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New privacy rules may bring in sweeping new changes for risk managers, patients

'This is going to change the . . . entire way we do care'

The Clinton administration leaves health care risk managers with a final regulation establishing the first-ever federal privacy protections for personal health information. Risk managers say the rule's implementation may not be easy.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, which applies to health insurers, virtually all health care providers and clearinghouses, is intended to give consumers more control over and access to their health information; set boundaries on the use and release of health records; safeguard that information; establish accountability for inappropriate use and release; and balance privacy protections with public safety.

The administration changed the proposed rule by strengthening several key protections, including: extending protections to personal medical records in all forms including paper records and oral communications; providing for written consent for routine use and disclosure of health records; protecting against unauthorized use of medical records for employment purposes; and ensuring that health care providers have all the information necessary to appropriately treat their patients.

The impact of the regulation on health care providers will be tremendous, says **Geri Amori**, PhD, ARM, FASHRM, risk manager with Fletcher Allen Health Care in Burlington, VT. Amori also is president of the American Society for Healthcare Risk Management.

"This is going to change the entire way we use

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technology and the entire way we do care now," she says. "It's going to have some significant implications on the care we provide. It has to. We won't know what all of those are until we're into it more."

Rule addresses public's concerns over privacy

In releasing the final rule, White House officials said Americans are increasingly concerned about losing their privacy. Recent studies show a rising level of public concern about privacy issues. In 1999, more than 80% of people surveyed agreed with the statement that they had lost all control over their personal information.

"Personal health information can be distributed without consent for reasons that are unrelated to treatment," President Clinton said in releasing the rule. "Under the current loose patchwork of state laws, information held by an insurer can be passed on to a lender who can then deny that patient's application for a home mortgage or a credit card, or to an employer who uses it in personnel decisions. Personal health information may be disclosed for insurance underwriting purposes, market research, or any other reason without any safeguards to protect it against misuse."

Proponents of the new rule also point out that patients are often unable to access their own medical records. In addition, patients wishing to access or control the release of such records may be unable to do so because of overwhelming barriers established by their insurance company, health care provider, or anyone else who holds their records. The final regulation, which will be fully implemented within two years, is being issued under the authority of the bipartisan Health Insurance Portability and Accountability Act (HIPAA) of 1996. **(See article, p. 17, for more details on the rule.)**

Amori says the rule should give patients more of a sense of control.

"It's going to bring to active consciousness something about which many people have been concerned for a long time — privacy in an era of technology," she says. "When I was a kid, my doctor used a 3-by-5 card with my health information on it. As we've grown, the amount of technology and the way we use it has grown exponentially. It was inevitable that we would need legislation."

Amori compares the privacy rule to last year's Institute of Medicine (IOM) report on medical

errors. The privacy rule will stir up trouble for risk managers, she says, but it actually is based on sound risk management principles.

"Like the IOM report, it lends backbone to a lot of things we have been saying we needed for a long time," she says. "But it also complicates some of the things we deal with, like ethical issues and payment issues. It is going to increase the complexity of some of our tasks, and it will introduce some new variables."

Recognizing the savings and cost potential of standardizing electronic claims processing and protecting privacy and security, the Congress required that the overall financial impact of the HIPAA regulations reduce costs. As such, the financial assessment of the privacy regulation includes the 10-year, $29.9 billion savings the Department of Health and Human Services projects for the recently released electronic claims regulation and the projected $17.6 billion in costs over 10 years projected for the privacy regulation. This produces a net savings of approximately $12.3 billion over 10 years for the health care delivery system while improving the efficiency as well as privacy protections.

"I don't think the rule is bad. Like the IOM report, it's a thorn but a good thorn," Amori says. "It's what needs to happen, but it's not going to be easy." **(The privacy rule is only one part of the HIPAA regulation. See p. 18 for an explanation.)**

Bush administration asked to review rule

Some providers have expressed concern that the rule places an unreasonable burden on them to obtain consent from patients before disclosing medical information in almost any way. The requirement was strengthened from the original proposal so that now the patient must give written consent for just about any type of information release. Providers will have to retain the consent forms for a minimum of six years.

Under the new rule, patients may ask health care providers to restrict how medical information is used within the health care system for treatment, payment, or any other function. And after providing consent, restricted or not, for such purposes, the patient can revoke the consent.

The rule essentially gives the patient a great deal of control over how any medical information is used, and that will be a difficult change for providers, Amori says. Even though providers have long acknowledged that they must protect a patient's medical information from prying eyes, Amori says they also have been the arbiters of who gets to look and who doesn't. The HIPAA regulation takes that control from the provider and gives it to the patient.

"We can no longer be the beneficent paternalist," Amori says. "This rule will fly in the face of a lot of old-style medicine. It will change a lot of the routine ways things are done."

Consider the exposure

Amori says the rule creates a lot of new exposures for risk managers to consider. The government can impose fines for not adhering to the privacy regulation, and Amori says it is inevitable that hospitals will be hit with those penalties. It is uncertain how those fines might be covered by insurance policies, but Amori says she doesn't expect they would be covered since government fines usually are not.

As soon as the rule was released, health care organizations started squealing and promptly went to the incoming Bush administration for help. The Health Care Leadership Council, an association of 50 chief executives from large health care companies, immediately sent an appeal to the Bush administration, asking for "a more balanced approach to protecting privacy." The American Hospital Association also released a statement saying it would ask the Bush administration for help in changing the rule.

The American Medical Association also expressed concern. The association agrees in principle with the Clinton administration's latest effort to safeguard the privacy of each individual American's medical records, according to **Donald Palmisano**, MD, of the American Medical Association's Board of Trustees. However, Palmisano cautions that patients and physicians will not know the real benefits, burdens, and costs until the complex maze of new rules and regulations is closely analyzed.

"This is a big step and the devil really is in the details this time," Palmisano says. "It's important to make sure that good intentions don't produce unintended consequences. We will be closely examining the new rules to make sure there are no dangerous loopholes or unexpected problems."

Palmisano, a New Orleans surgeon and attorney who is a national expert on patient privacy and confidentiality issues, says there are three things he considers essential for patients' medical information to remain secure.

"Nothing should be disclosed without the patient's consent," he says. "Unfettered access to

a patient's health information by government agencies and law enforcement is unacceptable. A patient's physician must not be unfairly held liable for any misuse of confidential patient information by some third party who might also be doing business with that physician."

Some changes good, some not so good

The HIPAA privacy rule was changed in some significant ways from its earlier proposal, and risk managers are likely to find that some of the changes are good and some aren't. **Jack Rovner**, partner and co-chair of the Chicago health law practice group for Michael Best & Friedrich, says he is impressed with how much the rule was changed in response to the concerns of health care providers.

"They paid a lot of attention to industry comments and the need to accommodate some industry functions that the proposed rule would have made problematic," he says. "They kept in the forefront the government's idea that protections are necessary for the patient, so it's still a strong piece of rulemaking."

Rovner says two of the most talked-about changes aren't likely to hit health care providers hard. The final version of the rule requires that patients give written consent for virtually every release of medical information in the course of treatment, even going from one hospital department to another. That may be overkill in some providers' view, but it shouldn't create too much of a problem because providers already do that or something very close to that, Rovner says.

"You sign an informed consent when you first go for care," Rovner says. "How much you have to change that procedure to comply with this rule depends on how extensive the consent already is."

Rovner notes, however, that the rule now provides penalties for not obtaining proper consent. Many providers will not have to change their procedure much for the initial consent, but the ramifications of failing to do so may be much greater than before.

Some providers have expressed concern about a change that extends the privacy protections to all medical records, both paper and electronic. The previous proposal covered only electronic records. While that change may seem like it increases the compliance burden, both Rovner and Amori say providers won't see much difference.

"The truth is that anything you have on paper these days, you probably have on computer, and vice versa," Amori says. "So that information would be covered in either case. The change could be more significant for some rural hospitals that don't use computers much, making the rule have more effect for them than it would have before."

The final version of the rule includes a major change that risk managers will welcome. In the proposed version of the rule, providers could make available only the "minimum-necessary" information about a patient even when the patient gave consent for the information transfer. That provision raised all sorts of questions about how doctors would communicate with each other, with some analysts suggesting that the primary doctor would have to be cryptic when talking with a specialist for fear of revealing too much patient information. No one in the health care industry liked that scenario, and it apparently won't come to pass.

Now, the rule states that the "minimum-necessary" provision does not apply to such doctor-to-doctor consultations. "That's a major change and a good one," Rovner says.

But the "minimum-necessary" provision still applies to a great many situations.

"The 'minimum-necessary' provision says that employees should only see information they need to do their job. You can't just hand over the medical record and let them find what they need," he says. "That's going to require some major analysis of what everyone's job functions are and how you can control information so they get what they need to do their jobs but nothing else. Claims processing doesn't need to see the same information that the nursing staff does."

Sharing information

Other changes in the final rule allow integrated health care organizations to share information as if they were a single entity, even if they actually are several facilities. This change recognizes the "real world of how health care is delivered," Rovner says. In a hybrid organization with both health care and nonhealth care members, the rule allows the information to be shared between the health care entities but not with the others.

Also, protected health care information cannot be provided to any human resources department within the organization. The only exception is a situation, such as workers' compensation treatment, in which an outside employer has purchased the health care and the patient has consented to such a release.

For risk managers, the work starts now. Rovner and Amori suggest that health care risk managers start assessing how much current policies and procedures will have to be changed to comply with the rule. Amori suggests that the greatest impact probably will be felt on the financial side of the health care operation. The rule makes it clear that billing employees, for instance, must not have access to protected patient information. It is not sufficient to ensure that they do not disclose or otherwise misuse the information; systems may have to be revamped to ensure they do not even have access to that information.

Much of the risk manager's work will involve assessing just what information is necessary for certain staffers to do their job. And risk management experts agree that there are a lot of gray areas and unanswered questions that will not be settled until providers move forward and try to comply with the rule.

"We recently looked at some of the envelopes we use to mail information to OB/GYN patients, and that got us wondering," Amori says. "If the envelope says OB/GYN on the outside, does that reveal too much information about the patient? We don't know how far this is going to go. Questions are going to come up as we move along." ■

Privacy rule requires attention to consent

The recently released privacy regulation, which will be fully implemented within two years, is being issued under the authority of the bipartisan Health Insurance Portability and Accountability Act (HIPAA) of 1996. These are the primary goals of the new rule:

• **Inform consumers how their health information is being used.** This new regulation requires health plans and providers to inform patients about how their information is being used and to whom it is disclosed. It also gives each individual patient a right to a "disclosure history," listing the entities that received information unrelated to treatment or payment that must be provided within 60 days.

• **Limit the release of private health information without consent.** This rule establishes a new federal requirement for doctors treating patients and hospitals to obtain patients' written consent to use their health information even for routine purposes, such as treatment and payment. Other nonroutine disclosures would require separate, specific patient authorization.

• **Give patients access to their own health file and the right to request amendments or corrections.** The regulation gives patients the right to see and copy their own records as well as the right to request correction of potentially harmful errors in their health files. These access and amendment rights are a core part of efforts to protect individual privacy. Without them, a person with an improper diagnosis in his or her medical file could be denied health insurance and left no redress.

• **Restrict the amount of information used and disclosed to the "minimum necessary."** Currently, health care providers and plans often release a patient's entire health record even if an employer or other entity only needs specific information, such as the information necessary to process a worker's compensation claim. This new regulation restricts the information that is used and disclosed to the minimum amount necessary.

• **Require the establishment of privacy-conscious business practices.** The regulation requires the establishment of internal procedures to protect the privacy of health records. They include: training employees about privacy considerations in the workplace; receiving complaints from patients on privacy issues; designating a privacy officer to assist patients with complaints; and ensuring that appropriate safeguards are in place for the protection of health information. Many responsible doctors, hospitals, and health plans already provide these common-sense services for their patients, and were instrumental in advocating for a national standard.

• **Create new criminal and civil penalties for improper use or disclosure of information.** In the past, there often has not been any legal basis to prosecute individuals who inappropriately disclose private medical information. This rule applies the standards included in HIPAA to create new criminal penalties for intentional disclosure up to $50,000 and up to a year in prison. Disclosure with intent to sell the data is punishable with a fine of up to $250,000 and up to 10 years in prison. The regulation also establishes new civil penalties of $100 per person for unintentional disclosures and other violations (up to $25,000 per person per year).

• **Require that information be disclosed only for public health priorities and other responsible research.** The regulation balances the need to protect the public health and support carefully

monitored medical research against the need to protect personal medical records from misuse and abuse. The regulation recognizes that threats to public health, such as life-threatening and easily transmitted infectious diseases, will require appropriate monitoring by public health authorities. The regulation encourages health professionals to use deidentified records whenever possible.

• **Limit the disclosure of information without sacrificing public safety.** The rule strikes the proper balance between protecting privacy and meeting the needs of law enforcement. Medical records often are important to the investigation and prosecution of serious criminal activity. At the same time, Americans must not be discouraged from seeking health care because of concerns about having their information inappropriately given to others.

In response to over 50,000 comments submitted by the public, the final regulation was changed in these ways:

• **Extending coverage to personal medical records in all forms including paper records and oral communications.** The proposed regulation released last year was limited to electronic records and any paper records that previously existed in electronic form. The final regulation provides protection for paper and oral in addition to electronic information, creating a privacy system that covers all personal health information created or held by covered entities. Comments received on the proposed regulation affirmed that the administration had the authority to extend coverage to paper records and overwhelmingly supported broadening the regulation to these records because it would be impractical to have two separate sets of privacy standards for different sets of records.

• **Requiring consent for routine use and disclosure of health records.** The proposed regulation released last year allowed routine disclosure of health information without advance consent for purposes of treatment, payment, and health care operations. The final regulation ensures that written consent for disclosures by front line providers even routine ones be obtained in advance. This new requirement was strongly supported by physician and patient advocacy groups.

• **Protecting against unauthorized use of medical records for employment purposes.** The proposed regulation did not clearly explain the regulation's limits on large self-insured employers' access to personal health information for employment or other purposes unrelated to health care without consent. The final regulation clarifies that these employers cannot access medical information for purposes unrelated to health care.

• **Ensuring that health care providers have all the information necessary to appropriately treat their patients.** For most disclosures of health information, such as health information submitted with bills, providers may send only the minimum information needed for the purpose of the disclosure. However, when treating patients, health care providers often need to be able to share more complete information with other providers. The final rule gives providers full discretion in determining what personal health information to include when sending patient records to other providers for treatment purposes. ■

Other components added to rules list

The recently released privacy rules are only the latest part of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that risk managers must deal with. HIPAA also requires every health plan, health care institution, and practitioner who maintains or transmits health information in electronic form, to be in compliance with the Administrative Simplification mandates within two years.

HIPAA requires significant work from health care providers, says **Jack Rovner**, partner and co-chair of the Chicago Health Law Practice Group for Michael Best & Friedrich. Before the end of this two-year implementation window, each health care provider and plan will need to examine and evaluate its patient data privacy and electronic data security and transmission policies, procedures, and practices, as well as its electronic health information exchange capabilities and protocols. It will need to review and audit every operation and every business relationship that may involve use, disclosure or electronic transmission or storage of individually identifiable health information.

Rovner says HIPAA gives HHS the power to impose civil monetary penalties of $100 for each knowing failure to meet one of the HIPAA standard, up to a maximum annual fine of $25,000 for multiple violations of the same standard. As the cap applies only per standard, the exposure can

be far greater should a health care organization be out of compliance with multiple standards. For example, violations of 100 different standards 250 or more times each in any year would bring an exposure of $2.5 million for that year.

For knowingly obtaining or disclosing patient data in violation of HHS regulations, the penalties are $50,000 and one year in prison. If the infraction involves false pretenses, the penalties increase to $100,000 and five years in prison; if it involves commercial or personal gain or malicious harm, the penalties are $250,000 and 10 years in prison. This criminal exposure is both personal and corporate. There is also potential substantial liability under state negligent or other tort principles premised on noncompliance with these HIPAA standards.

Rovner notes that although HIPAA itself does not authorize private lawsuits by individuals, a state court could consider noncompliance to evidence lack of reasonable conduct sufficient to expose the noncompliant provider or plan to compensatory or even punitive damages to individuals harmed by the misuse, disclosure, or breach in integrity of their patient data. ■

Safety and errors have new standards

The Joint Commission on Accreditation of Healthcare Organizations recently approved standards directly focused on patient safety and medical/health care error reduction in hospitals. The new standards augment the nearly 50% of current Joint Commission standards related directly to patient safety. Requirements for establishing ongoing patient safety programs in organizations accredited under the Comprehensive Accreditation Manual for Hospitals will be added in the following standards areas:

• **Leadership** — Hospital leaders are to create an environment that encourages error identification and remedial steps to reduce the likelihood of future recurring errors. Such an environment includes minimization of individual blame or retribution for those involved in an error or in reporting an error. The focus will be on establishing an actual or virtual organizationwide patient safety program that uses internal and external knowledge and experience to prevent the occurrence of errors.

• **Improving Organization Performance** — Hospitals are to implement a program for proactive — that is, before an error has occurred — assessment of high-risk activities related to patient safety and undertake appropriate improvements. Those activities are to be selected by the hospital based on available knowledge and information, including information that is provided by the Joint Commission through its study of adverse events that seriously harm patients (sentinel events).

• **Management of Information** — Hospitals are to aggregate patient safety-related data and information to identify risk to patients; apply knowledge-based information to reduce these risks; and effectively communicate among all caregivers and others involved in patient safety issues to guide and improve professional and organizational performance.

• **Other Functions** — Hospitals are to place appropriate emphasis on patient safety in areas such as patient rights, education of patients and their families, continuity of care, and management of human resources. The standards state that the patient and/or the patient's family is informed about the results of care, including unanticipated outcomes.

The anticipated implementation date for the standards is July 2001. In developing the standards, the Joint Commission sought advice from a special expert panel that included patient safety and medical/health care error reduction leaders as well as representatives from government, hospitals, insurance companies, universities, and advocacy groups.

The new standards substantially expand upon current Joint Commission standards that require health care organizations to identify, internally report, and analyze sentinel events, and take action to prevent their recurrence. ■

HCA to settle criminal charges

HCA announced recently that it has signed an agreement with the criminal division of the Department of Justice and U.S. attorneys' offices in Atlanta; El Paso, TX; Miami; and Tampa, FL, to resolve all pending federal criminal issues in the Columbia investigation for $95 million.

The company already has signed a civil

settlement agreement with the civil division of the Department of Justice, first announced by the company in May 2000 to resolve civil false claims issues related to DRG coding, outpatient laboratory, and home health. The resolution of the case also includes the signing of a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services.

In announcing the settlement, Thomas Frist Jr., MD, HCA chairman and CEO, said, "Today's action represents one of the last steps needed to put the Columbia investigation behind us and allows us to move forward, maintaining our focus on providing quality patient care." Frist was named chairman and CEO of the company in July 1997 after the charges were made.

In exchange for a full criminal release for the company and its affiliates on all federal health care billing issues involved in the investigation up to the date pleas are entered, Columbia Management Companies Inc. and Columbia Homecare Group Inc. (nonoperating subsidiaries) have agreed to plead guilty to conspiracy, receiving unlawful remuneration, making false statements, and numerous charges related to DRG coding and cost reports.

Resolving the issues

The agreements resolve all federal criminal issues outstanding against the company and civil issues related to outpatient lab billing, home health issues, and DRG coding. In addition, representatives of state attorneys general have agreed to recommend to state officials that the company be released from corresponding criminal liability in all states in which the company operates. The company continues to discuss civil issues relating to cost reporting and physician relations with the government.

The criminal agreement also will result in the company divesting Deering Hospital in Miami. The company has been in discussions over the past few years with buyers interested in acquiring the hospital. The divestiture was agreed to as part of the overall criminal resolution, and does not reflect an admission or understanding that the facility was involved in the specific situations discussed in the agreement. In addition, the company has agreed to the exclusion from the Medicare program of Clearwater (FL) Community Hospital, which the company closed in February 1999.

As part of the criminal agreement, the company will pay the government approximately $95 million, which the company recorded as a special charge in the fourth quarter of 2000. The criminal agreement is conditional upon entry of pleas in federal district court and necessary court approvals, which are expected in the first quarter of 2001. Payment of the criminal settlement will be made by the company within five days after all necessary court approvals are obtained. As previously announced last in May, the civil agreement completed includes a provision for the company to pay the government $745 million plus interest. Payment of the civil settlement will be made upon court approval of the settlement, which is expected by late March. The accounting charge for the civil settlement was recorded in the second quarter of 2000. ■

Survey: Medical errors, malpractice are tops

The results of a new survey by the Kaiser Family Foundation and the Agency for Health Care Research and Quality (AHRQ) suggests that last year's media frenzy about medical errors sunk in with the public. They now report that medical errors are one of the primary criteria for judging health care quality.

The results of the national survey of more than 2,000 adults indicate that people are more concerned about mistakes happening when they are in the hands of the health care system than when they are flying on an airplane. The majority say that information about medical errors (71%) and malpractice suits (70%) would be the biggest help to them in determining the quality of providers.

Who do they trust?

The survey also found that the public is more likely to rely on recommendations of friends, family, and health professionals they know than on standardized quality indicators. However, the gap between relying on family, friends, and personal physicians vs. data has narrowed since 1996 when the survey was first conducted. The survey also shows although most Americans get their health coverage through the workplace, six in 10 do not believe employers are a trusted source of information on quality of providers, and few have consulted the Internet for such information.

Drew Altman, PhD, president of the Kaiser

Family Foundation, says he thinks the survey results can be traced directly to the recent furor over medical errors sparked by the 1999 Institute of Medicine Report.

"Media attention to the Institute of Medicine story has propelled the problem of medical errors to the forefront in just a short period of time. It's an amazing example of agenda setting," he says.

Americans are more likely now than in 1996 to say there are big differences in the quality of local health plans, hospitals, and specialists. For example, more than half of Americans (55%) say there are big differences in the quality of care among local health plans, an increase from 47% in 1996.

Are they experienced?

Provider experience also is important to Americans in informing them about the quality of a doctor or hospital: 66% say how much experience a hospital has in performing a particular test or procedure, and 65% say the number of times a doctor has conducted a specific medical procedure are important measures of quality. Patient experiences in getting care are also important to consumers. Whether the plan has programs to help people with chronic illnesses (67%), how easy it is for plan members to see specialists (66%), how quickly patients can get a doctor's appointment (64%), and the percentage of plan members who get preventive care for conditions such as high blood pressure (63%), were frequently cited as indicators of a health plan's quality.

John Eisenberg, AHRQ director, says the survey shows providers cannot ignore the public's concern about medical errors. "This study clearly shows that people are interested in information on the quality of the health care services they receive, but they don't actively seek out that information," he says. "All of us involved in producing quality information have both an opportunity and a responsibility to make this information more readily available, as well as to ensure that the information is reliable, valid, and useful in helping people make more informed health care decisions. This is a special opportunity to put research to work to improve health care quality."

The Henry J. Kaiser Family Foundation, based in Menlo Park, CA, is a nonprofit, independent national health care philanthropy that is not associated with Kaiser Permanente or Kaiser Industries. AHRQ is the lead federal agency charged with supporting research designed to improve the quality of health care, reduce costs, address patient safety and medical errors, and broaden access to essential services.

Findings from this survey were presented Dec. 11, 2000 at a conference in Bethesda, MD, "Informing Consumers About Health Care Quality," sponsored in part by AHRQ. ■

More near misses than medical errors

Only 3% of medication errors at U.S. hospitals result in a patient being harmed or dying, but there are far more "near misses," according to information released by the U.S. Pharmacopeia (USP).

The newly released USP report indicates that nearly a quarter (23%) of the medication errors occurring at hospitals in the study did not reach the patient. In 55% of cases, an error reached the patient but did not cause harm.

A broad definition of error

The report summarizes results of a yearlong study of data submitted to MedMARx, a national data repository created to allow hospitals to anonymously report and track medication errors in a standardized format. The analysis is based on 6,224 medication errors reported by 56 hospitals.

USP, a nonprofit drug data and standards-setting body, is the first to examine actual reported medication errors since the Institute of Medicine (IOM) drew national attention to the problem in 1999 in a landmark report on medical errors. To assess the whole picture, USP adopted a broad definition of error, which encompasses the so-called "near misses."

The majority of medication errors (40%) involved administering medication, vs. the 11% that were due to prescribing errors. Forty-five percent of the errors reported to the database involved multiple causes. More than half of the time, hospitals ascribed errors to a combination of "performance deficit" (meaning that the reason for the error could not be explained) and other factors. Contributing factors in the "performance deficit" category included distractions and workload increase.

A copy of the MedMARx data is available at USP's Web site, www.usp.org/medmarx. ■

'Failure-to-detect' causes rise in rates

Not only is the size of medical claims on the rise, the definition of malpractice is being broadened to include "failure to detect." That's the result of a new survey by Conning & Co., an insurance consulting company in Hartford, CT, that also suggests malpractice insurance rates are headed up.

Doctors are being held liable for diagnostic tests they are unable to perform based on the existing structure of some managed care companies, giving rise to the "failure to" litigation, says **Geri Riley**, vice president at Conning & Co. and author of the study. The survey also discusses the increased frequency of million-dollar claims, as juries have been desensitized to how large a sum of money this is.

"'Failure to detect' litigation is imposing a huge burden on the medical malpractice industry."

According to the Conning survey, "Medical Malpractice Insurance: Ills Diagnosed, Cures Elusive," 72% of medical malpractice insurance writers surveyed believed that the broadening definition of malpractice, particularly "failure to detect," was an important challenge facing the industry. Interestingly; only 53% of medical malpractice insurers cited the need for tort reform as an important issue; and only 58% of medical malpractice insurers reported that the erosion of ERISA protection (HMO's being cleared from malpractice suits) was an important issue.

"'Failure to detect' litigation is imposing a huge burden on the medical malpractice industry," Riley says.

The runaway costs of claims in a market where competition for new policies is already fierce presents a dismal outlook for the medical malpractice industry, Riley says. The Conning survey indicates that insurers hope to raise rates and gain market share, an unrealistic goal in the current medical malpractice insurance environment. Further, Conning concluded that many of these insurers do not have a focused strategy of how to reduce claims costs.

Eighty-one percent of medical malpractice writers surveyed indicate that their companies would experience higher costs. Seventy-six percent of survey respondents indicate that their companies intend to raise rates. These survey responses reflect the trend of worsening combined ratios. The medical malpractice combined ratio has increased substantially since 1994, when it was 98%, reaching 128.3% in 1999, a trend that does not appear to be changing course by analyzing the above numbers.

The entire Conning survey, "Medical Malpractice Insurance: Ills Diagnosed, Cures Elusive," is available from Conning & Co. for $295 by calling (888) 707-1177, or can be purchased through the company's Web site at www.conning.com. ■

A Richter scale for risks offers advice

To patients facing a major operation or medical procedure, it can be a simple, effective aid — a Richter scale for risks that helps patients sort out their treatment options. For providers, it could be a way to reduce exposure to medical malpractice claims.

Created by risk communication consultant and former Oxford University professor **John Paling**, it was originally developed to help his clients put environmental worries such as weapons storage and chemical emissions in perspective.

Paling says that after his chart was featured in 1995 in *Scientific American*, physicians convinced him of its potential in medicine.

"The scale's greatest benefit may be as a visual aid for doctors to use during counseling and informed-consent interviews with patients," he says. "It can help physicians communicate better with patients and reduce misunderstandings that can lead to patient dissatisfaction and malpractice claims."

Calculating odds

With the Paling Risk Perspective Scale, doctors can easily display the odds of different treatment options, helping patients compare the risks of each. Absolute certainty, a 1-in-1 occurrence, is on the far right end and the odds decrease by factors of 10 as you move left, or

down the scale. Patients understand the scale as easily as a pie or bar chart, says **Kenneth Kellner**, MD, professor of obstetrics and gynecology at the University of Florida College of Medicine.

"The risk scale certainly enhances the legal informed-consent process," Kellner says. "That should take a back seat, though, to its use as an educational tool to help patients and their families evaluate the risks of therapy, essentially without adding any extra time to the examination."

Though Paling's instrument is copyrighted, it is available to the public. Digital copies are available at www.healthcarespeaker.com, or by calling (352) 377-2142. Health care providers only need to register as a user to be granted permission to use the scale and reproduce it in their institution at no charge. ■

WA doctor hit with record verdict

A jury in Yakima, WA, has returned a unanimous, record verdict in a medical malpractice case for delayed diagnosis of prostate cancer.

Dan Peterson, MD, an internist from Yakima, was found negligent for failure to act upon rising, abnormal PSA tests and ordered to pay $4.5 million. PSA tests are a common blood test routinely used in men over age 50 to screen for possible prostate cancer. "Peterson saw all the red flags but did nothing. Help was just a phone call away," says the plaintiff's attorney **Reed Schifferman**. Peterson began screening Carl Pettijohn of Yakima in 1993 when Pettijohn was 52. Each year thereafter, the PSA level rose and laboratory results were twice

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flagged as abnormal by the reporting medical lab. The last PSA with Peterson was July 1996. Despite continuing to see Pettijohn, no further PSA checks were done. Peterson explained that he intended to do one at the next annual physical exam.

Pettijohn self-referred to a urologist in 1998 for a kidney stones checkup. The urologist also did a routine PSA test that was abnormal. The cancer was found a short time later and the prostate was surgically removed. By that time, the cancer was no longer confined to the prostate. The verdict is believed to be the largest verdict in King County against a doctor, and the county's second largest medical malpractice verdict. ■

Indemnification doubled for warming systems

Eden Prairie, MN-based Augustine Medical has doubled indemnification coverage to $500,000 for clinicians who properly use its Bair Hugger therapy in conjunction with the Ranger blood/fluid warming system. The original indemnification program was designed to protect clinicians who use Bair Hugger products up to $250,000. The new program provides malpractice indemnification to clinicians for using both the Bair Hugger and Ranger products. Coverage is effective if the products are used properly during surgery, and there is a judgment of malpractice for allowing a patient to become hypothermic.

"We have expanded this program to support those clinicians who practice the standard of care and ensure that every surgical patient is safe and warm. We are absolutely confident that using Bair Hugger blankets in conjunction with the Ranger blood/fluid warming system will maintain normothermia in surgical patients," says **Scott Augustine**, MD, company founder and CEO.

A growing body of medical literature, including eight outcome studies, demonstrates that maintaining normothermia with forced air warming significantly improves the outcomes of surgical patients. Augustine says maintaining normothermia (a core body temperature of 36° or higher) in surgical patients not only results in significantly better outcomes for patients, but also results in a $2500 to $7000 reduction in per patient hospitalization costs.

Augustine says the company's decision to expand this program was prompted by recent reference to forced-air warming as the de facto "community standard of care" for U.S. surgical patients. In addition, the increasing body of literature documenting the benefits of maintaining normothermia has brought more attention to the negative outcomes associated with hypothermia. He notes that the issue can be directly related to malpractice risk for physicians. "Perioperative hypothermia can be used as a cause of legal action against clinicians. Bair Hugger therapy represents the standard of care in maintaining normothermia; therefore, we are willing to indemnify clinicians who use our product."

The Bair Hugger Indemnification Program is available free to all operating room clinicians, including surgeons, anesthesiologists, nurse anesthetists, and nurses who register for the program, use Bair Hugger therapy properly, and follow the conditions and limitations of the policy. For more information or to participate in this program, call Augustine Medical at (800) 733-7775 or visit www.augustinemedical.com. ■

Healthcare Risk Management's
Legal Review & Commentary™
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Untimely treatment of preeclampsia leads to death: $1.1 million verdict

By **Mark K. Delegal**, Esq., and **Jan Gorrie**, Esq.
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News: After repeated visits to her obstetrician and the emergency room, a high-risk pregnant woman underwent an emergency cesarean. Prior to and during the delivery, she was not given appropriate care. She developed multiple pulmonary emboli and adult respiratory distress syndrome. She died 11 days after delivering a healthy baby girl. A Philadelphia jury returned a $1.1 million verdict against the hospital and physicians.

Background: The 26-year-old woman, in her 38th week of pregnancy, was diagnosed with high blood pressure by her obstetrician. She had been classified as high risk because she was extremely obese, weighing close to 350 pounds. Her mother had died of preeclampsia, also known as pregnancy-induced hypertension (PIH), while giving birth.

On Dec. 15, 1993, her original due date, the expectant mother went for a routine obstetrics visit. She had all three major symptoms of PIH — hypertension, swelling, and protein in her urine. The OB referred her to a teaching hospital for follow-up tests, including a nonstress test and biophysical profile. At the hospital, her blood pressure was found to be within normal limits, but she was diagnosed with preeclampsia by the hospital's attending resident physician. She was sent home with a prescription for iron supplements and told to return for a follow-up office visit Dec. 22 if she did not go into labor before them. Neither her obstetrician nor any one at the hospital advised her of the risks associated with her condition.

On Dec. 22, the expectant mother told her obstetrician she was having irregular contractions. Though her cervix was dilated 1 cm and 50% effaced, the doctor arranged for her to be induced the following day. Her obstetrician also ordered a nonstress test and urine dipstick to be done at the hospital. Notwithstanding her elevated blood pressure and abnormal dipstick results, the hospital staff neither admitted her nor questioned the obstetrician's instructions to delay inducement until the next day. Hospital staff also did not apprise her of the potential dangers due to preeclampsia.

The next day, instead of being admitted to the labor and delivery room, which was provided for in the hospital's protocols for high-risk pregnant women, she was kept in a waiting room until 9 p.m. During this period, her condition was not monitored, her vital signs were not taken, and routine laboratory studies were not conducted. According to the first nursing note taken on Dec. 23 at 9 p.m., the patient's blood pressure was elevated and she complained of headaches. Despite the resident physician and nursing assessments showing consistently elevated blood pressure readings from that point forward, she was not placed on blood pressure-lowering drugs, essential for controlling

her condition, until 8:40 the following morning — nearly 24 hours after her arrival at the hospital.

At about 11:30 a.m. on Dec. 24, the patient was rushed to the operating room for an emergency cesarean section and her baby was delivered. The baby girl was born healthy. The medical team neither initiated heparin therapy nor placed antithrombin hoses on the patient that might have lowered her blood pressure.

Failure to take such precautions created blood clots in her lungs and the onset of pulmonary edema. The patient briefly regained consciousness following the cesarean section, but her condition soon deteriorated. She was placed on a ventilator to assist with breathing and was transferred to the intensive care unit.

The plaintiffs claimed that her consulting and attending physicians failed to timely diagnose and appropriately treat her multiple pulmonary emboli and again failed to order deep-vein thrombosis prophylaxis in a timely fashion. Her endotracheal tube was also consistently malpositioned. She developed adult respiratory distress syndrome and died 11 days later.

"Management of labor is the most common focal point in obstetrical claims. Settlement is often advised because the protocols designed to avoid unnecessary delays in the case of known high-risk women are simply not followed, and in some instances, such as this case, seemingly ignored."

The plaintiff's estate brought suit against the hospital and physicians for negligence. The plaintiff's expert linked the development of the pulmonary emboli to the failure to treat her preeclampsia in an expedient manner. Prior to the seven-day trial's conclusion, several of the physicians, including the obstetrician who provided prenatal care and attended the delivery, settled for an undisclosed amount. The trial proceeded against the hospital and the jury ultimately rendered a $1.1 million verdict against the hospital and physicians; $200,000 was attributable to the wrongful death action and $900,000 was for the surviving child. The hospital was found 25% liable and the attending physician 75% liable. Of the hospital's share, the jury found the nurses 10% responsible under vicarious liability and the hospital itself 15% responsible under a theory of corporate negligence. In this jurisdiction, there can be a finding of corporate liability if the hospital fails to uphold any one of the following duties: a) to use reasonable care in the maintenance of safe and adequate facilities; b) to select and retain only competent physicians; c) to oversee all persons who practice medicine within its walls as to patient care; and d) to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the patients. The hospital was specifically found not to have provided sufficient oversight of all persons who practiced medicine at the facility because the staff nurses and residents did not recognize and / or report the patient's abnormal conditions in a timely fashion. The failure by staff to report changes in the patient's condition and / or question the physician orders that were not made in accordance with those changes were found to have been indicative of the hospital's negligence. In its defense, the hospital merely averred that the finding of corporate liability was not warranted under the law or the evidence.

What this means to you: "Protocols and procedures can be a risk manager's best friend, but can become their worst enemy if not adhered to and followed," states **Cliff Rapp**, vice president of risk management at FPIC Insurance Group in Tallahassee, FL. Protocols and procedures can be great tools for guiding health care practitioners on patient care, particularly when facilities have to do more with less staff. However, if something goes awry, plaintiffs' lawyers will go to great lengths to see if you have broken your own rules. This case presents an example of how damaging the failure to employ one's own policies, procedures, and protocols can be.

"When the patient first presented to the hospital on Dec. 15th, she clearly met criteria for being not only 'high risk' in terms of her obstetrical profile, but also 'at risk' given all clinical indices. The patient was at term, exhibited pregnancy-induced hypertension, and other symptomatology that was classically preeclamptic. She clearly needed to be admitted and delivered; and had the established protocols been followed, this would have occurred," Rapp says.

"It is difficult to imagine that any defense offered could overcome the fact that once the patient was finally admitted to the hospital seven days later than one might have expected, she essentially went untreated and unmonitored

for another 14 hours. In direct conflict with established policies and procedures, the patient languished in the wrong waiting room. Once an assessment was finally made, it is clear that the patient's condition had progressed to the fulminate stage and her blood pressure was out of control. Unfortunately, the delay in the delivery, without any antihypertensive treatment whatsoever, was allowed to occur despite the established treatment protocols begging a different course of action. This eventually led to the development of pulmonary edema, which further compromised the situation," notes Rapp.

"What may have otherwise been a defensible case became indefensible. Any potential causation defense relative to the wrongful death aspect of the case was forfeited by the failure to initiate prophylaxis for the prevention of the pulmonary emboli. Not only did the jury apportion liability against the physicians and nurses, but also against the hospital for failing to provide adequate oversight to those health care providers involved in the patient's labor and delivery. The hospital's very protocols were, no doubt, used to reach that decision," he adds.

"Management of labor is the most common focal point in obstetrical claims. Delay in diagnosis and treatment of preeclampsia is a leading factor necessitating settlement of such cases. Settlement is often advised because the protocols designed to avoid unnecessary delays in the case of known high-risk women are simply not followed, and in some instances, such as this case, seemingly ignored. Evaluation and treatment of high-risk obstetrical patients must, at a minimum, be in accordance with established protocols. Protocols are designed for that very purpose. If the protocols are not followed and no clear reason can be provided for such deviation, and an adverse result occurs, watch out for the plaintiff's attorney," concludes Rapp.

Reference

• Jackie P. Whittington, administratrix of the estate of Claudette E. Milton, deceased, and Kadijah Nicole Woods, individually, in her own right vs. Episcopal Hospital, et.al. No. 1858, Philadelphia County (PA) court of Common Pleas. ■

Disfigured hand: $800,000 verdict

News: A woman alleged that a staff nurse failed to properly monitor and discontinue her intravenous (IV) line after she complained of pain and discomfort. IV fluid leaked into her tissue, resulting in full-thickness skin loss, requiring eight subsequent surgeries and eventual disfigurement. A jury awarded $800,000 in damages against the hospital.

Background: With 25 hospitalizations for renal disease behind her, the 24-year-old patient alleged that during a hospitalization the nurse overseeing her care failed to properly monitor her IV line. Shortly after the nurse placed the IV line, the patient said she told the nurse that she was experiencing minor discomfort, pain, and swelling at the site of insertion. The IV infusion contained a vesicant-like product that was known to cause severe burning if infiltration occurred. Over the next two hours, the patient's hand swelled to double its normal size, and she suffered extreme extravasation before the nurse finally removed the line. As a result of the fluid entering her tissue rather than remaining in her blood vessels, the patient suffered full-thickness skin loss in her nondominant left hand. The injury to her hand required eight subsequent surgeries, including groin flap, skin grafts, and joint manipulation.

The plaintiff claimed the IV line should have been checked by the nurse every 20 minutes instead of every two hours based on the type of infusion material being administered. The plaintiff maintained that if the IV line had been properly monitored or if her had complaints been responded to in a timely manner that the line would have been removed sooner and the damage to her hand avoided or minimized.

The defendant hospital countered the allegations. The nurse testified that the patient had not complained about the IV line and that the site had been properly monitored. Nursing notes in the medical record indicated that the site had been monitored at least once per hour and that no problems had been detected until the infusion was complete. At trial, her kidney transplant surgeon testified that she could live a full and normal life.

The jury awarded the plaintiff $800,000.

What this means to you: "It stands to reason that any situation involving a high-risk transplant patient should be handled with increased vigilance, and that monitoring the IV line once per hour was simply not enough," says **Ellen L. Barton**, JD, CPCU, a Phoenix, MD-based risk management consultant. In this instance, you have a patient who has been hospitalized more times than her age receiving potentially caustic IV material. Using either factor and certainly the combination, it seems that the patient should have been deemed high risk and treated accordingly.

"While we will probably never return to the high nursing staff-to-patient ratios of the '70s and '80s, training, education, and documentation can be properly employed to cover some of the decrease in nurse-to-patient ratios. In this case, there seems to be an issue of clinical competence regarding both the initial placement of the IV line and subsequent monitoring of the site. Practice might address the issue of IV placement technique. However, even with poor placement, training and education on the need for sufficient monitoring would have likely mitigated the poor outcome. At $100,000 per additional surgery, a little more monitoring might have gone a long way to avoid the injury and the damages," says Barton.

While the patient testified that she reported her discomfort to the nurse, the medical record is completely absent of the patient's comments.

"In general, to rely solely on the patient's assessment of their condition will not necessarily give you the clinical evaluation needed to address their medical condition. First, any given patient might have a high tolerance or conversely low tolerance to pain. And second, the patient may not display the classic symptoms. This may make the clinician's judgment equally, if not more, important to determining what has transpired with the patient.

"However, if the patient has a lengthy medical history, such as this transplant patient, their personal assessment may carry additional weight. Repeatedly hospitalized patients with chronic illnesses are more prone to be familiar with their own condition and more experienced with medical care. Regardless of what the patient's background may be, the patient's comments or lack thereof should be noted in the medical record. Otherwise, one stands to create 'he-said / she-said' situations between the patient and health care providers, and the jury tends to side with their patient peer," adds Barton.

"Repeatedly hospitalized patients with chronic illnesses are more prone to be familiar with their own condition and more experienced with medical care."

"More often than not, one nurse is charged to cover all aspects of several patients' care. This makes education, training, and experience with patients' sensitivities and documentation of such essential. In this instance, the patient was probably very familiar with the setting and procedure, and it seems that she attempted to communicate her discomfort with the IV line. Based on the outcome and need for additional surgeries, she just might have been right, but it seems that no one was listening," notes Barton.

Reference

• *Sherry Sinclair vs. Rush-Presbyterian-St. Luke's Hospital,* No. 95L-6274, Cook County (IL) Circuit Court. ■