. ✦

TN hospitals reduce early elective births 75% in seven months

Hospitals participating in the "Healthy Tennessee Babies are Worth the Wait" partnership reduced preventable early elective deliveries by 75% over seven months, to 3.5% of all births, according to data released recently by the Tennessee Hospital Association (THA).

At the end of May 2012, preventable early deliveries at 37 Tennessee hospitals that provide labor and delivery services accounted for 14% of all deliveries. By the end of the year, that number had dropped to just 3.5% of all births, according to data reported by the hospitals.

The hospitals were participating in Healthy Tennessee Babies are Worth the Wait, a partnership launched last year by the Tennessee Center for Patient Safety, Tennessee Initiative for Perinatal Quality Care, Tennessee Department of Health, March of Dimes, and the THA, which helps improve awareness about the benefits of full-term delivery among expecting parents, their families, health providers, and organizations that serve pregnant women.

Evidence shows babies carried 39 weeks and beyond are healthier and at lower risk for developmental complications, says **David Adair**, MD, director of maternal-fetal medicine at Erlanger Medical Center-Baroness Hospital in Chattanooga, which participates in the program.

"Early elective deliveries are associated with increased maternal and neonatal complications for both mothers and newborns, compared to deliveries occurring beyond 39 weeks," Adair says. "There is a great deal of evidence that documents the upside of going full-term if that is possible without endangering the health of the mother or child. Studies suggest that in addition to being at a decreased risk of death, babies that stay in the womb 39 weeks or longer can feed, digest, and breathe better." ✦

Strategies offered for wrong patient med errors

Wrong-patient medication errors occur most often during administration and transcription, but patient safety can be improved by implementing strategies during all phases of the medication process, according to a new report from the Pennsylvania Patient Safety Authority (PPSA).[1]

During the period of July 1, 2011, through Dec. 31, 2011, 813 wrong-patient medication errors were reported to the PPSA. Errors most often occurred during transcribing (38.3%) and administration (43.4%) and least during dispensing (5.2%). Anti-infectives, opioids, and anticoagulants were the most common types of medications associated with wrong-patient events. While multiple factors might have contributed to each event, the most common were two patients being prescribed the same medication, improper verification of patient identification, and similar room numbers. Important risk reduction strategies include ensuring proper storage of medications and patient-specific documents, using healthcare technology fully, limiting verbal orders, and improving patient verification throughout the medication-use process.

Anti-infectives, opioids, and anticoagulants were the most common types of medications associated with wrong-patient events.

"Wrong-patient medication errors can occur at any phase of the medication-use process," the authors write. "While events reported to the authority suggest that these errors occurred most often during administration and transcription, implementing safety strategies at all nodes can help to ensure that the correct patient receives the correct medication."

The suggested safety strategies include improving patient verification, limiting the use of verbal orders, and empowering the patient to prevent and detect medication errors. The full PPSA report is available online at http://tinyurl.com/mjon44x.

Reference

1. Yang A, Grissinger M. Wrong-patient medication errors: an analysis of event reports in Pennsylvania and strategies for prevention. *Pa Patient Saf Advis* 2013; 10(2):41-49. ✦

COMING IN FUTURE MONTHS

- ✦ Hidden liability risks with EHRs
- ✦ Google Glass in the operating room?
- ✦ Form for better assessing fall risk
- ✦ Steps to a better risk management career

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. **According to Melissa L. Taylormoore, JD, an associate with the law firm of McGuireWoods, what do the recent settlements involving discrimination claims by people with hearing disabilities indicate about the obligation to pay for interpreter services?**
   A. The agreements contribute to the case law that clearly shows the cost is going to fall to the provider.
   B. The agreements are consistent with case law determining that the cost will fall to the patient or insurer.
   C. The agreements indicate that the cost can be charged to a private insurer but not a government third-party payer.
   D. The agreements provide no suggestion as to who is responsible for the cost.

2. **According to Taylormoore, what does the Americans with Disabilities Act require in regard to making sign language interpreters or other accommodation available for people with hearing disabilities?**
   A. The assistance must be available 24 hours a day, seven days a week.
   B. A reasonableness standard applies, so it might not be necessary to have interpreters present at all times, but there must be plans to make one available quickly.
   C. The provider is required to have interpreters immediately available at least eight hours per day.
   D. The provider is not obligated to have interpreters available.

3. **At Forest Hills Hospital, what is done with the video recordings of operating room activity?**
   A. They are kept indefinitely as part of the patient record.
   B. They are erased after 24 hours.
   C. They are erased after one year.
   D. The patient is given the option of keeping the recording or erasing it.

4. **At Natividad Medical Center, what was one problem solved by the "Know Your Physician" program?**
   A. Call schedules were sent by fax to unit directors and not posted for all staff to see.
   B. Physicians did not comply with rules requiring display of identification badges.
   C. Physicians were not signing in to the computer system when they conducted rounds.
   D. Personnel lists were not regularly updated by the human resources department.

HIPAA Regulatory Alert
Supplement to *Healthcare Risk Management* and *Hospital Access Management*

Don't let the broader meaning of business associate trip you up

Downstream data companies especially affected by new definition

Business associates have been required to comply with the HIPAA Privacy Rule since February 2010 as a result of the HITECH Act, but the Office for Civil Rights (OCR) held off on any enforcement activities. That position is changing this summer.

On Sept. 23, the HITECH Act requires enforcement of business associate agreement (BAA) policies, and the definition of business associates has been broadened in a way that means healthcare providers might have more than they thought, especially when it comes to data contractors who work with protected health information (PHI).

The definition of business associates was expanded to include more "downstream" entities, including subcontractors, data transmission companies, and personal health record providers, explains **Careen H. Martin**, JD, an associate with the law firm of Nilan Johnson Lewis in Minneapolis. Under the recently released HIPAA Omnibus, the definition of a business associate has been expanded to include organizations that provide data transmission of PHI to covered entities and that require access on a routine basis to that PHI. The new definition of business associate also includes any subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

Prior to the new HIPAA Omnibus, the definition of business associate did not explicitly include organizations that provide data transmission and did not include all downstream subcontractors, Martin notes. "HHS had indicated that entities that act as mere conduits for the transport of protected health information but do not access the information other than on a random or infrequent basis, such as the U.S. Postal Service or United Parcel Service and their electronic equivalents, such as Internet service providers, are not business associates," she says. "However, now HHS has indicated that a data storage company or personal health record vendor may qualify as a business associate, even if the entity does not actually access the PHI or only does so on a random or infrequent basis. HHS has emphasized that the difference is between transient verses persistent nature of an opportunity to view PHI."

That guidance on the mere conduit exception can be tricky to apply, cautions explains **Stephen Wu**, JD, a partner with the law firm of Cooke Kobrick & Wu in Los Altos, CA. The final rule explains that a data company, such as a host that holds PHI on its servers, is a business associate if it maintains that data for any period of time. Data simply passing through a company's servers, such as when a phone company's systems are used to transmit PHI from one place to another, would not necessarily make the vendor a business associate.

"The issue for HHS seems to be the fact that it is permanently or indefinitely there, rather than passing through on a wire," Wu says. "Sending an e-mail through a server isn't like that. Once you pull an e-mail from a server, it disappears from that server."

The question can get murky. What about a phone company that also provides voicemail? If a doctor leaves PHI on a voice mail message that is not automatically or manually deleted after a certain time period, at what point does that count as PHI "storage?" Indefinite storage of such messages is a bad idea and could be reason to consider any voicemail provider a business associate, Wu says. By the same logic, a webmail provider almost certainly would be a business associate, Wu says.

New BAAs may be necessary for some vendors

The new definitions might require some healthcare providers to implement BAAs with contractors with which they have previously never had such an agreement. Additionally, healthcare providers should review and amend existing BAAs to include the new definitions and ensure the business associate agrees to implement its own business associate agreement with all of its subcontractors, who are now directly responsible for complying with HIPAA.

HHS has also indicated it will be performing compliance audits of covered entities and business associ-

ates, Martin says. Failure to comply with the HIPAA privacy and security regulations could lead to monetary penalties.

Determining who is a business associate always has depended on the HHS guidance, which specified that certain types of vendors definitely were but still left it up to covered entities to make the decision in other cases. The new definition of a business associate adds to the previous list of contractors always considered business entities, Wu says. That list now includes claims processing, data analysis, utilization review, quality assurance, vendors that de-identify data or create limited data sets, transcription companies, and software vendors that host PHI off site or accessing it on-site.

No type of vendor was removed from the existing list of business associate, but new ones were added. Among the new additions is "an entity performing patient safety activities that are regulated."

The biggest change is that the definition now includes subcontractors of covered vendors, creating the possibility that a covered entity will have a long chain of business associates that could create a privacy breach, Wu explains.

HHS also specifies that certain types of workers are not business associates, including janitors, plumbers, electricians, and photocopy repair workers.

Cloud storage is now a concern

A covered entity's consideration of who its business associates need not change dramatically if you already used a broad definition, says **Brad Rostolsky**, JD, a partner with the law firm of Reed Smith in Philadelphia. Ultimately a business associate is any person or business who is not a member of the covered entity's workforce and who receives, accesses, or creates PHI for or on behalf of the covered entity. However, he says there are some important aspects to the HITECH Final Rule that are worth consideration from a compliance perspective as well as a business perspective.

The advent of business associates and their subcontractors becoming directly regulated might have an impact on covered entities' overall cost of doing business, Rostolsky says, with many of these vendors reconsidering the extent to which they will provide significant indemnification in light of their own direct exposure. They also might question whether their services are appropriately priced for a post-HITECH business environment.

Covered entities also will need to give serious consideration to the compliance exposure associated with the use of cloud storage vendors, Rostolsky says. Cloud providers generally have resisted the position that they are necessarily business associates, and though the final rule make it clear that any vendor that stores PHI — regardless of whether the vendor ever looks at or accesses that PHI — is a business associate, this push-back from cloud vendors continues, he says.

"Adding to the dilemma, the Office for Civil Rights [OCR] seems inclined, as least for the foreseeable future, to focus its enforcement efforts in this regard on the covered entity side of this equation," Rostolsky says. "So covered entities who store PHI with a cloud provider that has not signed a business associate agreement will likely be the primary — if not only — target of OCR."

On the flip side, Rostolsky says covered entities who have engaged cloud providers over the past number of years face a significant logistical challenge. These covered entities will need to weigh the risk associated with using a cloud provider who will not sign a BAA against the challenge of moving all of their cloud-based information to a HIPAA-compliant vendor.

"Although an audit may certainly shine OCR's light on this issue, everyone knows that breaches happen," he says. "And a breach by a vendor who has not signed a business associate agreement will likely be viewed by OCR as a significant failing."

SOURCES

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Privacy rules are being enforced aggressively

The government is taking a more aggressive approach to enforcing HIPAA and the HITECH Act, and healthcare providers should expect significant enforcement action in 2013, a Philadelphia attorney warns.

While enforcement of PHI rules have been lax in the past, the Department of Health and Human Services (HHS) recently has imposed penalties of more than $1 million against companies found in violation of HIPAA, warns **Christopher Ezold**, JD, partner with the Ezold Law Firm. For example, the Alaska Department of Health and Social Services agreed to pay a $1.7 million fine to settle possible violations. Blue Cross Blue Shield of Tennessee agreed to pay $1.5 million to settle potential HIPAA violations. Smaller employers also have found themselves on the receiving end of a HIPAA audit.

"This is a strong reminder for businesses to revisit their compliance programs," Ezold says.

HHS's Office for Civil Rights (OCR) has stepped up HIPAA audits of covered entities that are subject to HIPAA, Ezold notes. OCR has begun levying significant

monetary penalties for violations of HIPAA's privacy rule. In practice, Ezold says, OCR is not interested in small fines; it has levied penalties in the hundreds of thousands and even millions of dollars for what appeared at first glance to be small issues.

To protect your organization, Ezold advises holding an annual internal review to ensure that the privacy requirements are being met. OCR will not consider a once-and-done review to be sufficient; annual reviews provide better protection than merely doing an initial assessment. "If OCR comes knocking, you may be able to avoid significant liability by showing that you have engaged in a good faith attempt to meet your obligations," says Ezold.

Ezold recommends taking these steps:

- Designate a HIPAA compliance officer.
- Create privacy and security policies that comply with HIPAA and HITECH.
- Determine which employees have access to PHI.
- Limit access to PHI operationally and in policy to those employees who "need to know."
- Review physical and encryption security for PHI.
- Schedule annual reviews of policies, operations, and regulations.
- Create annual risk analyses and security plans.
- Have policies in place regarding breaches of PHI security.
- Schedule annual computer network security reviews.
- Safeguard all physical/documentary PHI in a locked location.
- Create policies for reviewing and shredding old documents.
- Ensure that no one keeps PHI on any mobile digital device.

"Given that most businesses review their policies at the end of the year, this is an ideal time to have your counsel or compliance officer examine your own policies to ensure that you would not become an unfortunate victim of an OCR audit," Ezold says. "A small investment in time now could prevent extremely painful repercussions down the road if you are not in compliance."

SOURCE

• **Christopher Ezold**, JD, Partner, Ezold Law Firm, Philadelphia, PA. Telephone: (610)-660-5585. Email: cezold@ezoldlaw.com. ■

Notices of privacy practices must be updated soon

The HIPAA Omnibus requires that covered entities update their Notices of Privacy Practices by Sept. 23, 2013, and it is important to make sure you have complied by the deadline, says **Gregory W. Bee**, JD, a partner with the law firm of Taft in Cincinnati, OH.

"The changes aren't that dramatic, but there are elements that you must include now that you did not before," Bee explains. "With some issues like using PHI for fundraising, there previously was some less precise language about how it could and could not be used, but the final rule makes it clear that patients must be given the ability to opt out, and they must be notified of that."

One change that could cause headaches for some providers involves the right to restrict disclosures. Previously, a patient could request that PHI not be disclosed in certain circumstances or to certain entities, but they could not insist that PHI not be disclosed to insurers or others involved in the payment process. Now the rule clarifies that if the patient paid out of pocket, he or she can request that the PHI not be disclosed to insurers.

"It's a way for the patient to keep some information confidential if they've paid out of pocket," Bee says. "There will be a lot of questions about how to operationalize that."

Bee provides this summary of the updates that healthcare providers are required to make to their Notices of Privacy Practices under the Final Rule:

- A statement that the covered entity must obtain an authorization for the use and disclosure of psychotherapy notes, marketing, and the sale of protected health information. (Covered entities that do not record or maintain psychotherapy notes are not required to include a statement about the authorization requirements for uses and disclosures of psychotherapy notes).

A statement informing individuals of their right to opt out of receiving a covered entity's communications to raise funds for the covered entity (if the covered entity intends to contact individuals to raise funds for the covered entity).

A statement informing individuals of their right to restrict disclosures of protected health information to a health plan in which the individual pays out of pocket in full for the healthcare item or service.

A statement of the right of affected individuals to be notified following a breach of unsecured protected health information. (The specifics regarding the covered entity's procedures regarding breach notification do not have to be specified in the Notices of Privacy Practices).

SOURCE

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HIPAA case settled for $400,000

Some of University's clinics subject to privacy law

Idaho State University (ISU) has agreed to pay $400,000 to the Department of Health Human Services (HHS) to settle alleged HIPAA violations. The settlement involves the breach of unsecured protected health information (PHI) of about 17,500 patients at ISU's Pocatello Family Medicine Clinic.

ISU operates 29 outpatient clinics and is responsible for providing health information technology systems security at those clinics. Between four and eight of those ISU clinics are subject to the HIPAA Privacy and Security Rules, including the clinic where the breach occurred.

The HHS Office for Civil Rights (OCR) opened an investigation after ISU notified HHS of the breach in which the PHI of about 17,500 patients was unsecured for at least 10 months, due to the disabling of firewall protections at servers maintained by ISU. OCR's investigation indicated that ISU's risk analyses and assessments of its clinics were incomplete and inadequately identified potential risks or vulnerabilities. ISU also failed to assess the likelihood of potential risks occurring.

OCR concluded that ISU did not apply proper security measures and policies to address risks to PHI and did not have procedures for routine review of their information system in place, which could have detected the firewall breach much sooner, according to OCR Director **Leon Rodriguez**.

"Risk analysis, ongoing risk management, and routine information system reviews are the cornerstones of an effective HIPAA security compliance program," Rodriguez said in a statement announcing the settlement. "Proper security measures and policies help mitigate potential risk to patient information."

ISU has agreed to a comprehensive corrective action plan to address the issues uncovered by the investigation and its failure to ensure uniform implementation of required HIPAA Security Rule protections at each of its covered clinics.

The Resolution Agreement can be found on the OCR website at http://tinyurl.com/ISUagreement. ■

Mass email breaches privacy of 10K patients

Protected health information (PHI) of 10,200 patients of Dent Neurologic Institute in New York was inadvertently sent to more than 200 patients recently in an email attachment. The healthcare provider acknowledged the error publicly soon after it was discovered.

"The list was mistakenly attached to a routine email that was being sent to patients by a clerk in the DNI administrative office," CEO **Joseph V. Fritz Dent** said in a statement. He called the breach an "inexcusable event." The institute has offices in Amherst, Orchard Park, Derby and Batavia.

The PHI, which included patients' names and home addresses, their doctors' names, last appointment dates and their email addresses, was contained on an Excel patient spreadsheet. The information did not include specific information about the patients' medical conditions, birth dates or Social Security numbers.

Institute officials contacted the 200 patients who received the email and asked them to delete the message, Dent said. They notified the state Department of Health and stated that the clinic will send a letter of notification and apology to all the patients involved in the breach. ■

Hospital chain to pay $275k for privacy violations

Hospital chain Prime Healthcare Services, which owns or operates 23 hospitals in California and four other states, has agreed to pay $275,000 to settle a federal investigation into alleged violations of patient privacy.

The case stemmed from allegations that Prime Healthcare and its Shasta Regional Medical Center violated patient confidentiality by sharing a woman's medical files with journalists and sending an email about her treatment to nearly 800 hospital employees. These violations allegedly occurred as the hospital responded to a story published by California Watch, a nonprofit news organization that featured patient Darlene Courtois and allegations that the hospital was overbilling Medicare. The alleged breach of confidentiality was revealed in a January 2012 column in the Los Angeles Times.

In 2012, California regulators fined the Ontario-based hospital chain $95,000 for the unauthorized disclosure of medical information in this matter. The company is appealing that state fine.

In the federal settlement announced recently, Prime Healthcare did not admit to any wrongdoing. The company and hospital said they "firmly believe that they would have prevailed in this matter based upon the merits." ■

Legal Review & Commentary

A Monthly Supplement to HEALTHCARE RISK MANAGEMENT

Commissioners approve $20 million settlement for boy's brain damage suit against county hospital

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News: County taxpayers will pay $20 million to the family of a 3-year-old boy who suffered serious brain damage after undergoing outpatient surgery at the county's hospital. While the county did not admit liability, its commissioners voted to pay $20 million to settle the medical malpractice suit that the boy's family brought against the hospital. The settlement monies will be used to provide for the boy's care and medical support for the remainder of his life.

Background: The 3-year-old boy underwent elective outpatient surgery for an undescended left testicle at the county's hospital. While in the recovery room, the boy fell into cardiac arrest and stopped breathing. It is alleged that the boy went without oxygen for about five to seven minutes before hospital staff initiated cardiopulmonary resuscitation (CPR). Also, it was alleged that he received no assisted ventilation from the medical staff until after he suffered cardiac arrest.

As a result of the heart attack and oxygen deprivation, the boy suffered permanent brain damage.

The county's hospital was able to revive the boy; however, he was without a pulse for a period not less than 15 minutes. As a result of the heart attack and oxygen deprivation, the boy suffered permanent brain damage.

In a statement to the press, the family's attorney claimed that the county hospital should not have left the boy in the recovery room alone while he was in an overly sedated state. He claimed that the county hospital failed to monitor or tend to the boy until he went into cardiac and respiratory arrest. He said that there was a video of the boy running along the beach and yelling to his parents. And he highlighted that now, the boy cannot walk, cannot talk, and is incontinent. He also noted that the boy is tube-fed and that he requires care and treatment for every aspect of his life.

The county's board president told reporters that the hospital's CEO has taken steps to prevent a repeat of the mistake. She also noted that disciplinary actions were taken against several individuals who were involved. She is quoted as saying, "I think in any human enterprise, bad things happen. This was a particularly bad thing that happened."

The commissioners approved the settlement without discussion or opposition. The money will come out of the county's self-insurance fund. Despite this vote, and the president's statements above, the settlement will also stipulate the county does not admit liability for the boy's injuries.

Financial Disclosure: Executive Editor **Joy Daughtery Dickinson** and Nurse Planner **Maureen Archambault** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Christopher U. Warren, Allison Angel, Leanora Di Uglio,** and **Jonathan D. Rubin,** co-authors, have no relevant relationships to disclose.

The boy's family would not talk publically about the settlement. Their attorney said, however, that the money will be used for around-the-clock long-term care, occupational and speech therapy, and future surgeries.

What this means to you: The day probably started as a typical day in the postanesthesia care unit (PACU.) The operating room was full with adult and pediatric inpatient and ambulatory patients who were scheduled throughout the day. The PACU staff had the knowledge and skills necessary to promote positive outcomes in perianesthesia care for adult and pediatric patients, including the uniqueness of age-related pathophysiologic and anatomical differences found in the pediatric patient. Hospital PACU policies and procedures were established that complied with state, regulatory, and accreditation requirements. So what went so wrong that resulted in severe brain damage in a 3-year-old patient who underwent elective outpatient surgery?

Based on the summary of the case presented above, it is hard to identify the one process point in the delivery of post anesthesia care that failed. As I am sure when the county hospital performed its root cause analysis after this event, there were a number of process failure points that could have been involved. The root cause for this unfortunate outcome could stem from one or more of them. However, based on current patient safety literature, there are a few areas that risk managers should keep in mind when reviewing patient safety processes and policies. The Joint Commission's most recent Sentinel Event Alert No. 50, released in April 2013, is probably number one on every risk manager's list: alarm fatigue. *(For more information about the S*entinel Event Alert, *see "TJC warns about alarm fatigue putting patients at risk,"* Healthcare Risk Management*, June 2013. To access the Sentinel Event Alert, go to http://www.jointcommission.org. Under "Topics," select "Sentinel Event – Sentinel Event Alert." The alerts are listed on the left side of the page.)*

In any hospital, there are multiple alarm sounds on every unit: heart monitor alarms, bed or chair alarms, IV infusion pump alarms, call bells. The PACU is no exception. All patients in the PACU are subject to various patient safety monitoring devices; however, members of the PACU staff might have determined that they do not need to rely on the alarms, because a PACU nurse is never very far away from a patient. Thus, it might not have been unusual for staff to mute or lower the alarms, reset the alarms at the lowest setting, or not respond to an alarm because of the competing alarm sounds or the false positive alarm signals they hear throughout the day. The Joint Commission is now recommending that a healthcare entity establish an alarm management program that will, among other tasks, establish guidelines for alarm settings on alarm-equipped medical devices used in high-risk areas; establish guidelines for the tailoring alarm settings based on individual patient needs; and inspect, check and maintain alarm-equipped devices.

> ***"I think in any human enterprise, bad things happen. This was a particularly bad thing that happened."***

Another critical area to review in the PACU is the ability of the staff to keep all patients in their direct line of sight throughout the patient's entire stay in the PACU. Patient privacy does not trump the need for staff to be able to visually observe a patient in the immediate postoperative period at all times, and some facilities have banned the use of privacy curtains during the immediate postoperative period. Although it would be surprising if the PACU staff used a privacy curtain for a pediatric patient, it might have been possible that the PACU staff member was using the privacy curtain to tend to an adult patient in the adjacent cubicle, which would have prevented other staff members from having this pediatric patient in their direct view at all times. Each facility should review their use of privacy curtains in the PACU and ensure that if they are used, they are used cautiously and infrequently.

It is unclear from the case described to know whether the patient was monitored appropriately during his stay in the PACU. Professional associations, such as the American Society of Anesthesiologists and American Society of PeriAnesthesia Nurses have established guidelines for postanesthesia monitoring. It would be surprising if the county hospital did not adhere to these national guidelines. Postanesthesia monitoring guidelines include, among other elements: re-evaluation of the patient by the anesthesia care team upon admission to the PACU with a verbal report to the PACU nurse; initial assessment of the patient upon PACU arrival; and continual monitoring of oxygenation (quantitative method such as pulse oximetry), ventilation, circulation, level of consciousness, and temperature. According to the ASPAN, the pediatric population requires special

consideration for the assessment of the pediatric respiratory system and subsequent airway management, pain management, pediatric-specific surgical procedures, and illnesses. This assessment would require consultation with the anesthesia provider to determine if the standard post-anesthesia monitoring guidelines were appropriate for this 3-year-old patient, given his medical history, age, and surgical procedure. Another unknown element that might change the manner in which this patient was monitored was whether the patient received any pain medications during his stay in the PACU. Certainly, due to the potential for respiratory depression after pain medication, closer monitoring, including a 1:1 staff-patient ratio, might have been in order.

The PACU is a fast-paced, high-risk specialty area. Patients flow in steadily and are discharged in stable condition within a few of hours after arrival. At times, patient care in the PACU can seem to be almost routine, which is when staff might become complacent with policies and practices. This is the time when errors, either human or situational, can occur. It is important to recognize the need for ongoing surveillance and monitoring of patient care processes, not only in the PACU, but throughout the healthcare facility. Routine risk assessments will assist staff with keeping patient safety at the forefront of their everyday practice and prevent an adverse event that will forever impact the life of a patient and his family.

Reference

12L-013-761. Circuit Court of Cook County (IL). ✦

Hospital pays $6.5 million to family of man who died of a sodium overdose after being left unattended for 12 hours

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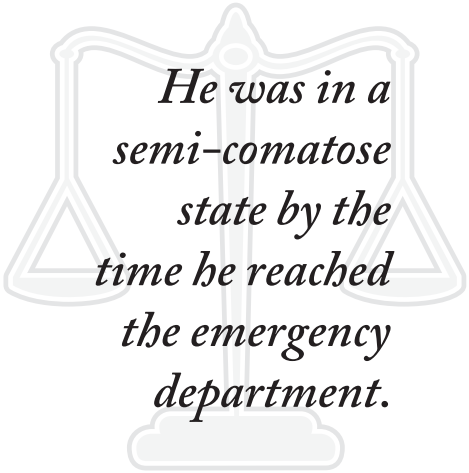
News: A Connecticut jury recently awarded $6.5 million to the family of a 44-year-old medical malpractice victim who suffered a sodium overdose resulting in brain damage and lapse into a permanent vegetative state while admitted to a local hospital. After four days of deliberation, the jury found for the family who brought the action on patient's behalf, and deemed the hospital guilty of medical malpractice for failing to adequately monitor his sodium levels.

Background: On March 1, 2006, a 44-year-old father of three was found by his wife lying unconscious on the floor of their Connecticut home. He was rushed to the local hospital and admitted to the intensive care unit (ICU) for excessively low sodium levels, a condition not uncommon to distance runners and people who consume large quantities of alcohol. In such cases, the patient should be hooked up to an intravenous drip of saline solution to increase and stabilize the level of sodium in their blood. However, continued monitoring is imperative, as it is equally dangerous to allow the patient's sodium levels to increase too much or too quickly.



This is precisely what is claimed to have happened in this case. Prior to his hospital admission, the decedent took up drinking to cope with the loss of his job. In February 2006, he stopped drinking at the request of his wife, but he was vomiting due to alcohol withdrawal. The vomiting in turn exacerbated the levels of sodium in his blood, leading to his March 1, 2006, hospitalization. He was in a semi-comatose state by the time he reached the emergency department.

At trial, the plaintiffs conceded that the hospital formulated a proper plan of care involving the gradual and monitored administration of IV saline, but they argued that this plan was never followed. Instead, members of the ICU staff negligently permitted the patient's sodium levels to increase at a dangerous speed, which resulted in a condition known as central pontine myelinolysis (CPM). The man

eventually was placed on life support and passed away roughly two weeks after his admission.

His wife and three children thereafter filed a wrongful death action. The hospital refused to settle and argued that the patient was very ill when he arrived and had little chance of surviving. The jury apparently disagreed. After four days of deliberation, the jury awarded the family $3 million for the decedent's pain and suffering and another $3 million for loss of enjoyment of life, which factored in a 30-year life expectancy. The jurors also awarded $500,000 for the wrongful death. They found the hospital guilty of medical malpractice for failing to adequately monitor the patient's sodium levels and carelessly overseeing his treatment.

What this means to you: CPM does not occur on its own; rather it is a complication secondary to some other treatment. With a proper plan of care established, as confirmed by plaintiff's counsel during trial, what went wrong that resulted in the patient's demise? If this event was reported to you as the risk manager, there would be several areas to investigate to identify the causative factors.

One such area would be communication between the physician and pharmacist. Although the physician would be responsible for ordering treatment, in this case the amount of IV saline to be given per liter per hour, was this the correct IV infusion rate based on the patient's age, weight, and other medical conditions, or was there an opportunity for a dosage miscalculation that might have been identified by a pharmacist? Pharmacists bring specific expertise and need to be an active member of the healthcare team, especially for conditions that are not commonly seen in a healthcare setting.

Other communication issues that might have impacted the treatment that would require further investigation surround the physician's orders for clinical monitoring of the patient's sodium level, execution of the orders, and the reporting of the laboratory results. Communication areas to explore would include the following:

- whether the physician's order for repeat sodium levels were written with sufficient frequency or urgency and whether these orders were acted upon as written;
- whether there was a delay in communicating the order to the lab, and whether the blood was drawn as ordered;
- how the lab orders were reported (verbal versus electronic versus written) and whether they were reported in a timely fashion;
- to whom the results were reported and what actions were taken once the results were known.

Whenever evaluating the adequacy of a complex process, it is important to remember that the focus of the assessment should be on identifying the potential process failure points and not how well or poorly an individual healthcare practitioner performed. For example, as part of the investigation into this type of event, the risk manager should take the opportunity to review and evaluate the adequacy of the laboratory's policy for reporting panic values. Does this policy identify the what, when, who, and how lab results are to be reported when they reach the laboratory's defined abnormal and/or panic value range?

The use of an IV infusion pump to deliver the prescribed amount of IV saline solution also should be a focus of the investigation because there is a possibility that the nursing staff relied on the integrity of the IV infusion pump to provide the correct IV infusion rate with minimal oversight by staff. Any mechanical device can assist staff with providing care in a safe manner. However, if not used or monitored correctly, a mechanical device can cause significant harm.

It should come as no surprise to a risk manager that medication errors occur in all healthcare environments and that many of these medication errors involve IV infusion pumps. This step requires ongoing review and assessment of the maintenance and use of IV infusion pumps as a routine patient safety activity. When investigating this type of event, the risk manager should evaluate whether the IV pump was set to deliver the correct rate of infusion (in addition to the rate being correctly calculated), the alarms were set at a range and audible level to match the patient's condition and/or manufacturer's recommendations, and the pump has had the necessary preventive maintenance, including calibration. Even if all these tangible activities were done appropriately, it would be necessary for the risk manager to assess whether staff relied upon a mechanical device to alert staff of a problem in lieu of using their critical thinking skills and clinical assessment of the patient's condition.

Without further details, it is difficult to say what happened in this event that lead to the untimely death of the 44-year-old father of three. But, as with any untoward event, the actions or inactions of staff and the healthcare organization play a role. Whether it was staff's failure to follow a policy or failure of the hospital to provide necessary resources or infrastructure that promotes safe care, the patient, his family and the healthcare provider pay the ultimate cost.

Reference

CV08-5004962-S, Connecticut Superior Court. ✦