Healthcare RISK MANAGEMENT

March 2013 | Vol. 35, No. 3 Pages 25-36

Final HIPAA rule increases penalties, liability for associates

IT companies must meet same standards as healthcare providers

HIPAA now is more restrictive in terms of how the patient information can be used for marketing purposes.

The maximum penalty for a data breach under the Health Insurance Portability and Accountability Act (HIPAA) is now $1.5 million, six times higher than the original fine under the law. That change is just one of the significant changes in the final HIPAA rule released recently by the Department of Health and Human Services (HHS).

Some of the most significant data breaches, and the largest fines, have involved business associates.

"Much has changed in healthcare since HIPAA was enacted over 15 years ago," said HHS Secretary Kathleen Sebelius as she announced the final rule. "The new rule will help protect patient privacy and safeguard patients' health information in an ever-expanding digital age."

The final rule will be effective on March 26, 2013. Covered entities and business associates must comply with the applicable requirements of the final rule by Sept. 23, 2013. Covered entities and business associates will have up to one year following the compliance date to modify business associate agreements in accordance with the requirements of the final rule.

Under the final HIPAA rule, business associates that are trusted with protected health information (PHI) are subject to much stronger requirements and penalties. They must now adhere to many of the same HIPAA privacy and security rules as hospitals and other healthcare providers. Some of the most significant data breaches, and the largest fines, have involved business associates.

Data breach notification requirements of the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act also were strengthened. HHS made it more difficult to justify a decision not to notify when a security incident occurs. Under the soon-to-expire requirements, a breach must be reported only if it poses a "significant risk of financial, reputational, or other harm to the individual." The new rule eliminates this

INSIDE

AHC Media

www.ahcmedia.com

Financial Disclosure: Author **Greg Freeman**, 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.

risk-of-harm threshold and provides instead that the unauthorized acquisition, access, use, or disclosure of protected health information is presumed to be a reportable data breach unless a covered entity or business associate demonstrates that there is a low probability that the PHI was compromised.

Executive Summary

An update to the Health Insurance Portability and Accountability Act (HIPAA) increases the liability for business associates responsible for data breaches. The rule significantly increases the maximum penalty for non-compliance.

- ✦ Penalties are increased for non-compliance based upon the level of negligence, with a maximum penalty of $1.5 million per violation.
- ✦ The final rule expands the rights of individuals to receive electronic copies of their health records.

Maximum penalty now much higher

Violations of the data security requirements could be much more costly. Under the original rule, penalties for data breaches could cost a maximum of about $250,000, but under the new HIPAA final rule, HHS has increased the maximum penalty for noncompliance to $1.5 million per violation. *(See the story on p. 27 for more on the changes in HIPAA.)*

In a public statement, **Leon Rodriguez**, HHS Office for Civil Rights director, "This final omnibus rule marks the most sweeping changes to the HIPAA Privacy and Security Rules since they were first implemented. These changes not only greatly enhance a patient's privacy rights and protections, but also strengthen the ability of my office to vigorously enforce the HIPAA privacy and security protections, regardless of whether the information is being held by a health plan, a healthcare provider, or one of their business associates."

Risk managers should take particular note of the change in the standard for when a provider must publicly disclose a data breach, says **Andrew E. Blustein**, JD, a partner/director with the law firm of Garfunkel Wild in New Jersey and Connecticut. The previous standard relied on "significant risk," which Blustein says was a sizable threshold to cross.

"The new standard is really going to hit risk managers because, for a while at least, I think there is going to be an increase in what needs to be reported," Blustein says. "Now HHS presumes that there has been a data breach unless you can show there is a low probability that PHI was compromised. That's a pretty low bar. You have to prove, or demonstrate through a risk analysis, that the PHI has not been compromised."

Blustein suspects that, under those conditions, providers will end up sending out notification letters for breaches that are relatively minor but still could be construed to meet the requirement under HIPAA. He also notes that risk managers will have to do a risk analysis in "all situations" concerning a possible data breach, unless you decide to go

Healthcare Risk Management® (ISSN 1081-6534), including HRM Legal Review & Commentary™, is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Healthcare Risk Management®, P.O. Box 105109, Atlanta, GA 30348.

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

This activity is valid 24 months from the date of publication.

Healthcare Risk Management® is intended for risk managers, health system administrators, and health care legal counsel. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Executive Editor: **Joy Daughtery Dickinson** (404) 262-5410 (joy.dickinson@ahcmedia.com). Production Editor: **Kristen Ramsey.** Senior Vice President/Group Publisher: **Donald R. Johnston.**

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. For approximately 15 CE nursing contact hours, $545. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. Back issues, when available, are $87 each. (GST registration number R128870672.)

ahead and send the notification.

In the event of a potential data breach, covered entities and business associates must determine whether there is a low probability that PHI has been compromised by performing a risk assessment that addresses the nature and extent of the PHI involved, including the types of identifiers involved and the likelihood of re-identification; the unauthorized person who used the PHI or to whom the information was disclosed; whether the PHI was acquired or viewed; and the extent to which the risk to the PHI has been mitigated.

"This is not easy stuff. And if you're wrong, [reaching a conclusion other than] what the government would think, you are in a situation where you could be sanctioned by them," Blustein says. "This is a shift. Organizations always had to do these risk analyses, but now you've changed the standard from significant harm to this low probability."

Until there are more case studies and possibly guidance from HHS, risk managers will have to be conservative when analyzing possible data breaches, Blustein advises. Policies and procedures, as well as staff education, might need to be changed to reflect the new standards, he says. "You may have people on the frontline who are deciding what to report and not report based on the old standards," he says.

Burden is on the provider

HIPAA poses more of an obligation now than ever before on hospitals, says R. **Michael Scarano Jr.**, JD, a partner with the law firm of Foley & Lardner in San Diego.

> ***"Before it might have been implicit, but now it's explicit that the burden is on the covered entity to show that it was not a violation of HIPAA when you have a potential breach."***

"Before it might have been implicit, but now it's explicit that the burden is on the covered entity to show that it was not a violation of HIPAA when you have a potential breach," Scarano says. "Risk managers have some time to comply, but they should review their policies and procedures to make sure they're going to be compliant with the new requirements. It's entirely possible that you will need to do some self-assessment, policy changes, and education. Don't squander the time you have."

Because the final rule broadens the obligations of business associates and the definition of business associates, HIPAA is going to affect many more organizations now, says **M. Leann Habte**, JD, an attorney with the law firm of Foley & Lardner in Los Angeles. That change, in turn, broadens the responsibility of hospitals to ensure that their business associates are complying with the law, she says.

"In addition, you have to assess issues like whether there are any subsidies you're receiving for marketing that could be considered compensation for PHI, and that is not always as clear-cut as you might imagine," Habte says. "Organizations that are downstream contractors will have to do significant work to come into compliance, and you will have to have a process for ensuring that they do so in order to continue working with them."

SOURCES/RESOURCE

- Andrew E. Blustein, JD, Partner/Director, Garfunkel Wild, Great Neck, NY. Telephone: (516) 393-2218. Email: ablustein@garfunkelwild.com.
- M. Leann Habte, JD, Associate, Foley & Lardner, Los Angeles. Telephone: (213) 972-4679. Email: lhabte@foley.com.
- R. Michael Scarano Jr., JD, Partner, Foley & Lardner, San Diego. Telephone: (858) 847-6712. Email: mscarano@foley.com.

See the full final HIPAA rule at http://tinyurl.com/HIPAAfinalrule. ✦

Patients have more rights to records under final HIPAA rule

These are some of the key changes in the Health Insurance Portability and Accountability Act (HIPAA) final rule released recently by the Department of Health and Human Services (HHS):

- Business associates and subcontractors of business associates will have direct liability for compliance with certain provisions of the HIPAA Privacy Rule and the HIPAA Security Rule.
- The definition of a business associate has been broadened to include companies that only store or maintain protected health information (PHI).
- The requirements for providing notice of privacy practices were strengthened.
- Patients will have more rights to receive electronic copies of their health information.
- Patients will have more ability to restrict the disclosure of health information to a health plan for treatment for which the individual has paid out-of-pocket in full.
- Limits on the use and disclosure of PHI for marketing and fundraising purposes were expanded.
- PHI may not be sold without individual authorization.
- The "harm" threshold in the Breach Notification Interim Final Rule was replaced with a more objective standard. The new rule eliminates the risk of harm threshold and provides instead that the unauthorized acquisition, access, use, or disclosure of protected health information is presumed to be a data breach unless a covered entity or business asso-

ciate demonstrates that there is a low probability that the protected health information (PHI) was compromised.

• There are more protections for genetic information.

• The final rule streamlines individuals' ability to authorize the use of their health information for research purposes.

• The rule makes it easier for parents and others to give permission to share proof of a child's immunization with a school.

• HIPAA will no longer provide privacy protections for a decedent's health information to the same extent and in the same manner as living individuals. Under the final rule, the health information of individuals who have been deceased for more than 50 years will no longer be protected by the Privacy Rule at all. In addition, covered entities will be permitted to disclose PHI to a family member or other individual involved in the care of a decedent, unless this disclosure is inconsistent with a prior expressed preference of the decedent. ✦

ACA changes will increase risk in finance, tech areas

As provisions of the Affordable Care Act (ACA) come into play this year and for the next several years, the way healthcare is provided could change drastically, and that change has the potential for new or increased risks. At the same time, healthcare providers are taking on more risk through readmission penalties, bundled payments, and population health payments.

That change means risk managers should be actively looking for the new or heightened areas of risk facing their organizations, says **Maria Gonzalez Knavel**, JD, a partner with the law firm of Foley & Lardner in Milwaukee, WI. One of the biggest risks for hospitals comes from the recent change in how far back the government can go to collect overpayments, she says. Where the overpayment is the result of an error rather than fraud, the government can now go back five years instead of the previous three.

"That is definitely going to have an impact on all providers, but especially hospitals because of the volume of billing they have the subsequent chance of an error," Knavel says. "Also, with the ACA stating that you have to disclose overpayments within 60 days or it becomes a false claim, all of these provisions make it difficult to stay ahead of things on front end so that you get everything right and don't have to go back and have funds recouped."

Knavel says risk managers will play an important role in preparing for and managing these new or elevated risks. That role could be good in terms of your visibility within the organization and demonstrating your value. *(See p. 29 for more on how the ACA will affect traditional risk management concerns.)* "These are going to be challenging times for a risk manager in the next couple of years," Knavel says. "You could shine if you step up and effectively manage these risks for your organization."

> *"... risk managers should be actively looking for the new or heightened areas of risk facing their organizations."*

Paul Osborne, director with the healthcare consulting company Berkeley Research Group in Tampa, FL, was working recently with a healthcare provider regarding ACA changes coming in the next two years. "All of the things in this bill are starting to become real now, and people are starting to get pretty nervous out there," Osborne says. "We were talking about the excise tax that will be placed on all the covered lives, which kicks in later this year. A lot of the conversation is about how to adjust for that, with cost cutting or passing on more of the costs to employees through premiums."

Health exchanges also bring lots of questions, Osborne says. Healthcare employers are trying to figure out which employees will be included in the exchanges and what the resulting fees will be for the employer. *(See the story on p. 29 for more on financial risks. See the story on p. 30 for more on fraud and abuse concerns.)* "There are lots of unknowns out there and people are scared, trying to figure out how to accommodate these changes and avoid the penalties," Osborne says. "There is a lot of risk out there, and I don't think a lot of organizations have a clear plan for how they're going to handle it."

Much of the potential risks will come from the sharing of patient information

Executive Summary

The Affordable Care Act (ACA) will bring more changes to the healthcare industry in 2013 and beyond. Many of these changes will bring new or increased risks and potential liability.

- ✦ Many of the risks will be in healthcare finance and technology.
- ✦ Risk managers should act now to address potential problems.
- ✦ Accountable care organizations (ACOs) will produce many of the potential risks.

through accountable care organizations (ACOs), says **E. Todd Bennett**, director of market planning in healthcare for LexisNexis Risk Solutions, a consulting group in Alpharetta, GA. "Provider organizations need to be intentional about managing patient information across care settings. With unlinked technology platforms that are unable to identify unique patients at each touch point with the health system, siloed patient information gives rise to overutilization, unnecessary delays, increased opportunities for identity theft, and decreased patient satisfaction."

To counter these challenges, Bennett says leaders of accountable care initiatives need to develop a strategy for managing patient identities across care settings and every mode of interaction with patients. "Whether patients receive care and information through a patient portal, telephonically, or face to face, a targeted approach to patient identity management provides is necessary to manage patient population health effectively," Bennett says.

The changes coming from ACA will require coordination with many professionals, says **Joe Bohling**, principal with the healthcare consulting company Berkeley Research Group in Dallas.

"Make sure you are not going about this alone. You will need to interact with experts like your attorneys, outside law firms, insurance providers, insurance brokers, or consultants," Bohling says. "You are going to need some help navigating all the implications of what the ACA is bringing forward."

SOURCES

- E. Todd Bennett, Director, Market Planning – Healthcare, LexisNexis Risk Solutions, Alpharetta, GA. Telephone: (615) 942-7867. Email: todd.bennett@lexisnexis.com.
- Joe Bohling, Principal, Berkeley Research Group, Dallas. Telephone: (214) 233-3061. Email: jbohling@brg-expert.com.
- Maria Gonzalez Knavel, JD, Partner, Foley & Lardner, Milwaukee, WI. Telephone: (414) 297-5649. Email: mgonzalezknavel@foley.com.
- Paul Osborne, Director, Berkeley Research Group, Tampa, FL. Telephone: (305) 984-1029. Email: posborne@brg-expert.com.
- Ruselle Robinson, JD, Attorney, Posternak Blankstein & Lund, Boston. Telephone: (617) 973-6286. Email: rrobinson@pbl.com. ✦

Traditional risk concerns could see benefit from ACA

For traditional risk management concerns, the Affordable Care Act (ACA) actually might offer hope, says **Ruselle Robinson**, JD, an attorney at Boston-based Posternak Blankstein & Lund. A goal of the ACA is to improve quality of care and make it more patient-centered while reducing costs, so success in those areas should result in lower risk and liability for providers, he says.

"The encouraging news is that the intention is to reduce errors and improve quality of care, so if all of that comes off as planned, it should bode well for traditional risk concerns," Robinson says.

Robinson urges risk managers to focus on the potential benefits from the ACA, particularly the effort to promote best practices across the industry.

"People get accustomed to doing things a certain way, and risk managers certainly know how difficult it can be to get people out of their habits and to adopt a new way of doing things that has been proven to improve quality of care and patient safety," Robinson says. "The coming changes from healthcare reform could be the catalyst that helps you improve some of these processes." ✦

Alert finance leaders to impending risks from ACA

Revenue and finance will be affected significantly by healthcare reform, and key aspects of reform already are impacting revenue streams, says **Erin M. O'Connor**, Esq., practice leader with Cammack LaRhette Consulting in New York City.

"In order to ensure that quality continues to be delivered to patients in ways that maximize efficient utilization of the health system — not just when care is needed, but also to prevent care episodes — hospitals, physicians, and payers are looking to shape reimbursement to align those objectives," O'Connor says. "That's a start, but doesn't in and of itself create change."

O'Connor suggests that even if revenue is not usually a primary concern of risk managers, they should, at a minimum, ensure that leaders are aware of the coming changes and the potential impact on revenue. The risk manager can play a role in helping mitigate those financial risks through the implementation of quality improvement and security measures.

Critical to success is access to data to drive process and measure results across the care continuum as well as the organizational and human resources development plans to transform the workforce, O'Connor says. And there has to be an integrated way to measure it all to reinforce best practices and uncover improvement opportunities.

"Payers are trying to drive change, but they don't control how physicians practice. Hospitals have resources to support practice transformation, but without physician leadership fully committed to transformation efforts, alignment will be elusive," O'Connor says. "Practice alignment and integration models vary, and compensation is a key

component of those models. Hospitals have more control in an employed model, but also more risk if their employed physicians underperform."

Hospitals contracting with payers for risk arrangements brings more leverage to the negotiating table than a small independent practice might be able to — but to achieve results, hospitals must rely on physicians to practice in a way that maximizes efficiency without compromising quality, O'Connor explains. Health reform is trying to drive collaboration between what should be interdependent parties serving the health needs of a community to achieve optimal results of good care and good experience at reasonable cost.

"Experimentation is key to finding the right balance and best practice. Hospitals and physicians need reasonable room to experiment without fear of financial ruin," O'Connor says. "That said, organizations need to be nimble. The market is swiftly changing."

SOURCE

• Erin M. O'Connor, Esq., Practice Leader, Cammack LaRhette Consulting, New York City. Telephone: (212) 227-7770 Ext. 228. Email: eoconnor@clcinc.com. ✦

Fraud and abuse will continue to be a challenge

Hospital risk managers need to think about how the Affordable Care Act (ACA) is changing the laws governing fraud and abuse, says **Kathy Tayon**, JD, shareholder with the law firm of Fowler White Boggs in Fort Lauderdale, FL.

In 2010, the ACA gave the government even more tools to prevent healthcare fraud, including additional screening and enrollment requirements, data sharing across government, overpayment recovery efforts, and oversight of private insurance abuses.

"Risk managers should keep in mind that ideas that maybe seem good from a marketing or business perspective — giving gifts to patients for referrals or a physician investing in a healthcare business to which he or she refers, — may be illegal under federal or state healthcare anti-kickback laws or self-referral laws," Tayon says. "Risk managers need to educate both clinical and non-clinical staff about the anti-kickback and self-referral laws to ensure that any marketing programs are compliant."

The clinical staff needs to accurately and completely document the delivery and medical necessity of services provided, and those preparing the bills must understand the billing rules, she says. Policies and procedures must be in place to help ensure that all needed criteria to bill a service are met.

The ACA requires healthcare providers to create compliance and ethics programs that contain certain core elements as a condition of enrollment in the federal healthcare programs. Failure to do so could have catastrophic consequences when the organization cannot participate, she notes.

"Risk managers should develop written policies and procedures that promote and help ensure compliance with healthcare laws in developing and operating the organization," she says. "The policies and procedures should be part of the organization's everyday operations, and the organization should know and comply with them."

SOURCE

• Kathy Tayon, JD, Shareholder, Fowler White Boggs, Fort Lauderdale, FL. Telephone: (954) 703-3903. ✦

Perinatal program lowers annual claims 39%

Initial results from one of the nation's largest and most sophisticated perinatal improvement initiatives suggest hospitals can reduce harm to babies and mothers, and lower associated liability claims and pay-outs, through the use of high-reliability perinatal teams.

Results from Phase 1 (2008-2010) of the Premier Perinatal Safety Initiative (PPSI), a Premier healthcare alliance project, show that the 14 participating hospitals have reduced harm and liability since the program's baseline period (2006-2007).

In relation to harm, PPSI hospitals have reduced, on average:

• birth hypoxia and asphyxia, which can cause infant brain damage, by 25%;

• neonatal birth trauma, which can range from minor bruising to nerve or brain damage, by 22%. In addition, all hospitals were below the 2008 AHRQ Provider Rate, a national comparative rate measuring perinatal harm;

• complications from administrating anesthesia during labor/delivery, which include cardiac arrest and other cardiac complications, by 15%;

• postpartum hemorrhage, the most common cause of perinatal maternal death in the developed world, by 5.4%;

• the adverse outcome index rate, which measures the number of patients with one or more of the identified adverse events as a proportion of total deliveries, by 7.5%;

• Because of these improvements, approximately 110 fewer mothers and babies experienced these harms.

In addition, participants decreased the number of annual liability claims filed per delivery by 39% vs. 10% at non-participating hospitals. And whereas all PPSI hospitals averaged a total of 18 claims per year and projectwide during the baseline

period, that number dropped to 10 in 2009 and is trending at eight for 2010. Findings on liability claims and losses are current through November 2012. Because it typically takes two years or longer for a claim to be filed after an injury, final liability claims and losses will not be closed for some time, notes **Susan DeVore**, Premier president and CEO.

Launched in 2008 by Premier and affiliate liability insurer American Excess Insurance Exchange, RRG (AEIX), PPSI participants are large and small, teaching and non-teaching, system-based and standalone, with employed and non-employed physicians. They represent 12 states, in which approximately 250,000 babies were delivered over the collaborative's five years (2008-2012). "There's no other area in a hospital where providers routinely treat two distinctly different patients at the same time," DeVore says. "Even though childbirth is so complex and unique, serious adverse events during labor and delivery are rare. But they do occur. Sometimes they're preventable, but they're always devastating for babies, mothers, families, and care providers."

The PPSI results to date suggest that the strategies used can lower the incidence of certain infrequent, though serious, birth injuries and their associated liability claims. And the diversity of the participating hospitals also lends well to possible replication of the project and its results nationwide, she says. *(See the story below for more on how the program works.)* ✦

Care bundles, communication, teamwork get results

Leveraging knowledge gained from previous initiatives, including an Institute for Healthcare Improvement (IHI)/Ascension Health/Premier collaboration, hospitals in the Premier Perinatal Safety Initiative (PPSI) use two methods to create high-reliability healthcare teams: increased adherence to evidence-based care bundles, and enhanced communication and teamwork.

Research shows that grouping essential processes in care bundles helps clinical staff remember to take all of the necessary steps to provide optimal care to every patient, every time, says **Susan DeVore**, Premier president and CEO. Although many hospitals have long followed some or all of these individual care practices to improve perinatal outcomes, the key is consistently using all of them in concert.

Care bundle adherence is scored in an "all-or-none" fashion. The care team must provide all elements of care in the bundle to be given credit for its use. For example, one care bundle is focused on reducing the risks associated with augmenting labor, particularly in using oxytocin, a drug that accelerates a slow labor. This bundle has four elements that must be practiced consistently. If a team neglects to estimate the fetal weight before administering the medication, it would not receive credit for the work, even if team members successfully implemented the three other elements of the bundle.

PPSI hospitals have implemented the following strategies for certain high-risk protocols:

- **TeamSTEPPS:** Developed by the Department of Defense and the Agency for Healthcare Research and Quality (AHRQ), TeamSTEPPS produces highly effective medical teams that optimize the use of information, people, and resources to achieve the best clinical outcomes.
- **Situation Background Assessment Recommendation (SBAR):** An effective situational briefing strategy, used by the U.S. Navy, to communicate relevant case facts in a respectful, focused, and effective manner.
- **Simulation drills:** Exercises featuring actresses and mannequins reacting as real patients during the birthing process.

Rebecca Price, senior claims manager with Premier Insurance Management Services in Charlotte, NC, notes that in addition to resulting in fewer claims, the PPSI project provides a better defense for the claims that are filed.

"It might make some of those claims easier to defend, and when you make it easier to defend, trial attorneys are not as likely to take it to trial," Price says. "These tend to be very expensive claims to defend, and if you can truncate the timeline on those claims that are inevitably going to be filed, plus discouraging the filing of a large number of claims, you have tremendously improved the organization's financial health." ✦

ACOs will require operational, cultural changes

The growing prominence of the accountable care organization (ACO) model offers many potential benefits, but it also comes with many potential hazards, according to a recent report from Marsh Risk Consulting, based in New York City.

The Marsh white paper on ACOs was authored by **Donna Jennings**, vice president of clinical healthcare consulting in Atlanta and **Holly Meidl**, U.S. leader of the healthcare practice in Nashville, TN.

In the long run, they say, an accountable care model can help participating healthcare organizations improve their reputations, gain market share, and create more sustainable cost structures. But transitioning to accountable care will require hospitals and others to make significant cultural and operational changes — starting with the way they view patient care.

"And hand in glove with such

changes comes the identification and management of associated risks," the report states. "Risk assessments can also help to guide future decisions made by ACOs and participating organizations about their insurance programs. As coordination of patient care is improved across ACOs, many key exposures should decrease; however, temporary increases in exposures should be expected during the transition period."

Fortunately, many of these transition and ongoing ACO exposures can be addressed through a variety of existing insurance solutions. Directors and officers liability (D&O) insurance, which most healthcare organizations already buy, provides significant coverage for many of the risks that ACOs might face, including litigation filed by shareholders and others for any number of business decisions.

Jennings and Meidl note these other critical insurance options:

• Managed care errors and omissions (E&O) insurance, which protects the health plan or network coordinator from claims brought by patients, competitors, and regulators. Many healthcare providers currently do not purchase such insurance coverage, but any organization that is forming or joining an ACO should consider purchasing it.

• Provider excess loss insurance or provider stop loss insurance, which protects the financial stability of a healthcare provider by limiting its exposure to catastrophic individual health claims from services it has contracted to provide to managed care plan members.

• Cyber/data privacy insurance, which provides coverage for data breaches, whether intentional or unintentional, including the cost of notification to affected individuals. Healthcare organizations have long been buyers of cyber insurance, and awareness has continued to rise through a spate of high-profile data breaches in the industry.

• Medical professional liability insurance, or medical malpractice insurance, which provides coverage for claims of patient injury or harm as a result of a negligence by a physician or other medical professional. Many health care providers already purchase this insurance; others set aside reserves to draw upon in the event of a loss.

Healthcare organizations also should consider adapting their use of captive insurance companies, which are owned by the organizations themselves and offer several benefits, the Marsh report suggests. Traditionally, hospitals and others have used their captives to provide insurance to non-insured physicians. "Going forward, captives potentially could be used to provide insurance to network members that hospitals and others do not own, such as nursing homes or hospice facilities. Captives could also be used as a means to share financial risk associated with capitated payments across the network," the report says. "Even if an organization already purchases these insurance products or has a captive, new accountable care models raise new questions."

Jennings and Meidl suggest that risk managers ask these questions regarding any potential ACO relationship:

• Does the existing D&O policy respond to wrongful acts from building networks, choosing care models, and negotiating payer contracts?

• Does existing managed care E&O coverage address establishing a network of providers, managing patient care, and distributing shared payments?

• Has a provider excess program been put in place to protect at-risk managed care contracts?

• Does existing cyber/data privacy coverage address exposures for affiliated providers' access to the same patient data sources? Do affiliates have their own insurance for this exposure?

"Underwriters have not yet reached the point of demanding to review individual contracts that insureds have with other network participants. But they have demonstrated a clear interest in ensuring that the organizations they are insuring have well-defined plans for the transition to accountable care," the report says. "Risk managers would be well-served by engaging with their underwriters to explain their strategies and objectives for accountable care. Face-to-face meetings early in the transition process can help to eliminate many ambiguities and uncertainties and ease underwriters' doubts."

The free full Marsh report is available online at http://tinyurl.com/MarshACO.

Executive Summary

Accountable care organizations (ACOs) promise many benefits to patients and providers, but they also will bring risks. Risk assessments should be conducted to determine how ACOs will affect your organization.

- ✦ Some key exposures should decrease under an ACO model.
- ✦ The transition period might be the time of highest risk.
- ✦ Directors and officers liability (D&O) insurance should provide some help.

SOURCES

• **Donna Jennings**, Vice President, Clinical Healthcare Consulting, Marsh Risk Consulting, Atlanta. Telephone: (404) 539-8018. Email: donna.jennings@marsh.com.

• **Holly Meidl**, U.S. Leader, Healthcare Practice, Marsh, Nashville, TN. Telephone: (615) 340-2446. Email: holly.meidl@marsh.com. ✦

Surgical 'never events' occur 4,000 times per year

After an analysis of national malpractice claims, patient safety researchers from Johns Hopkins University in Baltimore, MD, estimate that a surgeon in the United States leaves a foreign object such as a sponge or a towel inside a patient's body after an operation 39 times a week, performs the wrong procedure on a patient 20 times a week, and operates on the wrong body site 20 times a week.

The researchers, reporting online in the journal "Surgery," say they estimate that 80,000 of these so-called "never events" occurred in American hospitals between 1990 and 2010, and they believe their estimates are likely on the low side.[1]

The findings, which are believed to be the first of their kind, quantify the national rate of "never events," occurrences for which there is universal professional agreement that they should never happen during surgery. Documenting the magnitude of the problem is an important step in developing better systems to ensure never events live up to their name, says study leader **Marty Makary**, MD, MPH, an associate professor of surgery at the Johns Hopkins University School of Medicine.

"There are mistakes in healthcare that are not preventable. Infection rates will likely never get down to zero, even if everyone does everything right, for example," Makary says. "But the events we've estimated are totally preventable. This study highlights that we are nowhere near where we should be, and there's a lot of work to be done."

By law, hospitals are required to report never events that result in a settlement or judgment to the National Practitioner Data Bank (NPDB). If anything, he says, his team's estimates of never events are low because not all items left behind after surgery are discovered. Typically, they are found only when a patient experiences a complication after surgery, and efforts are made to find out why, Makary says.

> *"... we are nowhere near where we should be, and there's a lot of work to be done."*

In their study, never events occurred most often among patients between the ages of 40 and 49, and surgeons in this same age group were responsible for more than one-third of the events, compared to 14.4% for surgeons over the age of 60. Sixty-two percent of the surgeons were cited in more than one malpractice report, and 12.4% were named in separate surgical never events. *(See the story, p. 34, for more on the study results.)*

Makary notes that at many medical centers, patient safety procedures have long been in place to prevent never events, including mandatory "timeouts" in the operating room before operations begin to make sure medical records and surgical plans match the patient on the table. Other steps include using indelible ink to mark the site of the surgery before the patient goes under anesthesia.

Procedures have long been in place to count sponges, towels, and other surgical items before and after surgery, but these efforts are not foolproof, Makary notes. Many hospitals are moving toward electronic bar codes on instruments and materials to enable precise counts and prevent human error. Surgical checklists, pioneered at The Johns Hopkins Hospital, also are often in place.

Along with better procedures to prevent never events, better reporting systems are needed to speed up safety efforts, says Makary. He advocates public reporting of never events, an action that would give consumers the information to make more informed choices about where to undergo surgery, as well as "put hospitals under the gun to make things safer."

Hospitals are supposed to voluntarily share never event information with The Joint Commission, but that step doesn't always happen, Makary says.

Executive Summary

A recent study has concluded that surgical "never events" happen at least 4,000 times per year in the United States. The events include items left behind, wrong-site procedures, and wrong procedures.

- ✦ The researchers say their estimates might be on the low side.
- ✦ Better reporting systems might be needed.
- ✦ The incidents resulted in almost 10,000 malpractice paid malpractice judgments over 20 years.

Reference

1. Mehtsun WT, Ibrahim AM, Diener-West M, et al. Surgical never events in the United States. *Surgery* 2012; Epub ahead of print.

SOURCE

• **Marty Makary**, MD, MPH, Associate Professor of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD. Telephone: (410) 502-6845. ✦

HCA must pay $162 million for charity care problems

Healthcare giant HCA, based in Nashville, TN, must pay a Kansas City, MO, charitable foundation $162 million and undergo extensive auditing after a judge found that the for-profit hospital operator broke key agreements regarding charity care and capital expenditures in its billion-dollar purchase of hospitals from Health Midwest in 2002.

Judge John Torrence, JD, of the Circuit Court of Jackson County, MO, ruled that HCA, the nation's largest investor-owned hospital company, did not spend as much money improving Health Midwest's existing facilities as it said it would. The judge also ruled that HCA did not abide by an agreement to provide at least as much charity care to the community as the Health Midwest's not-for-profit hospitals had provided before the sale. That amount was said to be $65 million annually.

The Health Care Foundation of Greater Kansas City (HCF) had sued HCA in October 2009 to ensure that it had complied with its more than $950 million obligation to charity care in the Kansas City area. The purpose of the lawsuit was to determine if HCA had complied with its obligations to make $450 million in capital improvements to existing Health Midwest facilities and provide over $500 million in charity care. HCF Chairman **Karen Cox**, RN, supported the ruling, saying "As a voice for the uninsured and underserved, the HCF Board of Directors felt it had the fiduciary responsibility to make sure that this population had been afforded the services promised to them through the sale of Health Midwest."

HCA issued a statement saying it would appeal the decision. "Rather than simply put money into the repair of old facilities, we built two new hospitals, spending hundreds of millions of dollars to ensure this community has high quality care," the company said in a written statement. "We believe we have complied with our agreement, exceeded our promises, and we continue to spend millions for the benefit of a community we love."

Health Midwest had operated 11 not-for-profit hospitals in Missouri and Kansas before the sale. ✦

11% of physician career has open med mal claims

The average physician spends 50.7 months, or roughly 11% of a 40-year career with an unresolved and open malpractice claim, according to a new study from "Health Affairs."

Study authors obtained data for 40,916 physicians across the country who were covered by a large, physician-owned liability insurer. They found the length of time between the date a claim was filed and the date it was resolved, or time to resolution, increased with the severity of the patient injury.

For example, 51% of claims for emotional injury were resolved within six months to one year. For claims involving a fatality or permanent disability, 62% took at least one year to resolve, and 17% took three or more years.

Researchers also found the time to settle claims varied depending on the physician's age or his/her specialty. On average, claims were solved more quickly for younger physicians.

Claims for physicians ages 30 to 39 were resolved within an average of 16 months, while that increased to 21 months for physicians over age 50.

The length of time between the date a claim was filed and the date it was resolved was greatest for pediatrics and obstetrics and shortest for nephrology and oncology.

An abstract of the report is available online at http://tinyurl.com/openclaim, with an option to purchase access to the entire article. ✦

Study finds ways to improve EHR quality measures

A federally funded study by Weill Cornell Medical College in New York City demonstrates ways in which quality measurement from electronic health records (EHRs) can be improved.

In a large cross-sectional study in New York state, researchers demonstrated that the accuracy of quality measures can vary widely. Electronic reporting, although generally accurate, can underestimate and overestimate quality.

"This study reveals how challenging it is to measure quality in an electronic era. Many measures are accurate, but some need refinement," says the study's senior author, **Rainu Kaushal**, MD, director of the Center for Healthcare Informatics Policy in New York City, and chief of the Division of Quality and Medical Informatics and the Frances and John L. Loeb Professor of Medical Informatics at Weill Cornell.

Healthcare providers and hospitals are being offered up to $27 billion

in federal financial incentives to use EHRs in ways that demonstrably improve the quality of care. The incentives are based, in part, on the ability to electronically report clinical quality measures. By 2014, providers nationwide will be expected to document and report care electronically, and by 2015, they will face financial penalties if they don't meaningfully use EHRs.

"Getting electronic quality measurement right is critically important to ensure that we are accurately measuring and incentivizing high performance by physicians so that we ultimately deliver the highest possible quality of care. Many efforts to do this are underway across the country," says Kaushal, also a professor of pediatrics, medicine, and public health at Weill Cornell and a pediatrician at the Komansky Center for Children's Health at New York-Presbyterian Hospital/Weill Cornell Medical Center in New York City.

For this study, Weill Cornell researchers analyzed clinical data from the EHRs of one of the largest community health center networks in New York state. The research team examined the accuracy of electronic reporting for 12 quality measures, 11 of which are included in the federal government's set of measures for incentives. What they found was fairly good consistency for nine measures, but not for the other three.

The study's lead investigator, **Lisa Kern**, MD, a general internist and associate director for research at the Center for Healthcare Informatics at Weill Cornell, said, "The variation in quality measurement that we found in a leading electronic health record system speaks to the need to test and iteratively refine traditional quality measures so that they are suited to the documentation patterns in EHRs."

The automated reports generally performed well. However, they underestimated the percentage of patients receiving prescriptions for asthma and receiving vaccinations to protect from bacterial pneumonia. A third measure suggested that more patients with diabetes had cholesterol under control than actually did.

The automated report said 57% of eligible diabetic patients had cholesterol controlled, while a manual check of the charts showed it actually was only 37%. Part of the problem is that physicians and nurses filling out the EHRs might be typing in information in a place that is not being captured by quality reporting algorithms. "EHRs create the opportunity to measure and provide feedback to clinicians regarding quality performance in real time, thereby improving clinical practice," says Kern, who is also an associate professor of public health and medicine at Weill Cornell.

Kaushal adds that "EHRs are not just electronic versions of paper records, but rather tools that enable transformation in the way care is delivered, documented, measured, and improved. The federal meaningful use program will enable the deployment of these promising systems across the country, thereby enabling health care to enter the digital age."

The full study is available online at http://tinyurl.com/EHRquality. ✦

COMING IN FUTURE MONTHS

✦ Telemetry unit cuts falls by more than half

✦ Does working fewer hours increase risk?

✦ Surgical fires — what you're missing

✦ Choosing the right counsel or law firm

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. **Under the final Health Insurance Portability and Accountability Act (HIPAA), what is the maximum penalty per violation for a data breach?**
   A. $250,000
   B. $500,000
   C. $1 million
   D. $1.5 million

2. **Under the soon-to-expire HIPAA requirements, a breach must be reported only if it poses a "significant risk of financial, reputational, or other harm to the individual." What is the new standard under the final HIPAA rule?**
   A. The loss of data is presumed to be a reportable data breach unless a covered entity or business associate demonstrates that there is a low probability that the protected health information (PHI) was compromised.
   B. The loss of data must be reported only if there is evidence that there has been financial, reputational, or other harm to the individual.
   C. The loss of data is presumed not to be a reportable data breach if the number of patients affected is less than 1,000.
   D. The loss of data must be publicly disclosed in all cases in which PHI is involved.

3. **According to Maria Gonzalez Knavel, JD, a partner with the law firm of Foley & Lardner, one of the biggest upcoming risks for hospitals comes from the recent change in how far back the government can go to collect overpayments. What is the change?**
   A. When the overpayment is the result of an error rather than fraud, the government can now go back five years instead of the previous three.
   B. When the overpayment is the result of an error rather than fraud, the government can now go back 10 years instead of the previous five.
   C. Regardless of whether the overpayment is the result of an error or fraud, the government can now go back 10 years instead of the previous five.
   D. If the overpayment is the result of fraud, the government can now go back 10 years instead of the previous five.

4. **In Phase 1 (2008-2010) of the Premier Perinatal Safety Initiative (PPSI), a Premier healthcare alliance project, how much did the participants decrease the number of annual liability claims filed per delivery?**
   A. 21% vs. 6% at non-participating hospitals
   B. 39% vs. 10% at non-participating hospitals
   C. 59% vs. 10% at non-participating hospitals
   D. There was no statistically significant decrease.

Legal Review & Commentary

A Monthly Supplement to HEALTHCARE RISK MANAGEMENT

Transcription error results in medication dose that is fatal and $140 million verdict

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

Laura A. Russell
Associate
Kaufman Borgeest & Ryan
Westchester, NY

Bruce Cohn, JD, MPH
Vice President
Risk Management & Legal Affairs
Winthrop-University Hospital
Mineola, NY

News: A 59-year-old woman was discharged from a hospital after undergoing treatment for a clogged dialysis port. Shortly after returning home, she developed complications. Her physician directed that she be admitted to a rehabilitation facility for additional treatment. Operating from the hospital physician's discharge summary and a physician order prepared by the hospital, staff at the rehabilitation facility gave the decedent 80 units of Levemir insulin, which was 10 times the dosage prescribed by her physician. The decedent went into full cardiopulmonary arrest, was resuscitated, but never regained consciousness and died eight days later. A jury awarded the decedent's family $140 million in damages.

... staff at the rehabilitation facility gave the decedent 80 units of Levemir insulin, which was 10 times the dosage prescribed by her physician.

Background: A 59-year-old woman was discharged from a hospital after undergoing treatment for a clogged dialysis port. Shortly after returning home, she developed complications, and her physician directed that she be admitted to a rehabilitation facility for additional treatment. The treating physician dictated the discharge summary and medication orders, which were sent to a United States-based company for transcription. The company, in turn, subcontracted the services to two companies in India whose workers transcribed the physician's dictation. As a result of the arrangement, information dictated by the physician went through a computer in the United States to India, where the subcontractors' employees prepared the discharge summary and sent it back to the hospital.

Unfortunately, in this case, the subcontractors' employees incorrectly transcribed the dosage of Levemir insulin as 80 units instead of the actual amount prescribed by the treating physician, which was only 8 units. The hospital staff then sent the decedent's admission paperwork to the rehabilitation facility. Operating from the hospital physician's discharge summary and a physician order prepared by the hospital, staff at the rehabilitation facility gave the decedent 80 units of Levemir insulin, which was 10 times the dosage prescribed by her physician. The decedent went into full cardiopulmonary arrest, was resuscitated, but never regained consciousness and died eight days later.

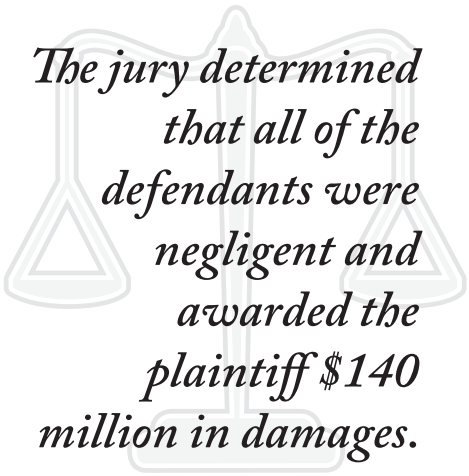
A lawsuit was filed by the decedent's estate against the hospital, its United States-based outsource transcription vendor, and the two Indian subcontractors. The plaintiff claimed that the hospital and

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. **Laura A. Russell, Bruce Cohn,** and **Jonathan D. Rubin**, co-authors, have no relevant relationships to disclose.

the transcription companies negligently transcribed the physician's discharge summary, failed to recognize and timely correct the error, and negligently hired and failed to properly supervise and train the transcriptionist. The plaintiff also claimed that the transcription service, which transcribed admission paperwork sent from the hospital to the rehabilitation facility, incorrectly transcribed the dosage of Levemir insulin as 80 units instead of the actual amount dictated/prescribed: 8 units. The plaintiff further alleged that the hospital staff was negligent in failing to follow its own procedures and multiple national patient safety standards. Specifically, the plaintiff argued that the hospital staff improperly prepared the decedent's admission orders from the unreviewed and unsigned transcription, which then were sent to the rehabilitation facility in the form of a doctor's order.

According to testimony, the original discharge summary form and medication reconciliation form were not accessible by hospital staff because they were being scanned into the hospital system by the records department. As such, the nurse used the unsigned discharge summary prepared in India and wrote the medication information onto the physician admission order containing the doctor's signature. As a result, the documentation appeared to be a valid order. However, the physician had not confirmed the information about the medication as transcribed by the Indian company. Plaintiff's counsel presented evidence that the hospital staff did not know that the transcription work was not being performed in-house or in another country. It was also revealed during trial that the hospital saved a mere 2 cents per line of text by using the outside company. Testimony also indicated the Indian firms operated under sub-par quality standards that are one-half to one-twelfth that of the United States in terms of acceptable error rate. Shockingly, officials from the U.S. transcription company claimed that Indian subcontractors used U.S. standards, but officials from those companies testified that in fact they did not.

All of the defendants denied liability in the jury trial. One of the Indian companies reportedly reached a settlement with the plaintiff for an undisclosed sum just before the jury rendered its verdict. The jury determined that all of the defendants were negligent and awarded the plaintiff $140 million in damages.



The jury determined that all of the defendants were negligent and awarded the plaintiff $140 million in damages.

What this means to you: $140 million is truly a shocking number. Even if the verdict is reduced on appeal or by negotiation, the hospital has a real issue with their insurance carriers and board of trustees, not to mention the exceedingly bad publicity that will go along with this news. A 59-year-old woman with a clogged dialysis port, not an uncommon scenario, is sent to a rehabilitation facility for further care, also a daily occurrence. What we have here is again the issue that has been highlighted by The Joint Commission and others: the failure to accurately communicate. Clearly, the specific facts of this case contributed to the high verdict.

The hospital chose to use a company in India for services as do many other healthcare organizations that outsource work to companies overseas. Many of these entities provide excellent clinical or administrative services up to par with U.S. standards. Many offer benefits in some cases such as overnight radiology services for which the time zone difference means that they are awake in what is the middle of the night in the United States. In this case, the testimony revealed that the overseas company did not comply with the accuracy that would be the standard in the United States and the amount of money saved was, at least to the jury's viewpoint, de minimus, both of which likely contributed to the adverse verdict. At least the overseas company had the good sense to settle prior to trial given the inflammatory nature of the facts of the case.

So what can risk managers take from this? If you are going to outsource any service, whether it is to a domestic or international company, take steps to investigate the accuracy or standards to which the outsourced company adheres. Make certain that the "error rate" or compliance with given standards are equal to or exceed what you would want from your own employees. The hospital's employees relied on an unsigned and un-reviewed discharge summary, which is always dangerous whether it is a summary or unsigned radiology or pathology report. One of the root causes of using the unsigned report appears to be the unavailability of the final document due to scanning. Again, technology is wonderful and can reduce errors, but documents have to be available to the providers at the point and time of care. The speed of the scanning might need to be secondary to clinical considerations.

On patient safety and clinical analysis, the amount of insulin transcribed was 10 times the prescribed dose. This difference was not picked up or questioned by the nurse who created the discharge paperwork or by anyone at the rehabilitation facility. A quick review of an electronic or paper reference might have been a clue that the dose was fairly large and at least caused the nurse to call a physician or pharmacist to verify the dosage. All providers, whether they be prescribers, dispensers, or administering clinicians, need to be aware of what orders are reasonable. They need to do the research if the answer is unclear.

Reference

JVR No. 1212200046, 2012 WL 6642470 (Ala.Cir.Ct.). ✦

Delayed diagnosis of aortic dissection results in $4.5M award for wrongful death

News: A 43-year-old man presented to the emergency department with complaints of chest pain. A CT scan of the chest without contrast showed evidence of a possible dilated ascending aorta. The patient was admitted to the hospital for further observation and testing. Multiple tests were ordered, but the orders never were entered into the hospital system and, therefore, were not performed. An echocardiogram was finally performed and indicated that the patient had an aortic dissection. Before a surgeon could be located, the patient died from complications of the ascending aortic dissection. The patient's family filed suit against the hospital and multiple doctors, and the case advanced to a jury trial. The jury awarded the patient's family $4.5 million.

Background: A 43-year-old man, with no history of cardiac issues and a history of smoking, presented to the emergency department with complaints of chest pain. At approximately 6:55 a.m., a CT scan of the chest without contrast showed evidence of a possible dilated ascending aorta. The radiologist informed the emergency department physician of the results and recommended that a CT angiogram of the chest be ordered to rule out certain conditions. The emergency department physician, in turn, ordered that a CT angiogram be performed once the patient was admitted to the hospital floor but did not otherwise order that it be performed while he remained in the emergency department. The patient was admitted to the hospital between 7 a.m. and 8 a.m. However, the CT angiogram ordered by the emergency department physician was never entered into the hospital system and, thus, was never performed. The patient was examined by the cardiologist between 10:30 a.m. and 11 a.m., and a CT scan of the chest with contrast was ordered. Again, the order never was entered into the hospital system and, again, never was performed. Thereafter, between 12:30 p.m. and 1:30 p.m., the cardiologist ordered an echocardiogram that was performed and indicated that the patient had an aortic dissection. At approximately 4:12 p.m., before a surgeon could be located, the patient died from complications of the ascending aortic dissection.

... before a surgeon could be located, the patient died from complications of the ascending aortic dissection.

A lawsuit was filed against the hospital, emergency department physician, internal medicine attending, cardiologist and the cardiology group, by the patient's mother. Plaintiff alleged that defendants failed to timely order and perform the CT scan of the chest with contrast and CT angiogram of the chest, and the plaintiff alleged that the defendants failed to timely diagnose and treat the decedent's aortic dissection. Specifically, plaintiff claimed that the emergency department physician was negligent in failing to order and obtain the CT scan with contrast in a timely manner and thus, failed to timely diagnose the aortic dissection. Furthermore, plaintiff claimed the internal medicine attending was negligent in failing to ensure that the CT scan of the chest with contrast was performed when the decedent was admitted and failed to ensure the decedent was examined by a cardiologist in a timely manner. Plaintiff further claimed that the cardiologist and cardiology group were negligent in failing to timely examine the decedent and order and follow up the results of the tests necessary to diagnose the aortic dissection.

The case proceeded to a jury trial. The emergency department physician, cardiologist, cardiology group, and internal medicine attending denied all allegations of negligence in the matter. The hospital was the only party to admit to the allegations of negligence. The jury determined that the internal medicine attending and the hospital were negligent and proximately caused the decedent's death. The jury's $4.5 million award included $500,000 for pain and suffering, with the remainder allocated to the decedent's four children in pecuniary loss. The attorneys for the hospital and the internal medicine attending reached a high/low agreement with the plaintiff wherein they would pay $3.5 million of the verdict. The hospital was responsible for $2 million. The high/low agreement reportedly was reached with other defendants who were not found negligent but were still required to contribute to the verdict.

What this means to you: The failure to diagnose a "triple A" in young, otherwise healthy individuals has received a lot of coverage in literature recently. In the typical case, the investigation reveals that the physicians don't consider the diagnosis in the absence of alarm or traditional symptoms. Sadly in this case, it appears that the diagnosis might have been considered, yet the failure of the simple ministerial acts of getting the appropriate testing done and communicated contributed to the outcome.

We don't have a medical record to review, but the ordering of a CT scan by the emergency department physician seems to indicate that the doctor was considering something more complex than angina, pneumonia, or the other more common causes of chest pain. So where did it go wrong? The radiologist conveyed the results of the CT scan with contrast showing the possibility of a dilated aorta, which had the potential to be a significant threat to the patient's life or health. It appears from the recitation of facts that the radiology department complied with their standard of care by conveying the information to the emergency department attending physician and recommended a follow-up test. The emergency department physician ordered the test to be done after admission. This sequence of events highlights a common "falls-through-the-cracks" scenario common in hospitals. The period between the point in time when an emergency department physician decides to admit, and the point at which the admitting resident or attending takes over the care, is when we in the hospital need to be especially vigilant. If the emergency department physician on the basis of the CT scan thought the second test was necessary, should he/she not have ordered it immediately rather than waiting for admission?

In this case, eventually an echocardiogram revealed the presence of an aortic aneurysm, but it was too late to save the patient.

The second order was not entered into the system; this is the advantage and disadvantage of electronic ordering. In the old "paper system," a provider would write an order and place it in a location for retrieval by radiology or other support service. The advent of computerized ordering has streamlined this system and eliminated the "missing paper order" problem, but it creates issues of its own. The order has to be put into the system, which also sometimes requires that one clinical system communicate with another system, i.e. the clinical system has to trigger a notification in the radiology computer system. Hospital clinical staff and IT staff should be running quality assessment programs to ensure that everything that should be done is done and is accurately communicated. In this case, eventually an echocardiogram revealed the presence of an aortic aneurysm, but it was too late to save the patient.

So what do we take away from this case that might help our institutions avoid having a similar event? Ensure that physicians in the emergency department and other locations follow through. The emergency department doctor had a suspicion, which ultimately was right, but he/she may have failed to close the loop. Providers who put orders into electronic systems need to cycle back and make sure the orders have indeed been entered and are being done. From a clinical perspective, an assessment should be done to analyze whether the most efficacious test was done timely. In this case, the simple ultrasound eventually diagnosed the condition, albeit late. If there were a clinical suspicion of an AAA, would a fast exam in the emergency department have led to a quicker diagnosis and a better chance at saving the patient? The hospital in this case reportedly conceded liability and, we hope, was able to identify the root causes to prevent the same scenario from happening again.

Reference

2012 WL 5990342, No. 08-L-827 (Ill.Cir. Ct.). ✦