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IN THIS ISSUE

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EMRs might reduce malpractice liability, but effects not certain

Accurate data entry, good computer security key to success

Wider adoption of electronic medical records (EMRs) has been a goal in health care for years, and progress is expected now that President Obama's economic stimulus plan includes $19 billion to help medical care facilities switch to electronic records. Risk managers have long thought, or at least hoped, that EMRs would result in fewer medical errors and malpractice lawsuits. The country may find out soon if that is true.

Legal experts say there is good reason to think that EMRs will reduce malpractice lawsuits or at least offer better support for their defense, but other observers say those benefits are far from certain. There may be some unintended consequences and hidden downsides that will outweigh the positive effects on lawsuits, they say.

The president's rationale for EMRs is that they will provide a streamlined and consolidated process of tracking patient care, which will in turn lower administrative expenses, and by extension, the costs of health care

EXECUTIVE SUMMARY

The Obama administration is pushing hard for adoption of electronic medical records (EMRs) and some risk management experts expect to see a corresponding decline in malpractice lawsuits. Others caution, however, that the adoption of EMRs may not result in any significant decline in malpractice cases or liability.

- EMRs may reduce medical errors caused by poor handwriting or incomplete records.
- Electronic record-keeping may improve documentation of care overall.
- There may be hidden drawbacks to EMRs that will offset any potential improvements in documentation.

overall. The money in the stimulus bill is intended to spur what has so far been a slow adoption of the technology. A recent study of hospitals found that only 1.5% is fully computerized, and only another 7.6% have some sort of basic electronic medical record system.[1]

A recent study from the Harvard Medical School and the School of Public Health gained some attention with its finding that 6.1% of physicians who used computers to keep records had paid a malpractice claim in the past 10 years, compared with 10.8% of physicians who relied only on a paper system.[2] **(See p. 64 for more on the Harvard research.)** But then doctors at Harvard wrote in *The Wall Street Journal* that "The impact of medication errors on malpractice costs is likely to be minimal, since the vast majority of lawsuits arise not from technical mistakes like incorrect prescriptions, but from diagnostic errors, where the physician makes a misdiagnosis and the correct therapy is delayed or never delivered. There is no evidence that electronic medical records lower the chances of diagnostic error."

Many possible benefits

The potential benefits regarding health care risk management are numerous, says **Ed Fotsch**, MD, CEO of San Francisco-based Medem Inc., which provides records management systems and other services for health care providers.

"EMRs have the potential to improve medical documentation while at the same time using technologies to facilitate reminders and prompts for appropriate medical therapies. This can, in turn, enhance patient safety and reduce the risk of medical liability," he says. "Traditional paper-based records do not offer these advantages, and paper-based medical charts are frequently misplaced or incomplete."

Fotsch says malpractice liability carriers are keenly aware of the patient safety and risk mitigation potential associated with EMRs, which is why a number of these companies — including Connecticut Medical Insurance Co., Midwest Medical Insurance Co., Physicians Insurance Agency of Massachusetts, Princeton Insurance, and Texas Medical Liability Trust — now offer premium credits and/or discounts for physicians or groups that use EMRs.

For example, Midwest Medical Insurance Co. announced an EMR premium credit of 2% to 5% in September 2007. To qualify for the credit, the EMR system must meet certain requirements, including use by 75% of group providers.

"EMRs have the potential to decrease the number of malpractice claims by improving patient care and safety via automated reminders, medication interaction checking," Fotsch says. "And they have the potential to improve the defense against a claim by improving documentation."

Gina Greenwood, JD, an attorney with the law firm of Baker Donelson in Macon, GA, agrees that EMRs, when used correctly, can provide invaluable medical facts about patients that can help reduce medical errors and prevent malpractice suits. For the most part, patients are poor medical historians, rarely able to articulate in a concise

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manner the primary facts that a physician needs to know in order to provide proper and safe care, she says. Patients also may be intimidated by physicians and have the misconception that doctors are all-knowing, even where the physicians do not have access to past records from other practitioners. Patients also may think that the physician reviews the entire paper record cover to cover before entering the treatment room, which is rarely the case.

"Therefore, it is important for physicians to have electronic tools that summarize pertinent information to the physician in a format that is user-friendly and quickly accessible. Having a patient medical record at the physician's fingertips can be an invaluable tool for providing quality patient care," Greenwood says. "Not only will physicians benefit from the increased access to information, but they will also benefit from automated warnings and reminders that alert physicians and pharmacists of drug or other errors."

Greenwood points out a potential drawback that few EMR cheerleaders have considered. She says the medical community needs to understand that if the country ever reaches a point where physicians have access to one comprehensive medical record for every patient, the bar may be raised for what courts and juries may expect of physicians with regard to reviewing histories.

"Physicians will need to allow time between office/round visits to review all the facts, because they may be ultimately held to a higher standard of care for what they should have known," says Greenwood. "In other words, the electronic medical record will only be as good at preventing medical errors and malpractice suits as the electronic software product and the user."

William D. Yoquinto, JD, an attorney with the law firm of Carter Conboy in Albany, NY, says the electronic medical record could well improve record-keeping and reduce malpractice exposure in the long run. But, he says, until it becomes more ubiquitous and the use by professionals more fluent, "in my opinion, it currently presents as many additional challenges as benefits to the defense of malpractice actions."

One issue relates to the reproduction of the record. Making a paper copy of the record and displaying it to a jury can be a problem, because the format of EMRs is not designed to print well or be clear on paper. (Consider the result of printing a string of e-mails. The information is all there, but it is not clear and there is a tremendous amount of extraneous data.)

"One possible advantage and answer to the medical record reproduction concern will be when it is demonstrated in court in electronic form," Yoquinto says. "This could be very dynamic and interesting to jurors, many of whom will have familiarity with the use of computers from their own workplace. It will be an opportunity to show the jury how the record is created and allay concerns about record alteration."

Yoquinto notes that while the electronic record does offer some advantages, not the least of which is legibility, those benefits will not come without adequate training and willingness to learn the tool.

"Without that training and willingness to learn, the electronic medical record presents its own professional liability risks and challenges and will not achieve all its potential advantages, including those of reducing exposure to malpractice claims," he says.

Bruce A. Boissonnault, president and CEO of the Niagara Health Quality Coalition in Williamsville, NY, says there also could be a problem with how electronic medical records, over time, create databases that are easier to manipulate in ways that may not be positive.

"For example, with computers, hundreds of records can be upcoded in an instant for higher reimbursement. Also, with computers, the back-end EMR databases could be scrubbed to ensure that adequate post hoc rationalizations exist to

SOURCES

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justify outcomes after the fact," he says. "Finally, with one EMR, the lobbying pressure to get every profitable type of care programmed into the national EMR standard will be immense. Every specialty will want their pet project programmed into the EMR reminder systems. Science, not rent-seeking, must be the mechanism to determine what is and is not programmed into EMR reminder systems."

Maureen Martin, JD, senior fellow for legal affairs with the Heartland Institute, a think tank in Chicago that deals with health care issues, says there is no authoritative research establishing that computerizing medical records will reduce malpractice claims.

"I've looked at hundreds of malpractice cases in 27 years of practicing law, and I can only recall one stemming from prescribing the wrong drug, which a computerized medical record might have prevented, and the doctor was acquitted in that one," she says. "Many involve problems during labor or delivery, and most others, in my experience, result from a wrong diagnosis. Computerizing medical records won't reduce such cases."

The bigger risk, Martin says, is the "garbage-in/garbage-out" problem that afflicts all computer usage.

"Mistakes in data entry are inevitable. Studies have found mistakes are less likely when doctors and nurses create their records by hand," she says. "All in all, electronic medical records will create more problems than they will solve."

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2. Virapongse A, Bates DW, Shi P, et al. Electronic health records and malpractice claims in office practice. *Arch Intern Med* 2008; 168:2,362-2,367. ■

Harvard research suggests EMRs reduce risk

Recent research from Harvard University suggests that the adoption of electronic medical records (EMRs) could have a positive effect on reducing malpractice liability, says one of the lead authors, **David Westfall Bates**, MD, professor of medicine at Harvard Medical School in Cambridge, MA, and professor of health policy and management at the Harvard School of Public Health.

"When providers use electronic records in the outpatient setting, the likelihood of a paid malpractice settlement was about two-thirds as high," Bates says. "It did seem that those who used electronic records more had an even bigger effect. Among people who used electronic records a lot, they were about half as likely to pay a malpractice settlement."

Bates says the data weren't sufficiently detailed to pinpoint exactly why EMRs appeared to reduce malpractice payouts, but he theorizes that one reason is the clarity in the documentation. With computerized records, the notes often are more complete and clear than a handwritten record, he notes.

"It also is possible to display guidelines and reminders, with the option to note that you are ignoring the guideline in this case and why," Bates says. "That can make it easier to prove that you were following the standard of care and why you made some decisions."

Bates calls the research results encouraging — but not definitive — because the sample size was not sufficiently large for concrete conclusions.

"I think it is likely that insurance carriers will start offering reductions for adoption of electronic records, and risk managers have a key role-play in educating providers about the importance of selecting the right system and implementing it effectively," he says. ■

SOURCE

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Paper record system has its own benefits

The Harvard study suggesting lower malpractice risk from using electronic medical records (EMRs) must be viewed with some skepticism, says **Peter Hoffman**, JD, an attorney with Eckert Seamans in Philadelphia.

SOURCES

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"The conclusions were not statistically significant. It's not a study I would take to the bank, so to speak," he says.

Hoffman agrees that there are many potential benefits with EMRs, but he warns against the tendency to focus only on those and not also consider the downsides. For instance, Hoffman points out that a written note can provide the clinician more flexibility and the ability to write lengthier comments. The old ways of keeping patient records weren't all bad, he says.

"The flowsheets, for instance, allowed better productivity because health care workers could spend more time on their actual work. Where that method falls down is that it doesn't give you the extent of detail you might like to see," he says. "Part of the same issue applies to electronic records. So, instead of getting more specific, you get more general, with drop-downs on the screen. That can be a good thing or a bad thing, depending on how carefully the health care worker uses them."

Hoffman says he has seen EMRs in which he could not figure out what happened in the case, because there was not enough detail. He worries that providers may sacrifice necessary information for the sake of a digital record.

"Remember the labor and delivery charts we used to use, the fold-out Hollister-type forms? They were impossible to read, but they were packed with information," he says. "Now, they are not so packed. Nurses and doctors used to write on the fetal monitor strip, and it was useful information to have. Now, they can't do that because there's no strip to write on. They can put the same info in the computer, but do they?"

Similar issues worry **Stuart Grossman**, JD, an attorney with Grossman Roth in Boca Raton, FL. The successful adoption of EMRs will require that risk managers emphasize some of the same record-keeping goals that applied in paper records. The record, whether paper or digital, must tell a story and clearly document the key exchanges with the patient and the decision-making process, he says.

"I am concerned that there could be a tendency for people to become overly dependent on the computerized system, to just respond to the prompts without keeping in mind that they have to ensure there is a clear narrative of the patient care process," Grossman says. "Of course, that means you have to provide them with a system that at least allows that kind of thorough documentation, if not encouraging it. The first step in successfully using EMRs will be to provide your professionals with a system that allows them to do what you need them to do with that record." ■

Many negatives may come with using EMRs

The potential benefits of electronic medical records (EMRs) are easier to spot than the possible drawbacks, according to some risk managers. Consider both the pros and cons of EMRs before adopting the technology, they say.

William D. Yoquinto, JD, an attorney with the law firm of Carter Conboy in Albany, NY, cites these possible problems with EMRs:

• **When the electronic medical record is printed, it usually shows the date and time and identity of the person who printed it.** Depending upon the timing and the person doing the printing, this can highlight the date that the case became a concern and suggest to astute plaintiff's counsel some avenues of inquiry. For example, if the record is printed before there is an authorization by the patient and the person requesting is a hospital director of risk management and quality assurance, the attorney may be encouraged to pursue the claim and then certain avenues of discovery.

• **Another problem relates to the imprinting of time in the record.** Typically, the electronic medical record will automatically note the time the record is made. This can be confusing if the person making the record fails to record the time of treatment within the body of the typewritten entry. This automatic generation of time can be advantageous in comparison with the (fairly typical) untimed progress note or order within a hospital chart. To the extent that the professional delays in making documentation, however, it can give the impression of a delay in treatment, which requires more explanation.

• **There could be a problem regarding how the EMR relates to coded templates for examinations**

SOURCES

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of patients and autotext. If the recorder is not fluent in the use of the software, this can result in troubling inconsistencies of documentation. "In one case I had involving emergency department care of a septic patient, the emergency doctor's electronic record reflected both labored breathing and no shortness of breath. The system in that case had only been in use for about a month. So, they were on the uphill side of the learning curve."

• **An additional issue arose in the same case involving sepsis.** The computer-generated times for telemetry were clearly incorrect. In fact, the times recorded actually appeared to begin hours before the patient arrived in the ED. This not only made the record appear questionable, but it did not assist in demonstrating that the patient was well monitored when in the department. "We never had a satisfactory explanation as to how that occurred, but it brought to mind the old adage, "garbage in, garbage out."

Gwen Hughes, RHIA, CHP, director of e-HIM Consulting Services at Care Communications Inc. in Chicago, points out that EMRs are only as good as their design, implementation and the systems and behaviors of the individuals supporting and using them. She worries that the potential availability of data and metadata to attorneys under new rules of evidence may in fact increase malpractice suits or the size of awards. The fact that research has not yet demonstrated an increase in suits or awards may be a matter of timing, she says.

"Suits and awards may increase as EMRs become more prevalent and attorneys figure out how best to leverage the information contained therein," she says. "I'm not suggesting organizations should not move forward with implementation of EMRs. I'm emphasizing rather the importance of re-engineering processes to fully leverage the technology and the importance of strong systems around documentation, health information management, compliance, security, and risk to maximize the return on investment." ■

HIPAA compliance becoming even harder

With the American Recovery and Reinvestment Act of 2009 (ARRA) expanding the Health Insurance Portability and Accountability Act's (HIPAA) patient health information privacy and security protections beyond what most already considered a compliance nightmare, some legal and privacy experts are saying the expansion may have taken compliance from merely difficult to nearly impossible to achieve.

HIPAA previously applied only to individually identifiable protected health information used by health care providers, health plans, and health care clearinghouses; vendors providing administrative services to those covered entities were not covered by HIPAA. But ARRA applies several of HIPAA's security and privacy requirements to business associates, while also expanding the definition of business associate. ARRA also changes data restrictions, disclosure, and reporting requirements. **(For more on how ARRA changes HIPAA, see the Guest Column on p. 68.)**

In addition, the U.S. Department of Health and Human Services' Office of Inspector General has criticized lax enforcement of HIPAA, saying in a letter to CMS acting Administrator Kerry Weems that audits show "numerous, significant vulnerabilities" that put patient data "at high risk." *(Editor's note: For more on that report, go to*

EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act's (HIPAA) has been expanded and strengthened recently, making compliance even more difficult than before. Risk managers may have to turn to more technology and expect some inevitable violations.

- Recent federal legislation expands the scope of HIPAA.
- CMS may take action to enforce HIPAA more than in previous years.
- Data masking technology may be one tool for compliance.

SOURCES

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http:// oig.hhs.gov/oas/reports/ region4/40705064.pdf.)

The inspector general recommended that the CMS establish policies and procedures for conducting more HIPAA security-rule compliance reviews of covered entities.

Greg Scandlen, senior fellow and director of Consumers for Health Care Choices with the Heartland Institute, a think tank in Hagerstown, MD, was involved in formulating the new privacy provisions, but he still worries that HIPAA is growing too much. Scandlen would have preferred an entirely different approach to protecting patient privacy, but now that we have HIPAA, he says, fine-tuning and additional safeguards are necessary.

He says the new provisions will make compliance more difficult.

"I would argue that the federal government never should have gotten involved in health IT, and this is the consequence of its misadventure," he says. "Patient privacy is essential to the success of a health IT transformation, because otherwise we will never get patient buy-in. But privacy assurances would have been done better if health IT had been allowed to grow organically in the market."

With that method, various approaches could have been tried out on a small scale. The ones that best matched privacy and IT efficiency would have grown and the ones that didn't would have failed, Scandlen says.

"But once the feds start mandating and funding a new system, the regulatory process is the only safeguard available," he says. "This is a clumsy and inefficient way to do it, I grant you. But it was the result of overreaching by the feds."

Like many health care professionals, many people in the data industry think HIPAA was never really needed in the first place, says **Jeff Kubik**, president and CEO of Employee Benefit Risk Management Services Inc., a company based in Oak Brook, IL, that provides data management services to insurers.

"I have been in health insurance administration for decades, and HIPAA privacy has never been a health insurance industry problem," he says. "It was an unnecessary law from the get-go, and a huge waste of money. Furthermore, I never had a medical privacy issue raised and have never heard of an instance where medical privacy was voided."

Kubik says the recent changes to HIPAA are just an example of a federal law that is now entrenched and likely will be expanded again.

"They have created this impression that there is a big, serious problem involving people's privacy in health care, and I just don't think it's true," he says. "Nobody disagrees with keeping people's information private, but these burdensome laws just are not needed." ■

GUEST COLUMN

New laws clamp down access to medical records

By **Leila Narvid**, JD
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Patient privacy rights is hardly a new issue, but it became an especially hot topic in 2008, as reports of unauthorized access to the confidential medical records of celebrities brought to light health care security shortfalls at several medical centers and hospitals.

In September 2008, UCLA Medical Center terminated several employees for unauthorized access to confidential medical records of pop star Britney Spears. Earlier that same year, the Palisades Medical Center in New Jersey suspended more than two dozen employees without pay for accessing actor George Clooney's medical records when he was admitted for a motorcycle injury. More recently, health care workers were fired for accessing the records of the California woman who gave birth to octuplets.

These security breaches haven't just caught the attention of the tabloids. Government regulators are reacting also. At the federal level, the American

EXECUTIVE SUMMARY

Recent legislation at both the federal and state level is raising the bar for protecting the confidentiality of patient medical data. Federal laws have been strengthened, and California is leading the way with new state obligations.

- Covered entities and business associates are now required by federal law to notify individuals of a data security breach.
- California requires that any patient whose medical information has been discussed improperly must be notified within five days.
- Federal law authorizes state attorneys general to pursue injunctive relief or damages on behalf of state residents who have been affected by a privacy violation.

Recovery and Reinvestment Act of 2009 (ARRA) maintains and expands the current Health Insurance Portability and Accountability Act's (HIPAA) patient health information privacy and security protections. At the state level, California is leading the way with new laws to protect confidential patient information, and we can expect to see strict enforcement of these laws in 2009.

ARRA's changes to HIPAA

Previously, HIPAA applied only to the use and disclosure of individually identifiable health information (known as "protected health information") by health care providers, health plans, and health care clearinghouses (known collectively as "covered entities"). Vendors providing administrative services to covered entities were not directly subject to HIPAA's privacy and security provisions. Among the most far-reaching provisions of ARRA are those that apply several of HIPAA's security and privacy requirements to business associates. The definition of business associate is expanded to include organizations that provide data transmission of protected health information to covered entities and business associates and that require access on a routine basis to that protected health information (e.g., health information exchange organizations and regional health information organizations).

The ARRA provisions also include data restrictions, disclosure, and reporting requirements. Currently, covered entities may use and disclose only the "minimum necessary" protected health information for their business purposes but have considerable latitude to determine what the minimum necessary information is under the circumstances. Under ARRA, covered entities must first consider whether partially de-identified data, known as a "limited data set," could be used to accomplish their objectives and must limit their uses and disclosures to limited data sets if possible. A limited data set excludes basic identifying information, such as the individual's name, Social Security number, postal addresses, e-mail addresses, telephone numbers, and similar identifiers.

Restrictions for marketing purposes

Another change under ARRA is the ability of covered entities to use protected health information for marketing purposes without the individual's authorization. Specifically, communications with an individual about products or services that encourage the individual to purchase or use the product or service will be permitted without the individual's authorization only if the communication is made: a) to describe a product or service provided by or included in the plan of benefits of the covered entity making the communications; b) for treatment purposes; or c) for case management, care coordination, or to recommend alternative therapies, providers, or settings of care. In addition, the previously described communications will require patient authorization if the covered entity receives direct or indirect profit for making them.

There also is a change to the requirement for reporting security breaches. Previously, covered entities were obligated to mitigate harm caused by unauthorized disclosures of protected health information, but not required to give notice to the individuals whose information was inappropriately disclosed. Going forward, covered entities and business associates will be required to notify individuals when security breaches occur with respect to "unsecured" information. Unsecured information means information not protected through technology or methods designated by the federal government. In addition, if the breach involves 500 or more individuals, notice to the U.S. Department of Health and Human Services and the media also is required.

Covered entities using electronic health records will have to supply individuals with an accounting of disclosures from those records made for treatment, payment, or health care operations purposes during the three years that preceded the request. This requirement will undoubtedly increase

administrative burdens for covered entities, which currently are not required to account for such disclosures. This provision is subject to rule making, and the earliest date it will apply is Jan. 1, 2011.

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As far as enforcement, ARRA gives power to state attorneys general to bring actions to obtain injunctive relief or damages on behalf of state residents who have been, or are threatened, or adversely affected by violations of HIPAA. Previously, HIPAA did not permit individuals to obtain monetary damages for HIPAA violations and enforcement was handled at the federal level. The financial penalties for violations of HIPAA also have been increased, and a percentage of the civil penalties collected will be distributed to individuals harmed by the violations.

Most provisions will be effective one year after the date of ARRA's enactment (Feb. 17, 2010). However, the security changes generally will be effective 30 days after appropriate regulations are published. The changes to the enforcement provisions are effective for violations occurring after Feb. 17, 2009.

California takes additional steps

In addition to the federal obligations, many states are strengthening their requirements for protection of medical data. California, which often leads other states to follow suit on legislative issues, recently took action in the aftermath of a series of data breaches affecting many Californians in the last few years. In September 2008, Gov. Arnold Schwarzenegger signed legislation to improve patient privacy laws and address leaks of confidential health information. The laws became effective on Jan. 1, 2009. The bills — Senate Bill 541 ("SB 541") and Assembly Bill 211 ("AB 211") — significantly increase state fines for security and privacy violations involving patient health information and set new breach-disclosure standards and mandate security controls for preventing unauthorized access to patient data. "Unauthorized access" is defined as the "inappropriate review or viewing of patient medical information without a direct need for diagnosis, treatment, or other lawful use" as permitted under California law.

SB 541 imposes a requirement that any patient whose medical information has been discussed improperly must be notified within five days. In addition, AB 211 establishes a new state Office of Health Information Integrity that will be responsible for enforcing statutes governing the confidentiality of health care data and imposing administrative fines on entities that fail to comply with the rules. Another important aspect of AB 211 is that it provides an individual right for a patient to sue if his or her medical privacy has been breached, which is a legal mechanism that federal privacy law currently lacks. Specifically, the California law allows patients to sue a health care provider for either actual or nominal damages arising from any negligent disclosure or release of confidential patient information.

These statutes place more pressure on companies in California to comply with HIPAA, whose privacy and security provisions took effect in 2003 and 2005, respectively. In California, individuals now face fines and penalties for violating SB 541 and AB 211, for which they will be personally responsible, of up to $25,000. In addition, individuals also face criminal sanctions, as well as disciplinary action by licensing boards, for unauthorized access to or disclosure of medical information. Health care facilities will incur fines for failure to prevent or report unauthorized access to or disclosure of medical information.

Health care providers and health facilities in California should carefully review their existing security procedures to: 1) ensure that access to patient medical information is strictly controlled; 2) verify that they are capable of quickly detecting and reporting any security breaches to state officials; and 3) draft an incident response plan that should include immediate investigation of breaches and a notification plan for affected patients. In light of the fact that the new legislation creates a state office dedicated solely to enforcement and assessment of penalties, compliance is ever more critical. Another foreseeable consequence of the creation of the Office of Health Information Integrity is an increase in investigations being referred to professional licensing boards, such as the Medical Board of California, based on actual or potential privacy violations.

ARRA and California's new laws serve as a wake-up call for health care providers, contractors, and vendors who have access to or maintain confidential medical information. The penalty provisions for improperly accessing or disclosing confidential medical information apply to any individual or entity. Thus, many businesses that have avoided penalties because they do not directly provide patient care or services will no longer enjoy such protection under federal and state law. ■

Air ambulance report cites many dangers

Patients and air ambulance crews are dying at an alarming rate because the air ambulance helicopter industry has little oversight and poor organization, according to a recent safety review.

The report was released by the Flight Safety Foundation, a research group in Alexandria, VA. The analysis identifies eight "very high" risks within the industry and 18 "high" risks. **(*Healthcare Risk Management* recently provided extensive coverage on the dangers and liabilities of medical helicopters. For more on safety issues related to air ambulances, see February 2009, p. 13, and March 2009, p. 29.)**

The report comes at a time when the industry is facing increased scrutiny because of a sudden surge in crashes. Nine crashes killed 35 people, including six patients, from December 2007 to October 2008, prompting the National Transportation Safety Board to hold a public hearing to address the problem. Six patients were among the dead.

The recent report says part of the problem is that air ambulances are overseen by a patchwork of state and federal agencies that overlap or can leave some areas uncovered, unlike the tight regulation of the commercial airline industry.

The Federal Aviation Administration (FAA) issued a statement saying it welcomed the report. "It confirms what we believe: Reducing risk in helicopter EMS operations demands a systematic approach," the FAA statement says.

Not everyone was happy with the report. Manufacturer Bell Helicopter paid for the report but did not agree with the conclusions, so the company did not participate in the report's release. The report was released just prior to a congressional hearing on industry safety issues. There are two bills in Congress that aim to reform the industry.

The full report is available free online at www.flightsafety.org/pdf/HEMS_Industry_Risk_profile.pdf. ■

Most hospitals not meeting safety goals, Leapfrog says

Most hospitals still have not implemented standards proven to improve quality and save lives, even though it has been 10 years since the Institute of Medicine's (IOM) landmark report on the failure of U.S. hospitals to adequately protect patient safety. That is the conclusion of the 2008 Leapfrog Hospital Survey, which shows that only 7% of hospitals fully meet Leapfrog medication error prevention standards, and low percentages of hospitals are fully meeting mortality standards.

Leah Binder, MA, MGA, CEO of the patient safety organization, based in Washington, DC, says the survey results are disappointing.

"As the Obama administration and Congress consider health care reform options, it is clear we have a long way to go to achieve hospital quality and cost-effectiveness worthy of the nation's $2.3 trillion annual investment," she says. "According to our data, a majority of hospitals have significant safety and efficiency deficits."

Health care reform will seek to make the system more cost-effective, Binder notes, but the survey results do not bode well.

"Among surveyed hospitals, efficiency standards — defined as highest quality and lowest resource use —are met by only 24% of hospitals for heart bypass surgery, 21% for heart angioplasty, 14% for heart attack care, and 14% for pneumonia care," she reports.

Barbara Rudolph, PhD, MSSW, director of Leaps and Measures for Leapfrog, says results were not good for one of key Leapfrog standards — the implementation of computerized physician order entry (CPOE) to decrease medication errors.

"CPOE has been in place in our survey since 2002; and at this time, only 7% of our hospitals fully meet this medication error prevention standard," she says. "CPOE systems like this can actually reduce adverse events by about 88%, and if these systems were widely in place, we could prevent over 3 million serious medication errors a year."

In 2002, only 2% of the surveyed hospitals met the CPOE standard.

The voluntary Leapfrog Hospital Survey results include 1,276 hospitals in 37 major U.S. metropolitan areas, representing 53% of hospital beds in these areas. Binder says the 2008 hospital survey reveals relatively low percentages of reporting hospitals are fully meeting volume and risk-adjusted mortality standards, or adhering to nationally endorsed process measures for eight high-risk procedures, where following nationally endorsed and evidence-based guidelines is known to save lives. She cites these data showing compliance with standards:

- 43% for heart bypass surgery;

• 35% for heart angioplasty;
• 32% for high-risk deliveries;
• 23% for pancreatic resection;
• 16% for bariatric surgery;
• 15% for esophagectomy
• 7% for aortic valve replacement;
• 5% for aortic abdominal aneurysm repair.

In addition, the report cites these other results:

• Sixty-five percent of participating hospitals do not have all recommended policies in place to prevent common hospital-acquired infections (HAIs).

• Seventy-five percent do not fully meet the standards for 13 evidence-based safety practices, ranging from hand washing to competency of the nursing staff.

• Only 26% and 34% of reporting hospitals are fully meeting standards for treating two common acute conditions, heart attacks and pneumonia, respectively.

• Only 30% and 25% of hospitals are fully meeting standards to prevent hospital-acquired pressure ulcers or hospital-acquired injuries, respectively.

Binder and Rudolph says the report clearly indicates that, despite an initial surge of interest and calls to action, health care providers are not responding quickly enough to the IOM report.

"Progress on patient safety is moving too slowly," Binder says. "Consumers and purchasers of health care want hospitals to implement safety standards and procedures known to improve quality and reduce unnecessary injury and death. The safety goals Leapfrog promotes are achievable. More hospitals should be meeting the Leapfrog standards for common and high-risk procedures."

Binder notes that, though the results could be more encouraging, the Leapfrog survey helps explain why some aspects of health care quality are lower in the United States than might be expected when considering how much is spent per capita on medical care in comparison to other countries.

"There is a lot of concealed information in the health care world," Binder says. "It is only when you have something like Leapfrog with providers willing to share this information and purchasers willing to pressure them to do so that we're able to get a really good picture of the country showing where we are in terms of health care," Binder says. "We know in the macro statistics that something is wrong in American health care. It's only when we're able to go hospital by hospital and look at these results, looking at them in a transparent way, are we able to see where the problems lie."

Binder also points out that the surveyed hospitals are among the best in the country, which makes some of the results even more of a concern.

"So, it's disturbing but it also gives us something to work with," she says. "Now we know where the problem is and we have something we can work on."

The news was not entirely bad, however. The report includes these noteworthy improvements by surveyed hospitals in 2008:

• Thirty-one percent of hospitals now meet the Leapfrog ICU staffing standard, up from just 10% in 2002.

• Hospitals with all of Leapfrog's recommended policies in place to prevent common HAIs jumped from just 13% to 35% between 2007 and 2008.

• Sixty percent of hospitals have agreed to implement Leapfrog's "Never Events" policy when a serious reportable event occurs within their facility.

"The Never Events policy requires a number of measures in response to a never event, including not charging patients and their families for the expenses related to that event. We're seeing improvement in this area as well," Rudolph says. "Back in 2007, only 53% of hospitals agreed to the Never Events policy."

The full survey results and detailed information

CNE objectives

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

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

COMING IN FUTURE MONTHS

■ Technology that affects bottom line

■ Working with ethics committees

■ Risks from misunderstandings

■ Latest lessons from sentinel events

CNE Questions

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

21. According to William D. Yoquinto, JD, what is one potential benefit of electronic medical records (EMRs)?
A. EMRs are more secure than paper records.
B. An EMR could be very dynamic and interesting to jurors, many of whom will have familiarity with the use of computers from their own workplace.
C. EMRs are less expensive than paper records.
D. An EMR can be more easily altered and improved than a paper record, and it provides documentation of who made the change.

22. Under HIPAA, as revised by the American Recovery and Reinvestment Act of 2009 (ARRA), which is of the following is true regarding communications with an individual about products or services that encourage the individual to purchase or use the product or service patient information?
A. The communication will never be permitted.
B. The communication will be permitted only with the individual's written authorization.
C. The communication will be permitted without the individual's authorization, with no restrictions.
D. The communication will be permitted without the individual's authorization only if certain criteria are met.

23. Which is true of HIPAA under ARRA?
A. Going forward, covered entities and business associates will be required to notify individuals when security breaches occur with respect to "unsecured" information.
B. Going forward, covered entities and business associates will not be required to notify individuals when security breaches occur with respect to "unsecured" information.
C. Notification will be required only when security breaches occur with respect to secured information.
D. Notification is never required under HIPAA; health care providers may decide on a case-by-case basis when notification is appropriate.

24. According to the 2008 Leapfrog Hospital Survey, which of the following is true regarding full implementation of the group's CPOE standard?
A. 7% reported full compliance in 2008, up from 2% in 2002
B. 2% reported full compliance in 2008, down from 7% in 2002
C. 88% reported full compliance in 2008, up from 7% in 2002
D. 16% reported full compliance in 2008, down from 24% in 2002

Answers: 21. B; 22. D; 23. A; 24. A.

about the standards promoted by the Leapfrog Group are available online at www.leapfroggroup.org. ■

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

Failure to diagnose hyponatremia leads to coma, death: $8.5 M settlement

By **Radha V. Bachman**, Esq.
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News: A woman who suffered from long-standing depression presented to the hospital seeking an adjustment of her antidepressant medication. During hospitalization, she suffered seizures. The hospital was unable to determine the etiology of the seizures and transferred the woman to another hospital in the area. Upon transfer, she underwent an examination and laboratory testing. The woman's attending physician consulted a neurologist who performed an examination and a CT scan. The examination produced normal results, but the admitting physician's lab results revealed that the woman was suffering from hyponatremia. Before the condition was addressed, she suffered another seizure and went into cardiac arrest, ultimately going into a coma and never regaining consciousness. The woman died five years later.

Background: A 68-year-old woman suffering from depression arrived at a small psychiatric hospital seeking an adjustment of her prescription for antidepressant medication. During this hospitalization, the woman suffered seizures. In order to properly determine the cause of the seizures, the psychiatric hospital transferred the woman to a community hospital in the local vicinity that was well equipped to conduct such a study. The transfer occurred and the woman immediately underwent examination and laboratory tests by her attending physician. Her attending physician consulted a neurologist, who also conducted an examination and ordered a CT scan. While the neurologist's examination produced normal results, the attending physician's lab results were abnormal — showing hyponatremia. Hyponatremia is an abnormally low concentration of sodium in the blood. Untreated, acute hyponatremia, the form of hyponatremia in which sodium levels fall rapidly, can lead to rapid swelling of the brain, resulting in coma and death. These are exactly the complications that occurred in the woman. Before the physicians were able to implement any protective measures, the woman suffered another seizure causing her to go into cardiac arrest. She became comatose, never regained consciousness, and died approximately five years later.

The woman's husband, the plaintiff in the case, filed suit against both hospitals, the attending physician, the neurologist, a psychiatrist who was alleged to have treated the woman, and three other physicians who were alleged to have been involved in the woman's treatment. The plaintiff alleged that the woman's condition and subsequent death were a result of the defendants' failure to timely diagnose the woman's hyponatremia and that these failures fell below the standard of care.

Prior to trial, the plaintiff dismissed most of the defendants, including the psychiatric hospital. Liability for the medical professional liability in failing to timely treat the hyponatremia was clear enough, so the second hospital and the neurologist settled with the plaintiff for $1.75 million. The claim proceeded against the woman's attending physician's estate because the physician had died.

At trial against the physician's estate, both sides' experts agreed that the seizures experienced by the woman were a result of the undiagnosed hyponatremia. Plaintiff's counsel contended that the woman's doctors never realized that she was suffering from hyponatremia because they failed to review the lab results. In addition, he argued that the woman had suffered a minor seizure the evening after being transferred and while the doctor recorded the event, hyponatremia was never noted.

The neurologist testified that he had misread the lab results but that it was not his responsibility, but that of the attending physician's, to review the results, since the neurological examination and CT scan were normal.

The receiving hospital testified that the lab results were clearly handed to the attending physician or attached to the top of the woman's chart. Hospital protocol required the attending physician to ensure that he personally received the lab results. The hospital also relied on the argument of the neurologist that the attending physician was ultimately responsible for the lab results.

Defense counsel argued that the woman existed in a permanent vegetative state and, therefore, did not experience any pain and suffering. Nevertheless, the jury awarded $8.5 million in favor of the plaintiff.

What this case means to you: This case illustrates the basis for The Joint Commission's National Patient Safety Goal 02.03.01 (formerly Goal 2C): "The organization measures, assesses and, if needed, takes action to improve the timeliness of reporting, and the timeliness of receipt of critical tests, and critical results and values by the responsible licensed caregiver." As a result of The Joint Commission's standard, many hospitals have developed policies and procedures to address the issue of "notification of test results" — especially critical values. As part of the notification process, some hospitals have created special stickers in order to draw attention to the "critical" value or inserted a "Red Flag" alert if the medical records are electronic. "Critical" values are generally defined as a value that is at such variance with normal as to represent a pathophysiologic state that is life-threatening, unless some action is taken in a short time and for which an appropriate action is possible but may be fully defined by the particular health care provider based on certain patient-specific information.

Further, most hospital policies state that it is the laboratory's responsibility to communicate these values immediately to the designated caregiver. While this appeared to have occurred in this case, regrettably, the attending physician appears to have delayed in responding to them. Most policies also provide a sometimes elaborate mechanism to assure that "responsible, licensed, health care providers receive the results in the event that the attending physician is not readily available." The notification of critical test results is a two-way responsibility. The lab clearly has responsibility for notifying the attending physician, and the attending physician has the responsibility for acting on the critical test results and notifying the patient, if necessary. It is the latter responsibility that was not appropriately exercised in this case, to the detriment of the patient.

What is additionally interesting about this case is, apparently, the neurologist received the test results in a timely manner but misread them. Thus, even though the attending physician had ultimate responsibility — the neurologist's defense in this case — the neurologist had knowledge and thus could not escape responsibility for his own negligence in misreading the results. This case illustrates that even with effective notification systems, negligence still can occur. This case highlights the need for systems that may need further implementation and expansion to include mechanisms for assuring that prompt and effective action is taken in response to "critical values."

Reference

• Case No. 4159/99, Supreme Court, Ninth Judicial Circuit, Westchester County (NY). ■

Plaintiff falls, breaks hip: Defense verdict returned

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News: A man slipped and fell while getting out of his hospital bed, causing him to suffer a fractured hip and leg. The man and his wife sued the hospital for negligence, claiming that he had not been fitted with "gripper socks" and that nurses had not responded after the man had attempted to call them with the call light. A jury determined that the hospital had not been negligent and returned a defense verdict.

Background: A 60-year-old man was hospitalized for conservative care and rehabilitation after falling at home and suffering a pelvic fracture. A patient in the hospital's transitional care unit, the man then slipped and fell again as he attempted to get out of his hospital bed. He suffered an interochanteric fracture of his right hip and a fracture of his right femur.

The man and his wife sued the hospital for negligence, claiming that the man's fall was caused by the hospital's failure to fit him with "gripper socks" as required by hospital policy and by the nurses' failure to help him get out of bed. The plaintiffs specifically alleged that at the time of the fall, the man was confused and disoriented due to the pain medications he was taking. They also claimed that the nurses were aware that the husband was confused and had been trying to get out of bed without assistance, and yet they failed to call the doctor for orders or otherwise take steps to prevent a fall. Finally, the plaintiffs alleged that the man had used his call light to ask for assistance to the bathroom, but when no one came, he attempted to get up on his own and fell on the "slippery" floor. The plaintiffs contended that the delay in responding to the call light was substandard and that if basic fall precautions had been taken, as required by the hospital's policies and procedures, the man's fall would have been prevented.

The husband's alleged damages were $30,000 in medical costs and an unspecified amount for pain and suffering. He claimed that he suffered substantial leg shortening as a result of his injuries, and that he would walk with a limp for the rest of his life. The woman's alleged damages were $6,000 in lost wages, attributable to the fact that she had to take off work to care for her husband.

The hospital defended the suit, claiming that basic fall precautions were in place and that the man had been told not to get out of bed without using the call light to call for assistance. The hospital also denied that the man had called for assistance before his fall. After a jury trial, a defense verdict was returned.

A similar case took place in New Jersey where a jury exonerated a hospital nurse from allegations of negligence. In that case, the patient testified she rang her call buzzer for 30-45 minutes for help to get up to go to the bathroom, then got up on her own, leaned on a rolling tray table, fell and broke her hip. The nurse testified that she talked with the patient and wrote a progress note right after the fall about why the patient herself believed she had fallen. The patient said she wanted to get up and see what was going on the other side of the room and tripped on the leg of the tray table. She never mentioned her call bell not working or not being answered.

The first three days after her liver biopsy, the patient was handled as a high fall risk. She fell on the fourth day after the biopsy. Her physician had written an order for ad lib bathroom privileges. At the time of her fall, she was no longer a high fall risk and was in the hospital for observation.

What this case means to you: Falls and fractures usually are associated with the elderly and nursing homes, or youngsters falling or breaking bones during sporting events. Complications from fractures and head injuries are a well-known sequel of falls. Osteopenia and osteoporosis are underlying diseases and conditions that make a simple fall a higher risk to fracture.

Fall prevention is a focus of the patient safety initiative. While there are general interventions that can apply to any setting to prevent falls, some are tailored to a specific setting. For instance, hospitals, nursing homes, and other health care facilities should not have "throw" or small area rugs, as they tend to slip or wrinkle. In the home, use of those small rugs is discouraged, but when they are used, it is recommended that double-stick tape be used to secure them to the floor. Health care facilities should consistently evaluate the floor "wax" or protective coating in order to determine the "slip factor" and prevent falls. "Wet-floor" signs and other notices and barriers can go a long way in preventing injuries that occur as a result of unnecessary falls.

Each and every patient needs to be fully evaluated for fall risk on admission, periodically thereafter, and when there is a significant change in the patient's condition. Underlying illnesses, medications, conditions, or sedentary lifestyles can lead to deterioration of muscle strength, bal-

ance problems, or confusion that can increase a patient's risk of falling.

Risk managers should review their organization's fall prevention policy and procedure in detail, including the assessment tool. As a part of that assessment, the risk manager should make rounds on the units that report the highest incidence of falls to informally survey staff regarding causation. Such a survey would glean the understanding and follow-through by staff to implement the fall risk interventions detailed in the facility's policy and procedure manual. Barriers to complying with the fall prevention policy and procedure might also be identified. If slip-resistant socks or other devices are a part of the fall prevention policy, assessment that there is an adequate supply available is vital.

Part of the admission process should be to do a fall risk assessment. Based on the assessment, following the policy and procedure, interventions to prevent or reduce the risk of fall should be implemented and added to the patient's care plan. In this case, it is unknown if the slip-resistant socks were a part of the policy and procedure and, if so, whether they were actually supplied to the patient. When a patient with a known fall and fracture that resulted from the fall is admitted to a rehab center, the fall prevention activities should be a usual and customary practice for most of their patients.

Again, depending on the facilities' policy and procedure, that is the first line of prevention and defense; other interventions might be toileting rounds, or rounds to verify the call bell is within easy reach of the patient and that it works. The level of the bed should be assessed and set with the patient depending on his or her mobility and condition. A bedside commode is sometimes a part of the fall prevention procedure to make it easier for an alert, heretofore independent patient to take care of these needs if help is not readily available. It is important that whatever the intervention/prevention steps are that they are implemented and assessed periodically, and that they are in place on an ongoing basis.

Based on the facts detailed in the first situation, the patient came in to this *rehab* facility with a known risk for falling, having fallen at home and suffered a fractured pelvis. Rehab facilities, as a part of their rehabilitation services, work with patients to provide rehab services to return the patient to independent living as much as possible. Parts of those rehab services include increasing stability or fall prevention with adaptive devices or strengthening muscles.

According to **Patricia S. Calhoun**, JD, RN, of Tampa, FL-based Buchanan Ingersoll, the reason for a defense verdict in the second case is quite clear. First, the patient was not a high fall risk patient; she was on "activity ad lib" and this note shows no reason for any further fall precaution. The high fall risk initially ordered after the liver biopsy was simply a precaution in case she suffered a post-procedure complication such as internal bleeding, which could cause hypotension (often a cause of falls). Calhoun notes that the most important lesson here is the importance of documentation. Calhoun stresses the critical nature of the nurse's documentation of her conversation with the patient contemporaneously with the event, since it is likely that this documentation "proved" to the jury that the patient's account of the episode was inaccurate.

One complaint patients make on a frequent basis is that call lights are not answered on a timely basis. Many patients, particularly many in rehab centers, are accustomed to being independent and not relying on someone to help them in their activities of daily living (ADLs). While patients are educated to call for someone to assist, when they comply and the promised assistance is not forthcoming, they will sometimes take it into their own hands. This is particularly true when it involves a need to use the bathroom. This is an ongoing problem in all health care facilities, that is, how to promptly respond to a call light when all staff are busy assisting other patients, especially in light of lower patient-to-staff ratios. Response should be assessed by the relevant staff and administration.

While facilities often provide inservice education sessions to staff to emphasize those issues after such an unfortunate incident, often that is of little effect. If the risk manager were to interview each member of the staff, it is probable that all would indicate knowledge of the need to promptly respond to call bells, to conduct frequent toileting rounds, and what the policy and procedure for fall prevention entails. Further, staff might share in such interviews the barriers to compliance, such as staffing levels, frustration, leadership, teamwork, and other issues that would need to be and should be addressed.

Above all, the risk manager should conduct a root-cause analysis of this event to determine the basic cause of the failure of the facility's fall prevention interventions. The staff who are a part of such a root-cause analysis often learn more from this process than an inservice presentation. Being a part of the solution to correct and prevent another such incident often empowers staff, reduces frustration, and ultimately increases patient safety.

References

- Case No. VC046949, Los Angeles County Superior Court.
- Superior Court of New Jersey, Appellate Division. ■

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CNE Evaluation

Please take a moment to answer the following questions to let us know your thoughts on the CNE program. Fill in the appropriate space and return this page in the envelope provided. **You must return this evaluation to receive your certificate.** Thank you.

CORRECT ● **INCORRECT** ⊘ ✓ ✗ ⚠

1. If you are claiming nursing contact hours, please indicate your highest credential: ○ RN ○ NP ○ Other _____

	Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree
After participating in this program, I am able to:						
2. Describe legal, clinical, financial, and managerial issues pertaining to risk managers in health care.	○	○	○	○	○	○
3. Explain how these issues affect nurses, doctors, legal counsel, management, and patients.	○	○	○	○	○	○
4. Identify solutions, including programs used by government agencies and hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice.	○	○	○	○	○	○
5. The test questions were clear and appropriate.	○	○	○	○	○	○
6. I am satisfied with customer service for the CNE program.	○	○	○	○	○	○
9. I detected no commercial bias in this activity.	○	○	○	○	○	○
10. This activity reaffirmed my clinical practice.	○	○	○	○	○	○
11. This activity has changed my clinical practice.	○	○	○	○	○	○

If so, how? _____

12. How many minutes do you estimate it took you to complete this entire semester (6 issues) activity? Please include time for reading, reviewing, answering the questions, and comparing your answers to the correct ones listed. _____ minutes.

13. Do you have any general comments about the effectiveness of this CNE program?

_____

I have completed the requirements for this activity.

Name (printed) _____ **Signature** _____

Nursing license number ***(required for nurses licensed by the state of California)*** _____