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Health reform will bring more risks and compliance concerns

Act includes new provisions aimed at fraud and abuse

The Patient Protection and Affordable Care Act (PPAC), recently signed into law by President Obama, will affect many areas of concern for risk managers. Sorting through the lengthy and complex law will take some time, but it already is apparent that there are provisions that received little or no attention during the health care reform debate but which could create new compliance obligations and exposures for health care providers.

PPAC will have a big impact on providers separate and apart from expanding access to health insurance, says **Gina Kastel**, JD, a partner with the law firm of Faegre & Benson in Minneapolis. She is analyzing the provisions buried in PPAC and finding that there are many important changes that were not publicized.

"Enhancing laws designed to prevent waste, fraud, and abuse was a top priority as a means to cut federal health care program costs and find new revenue to pay for the legislation," Kastel says. "Risk managers can expect the trend toward increased enforcement will continue to grow."

She suggests risk managers pay attention to the following issues, which are not hitting the general news headlines:

• The act includes significant new fraud and abuse prevention provisions. The White House summary of the legislation and president's pro-

EXECUTIVE SUMMARY

The health care reform act recently signed by President Obama includes little-known provisions that will pose new risks for health care providers. Risk managers should study the act to determine how their organizations will be affected.

- Some effects may not be clear for months or even years.
- The act increases funding for fraud prevention.
- Compliance programs will be mandatory.

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posal stated: "The House and Senate health reform bills contain an unprecedented array of aggressive new authorities to fight waste, fraud, and abuse. The President's proposal builds on those provisions by incorporating a number of additional proposals that are either part of the administration's FY 2011 Budget Proposal or were included in Republican plans."

• Congress put its money where its mouth was on fraud prevention. The act increases funding for the Health Care Fraud and Abuse Fund by $250 million over 10 years.

• Compliance is becoming compulsory. All Medicare providers and suppliers will be required to implement compliance programs as a condition of enrollment. The U.S. Department of Health and Human Services (HHS) will be required to establish the elements of a compliance program for the various types of providers. "This provision should help level the playing field among health care providers, who have taken the time and trouble to make compliance a priority, and their competitors, who may not have done so," Kastel says.

• New providers and suppliers face new barriers when enrolling in federal health programs. For example, HHS will have to screen new providers and suppliers who wish to bill Medicare. Depending on the perceived risk of waste, fraud, and abuse for the category of provider, the screening may include criminal background checks, fingerprinting, unannounced site visits, database checks, or other measures the secretary deems appropriate. Also, the secretary is instructed to establish procedures to provide a provisional period of 30 days to one year in which new providers of medical or other items or services would be subject to enhanced oversight, such as prepayment review and payment caps.

• The act enhances the amount of civil monetary penalties that can be imposed for various legal violations. Some of the circumstances in which those penalties can be imposed also have been changed.

• The legislation continues the recent trend of frequent changes in the federal physician self-referral (Stark) law. One potentially helpful change requires the Secretary of Health and Human Services to develop, in consultation with the Office of Inspector General (OIG), a self-disclosure protocol for providers who violate the Stark law. In 2009, OIG announced it would no longer permit providers to self-disclose Stark violations that did not also involve a genuine federal anti-kickback violation. That left providers with technical violations of the Stark law in a quandary, as there was no clear mechanism to disclose violations of the statute. The act also permits the secretary to compromise fines and penalties related to Stark violations.

"These changes should help providers address Stark violations more efficiently and avoid disproportionate penalties for minor Stark infractions,"

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Kastel explains.

Another change to the Stark law impacts physicians who provide certain imaging services, relying on the Stark exception for in-office ancillary services to offer them without violating the prohibition on self-referrals.When those physicians make referrals for the services, they will have to inform their patients in writing that the patients could obtain the services from another provider and give the patient a list of other providers offering the service in the area where the patient resides, Kastel says.

The act also will severely limit the ability of physicians to own specialty hospitals by restricting the whole hospital exception under the Stark law. There are grandfather provisions for existing physician-owned hospitals, but their ability to expand or add new investors will be curtailed, she says.

• There are a number of new transparency provisions. These include provisions that require reporting concerning prescription drug samples and financial relationships between physicians and medical device and drug manufacturers.

• The legislation expands the Medicaid program — the Recovery Audit Contractor (RAC) program. Under this program, federal contractors currently have the power to audit Medicare providers and recover a portion of any overpayments they discover in the process.

Some effects not yet clear

Risk managers should start now with efforts to fully understand PPAC and its implications, advises **Christine G. Leyden,** RN, MSN, vice president and general manager for client services, and chief accreditation officer with URAC, an independent, nonprofit organization in Washington, DC, that promotes health care quality through its accreditation and certification programs.

"Hospitals and health care providers need to be aware of the resources available to them, such as the [U.S. Department of] Health and Human Services (HHS) web site, and their state department of insurance, which should be closely monitored by risk managers as various elements of the health care reform legislation roll out over the next several years," Leyden says. "Risk managers will need to identify changes with the time frames of the associated regulations from the new laws governing commercial insurance and the establishment of state qualified health plans. Otherwise, they will severely limit benefits of increased access to preventative health services and coverage to patients and consumers in the commercial sector."

Leyden says internal communication and collaboration will be a key component to achieving successful reform implementation. Risk managers need to talk to their corporate counsels about when certain changes go into effect, and they should evaluate existing contracts and the organization's market share analyses, she says. This will ensure that the organization is well positioned for compensated care arrangements with respect to the numerous phase-ins in health care reform.

Many of the other effects from PPAC may not be known for some time, suggests **J.R. Thomas**, president and CEO of MedSynergies, a company based in Irving, TX, that provides business services to health care providers. The law will bring many changes to the health care system in terms of access, payment system, and cost, he says.

"I don't believe we will know the impact of these actions for 12 to 18 months because of the jurisdictional fights between state and the federal governments and agencies or who will do what," he says. "I expect companies will take strict approaches to their health care insurance by reducing the benefit and increasing the price in anticipation. The mandated health insurance requirement will pose an adverse financial impact on the core, working middle class of this country, against the illegal immigrant who does not have to buy insurance, and it will act as a stimulus to employers to move jobs offshore, so they won't be subject to such mandates."

From the perspective of the health care business, there are a lot of absolutes, Thomas says.

"The fragmentation between hospitals and physicians cannot exist under this environment. There is margin pressure and technology pressure. There is no national technological infrastructure to achieve a measurement of quality health care in this country today," he says. "With the margin pressure that is coming, without fixing the sustainable growth rate or paying doctors, there won't be any money generated, and funding will have to come from outside. If banks aren't making loans to health care providers for these long-term assets, from where will it be funded?"

Thomas makes these additional observations about PPAC:

• Taxes will increase to cover health care, because Medicare and Medicaid are underfunded.

• Patients will pay more of their health care expenses out-of-pocket in terms of premiums and cost.

• Margins from hospitals and physicians' prac-

tices are going to decline.

• Capital expenditures for new technology will be required, but, without a viable bank marketplace, the source of those funds will be very difficult to find.

• There is a major difference in regard to quality and access to health care between a patient, medical provider, payer, and employer. Until these four groups have established a commonality in the view of quality of health care, nothing substantial will be achieved in terms of quality health care.

• The cost of collections is too high today at 15% of the benefit. This bill doesn't address any of those concerns and issues.

• It is not clear today who will administer, execute, and make this bill and the provisions within it operational, because it crosses CMS, IRS, and Health and Human Services, both at the federal level and the state government level. The jurisdiction over these functions is unknown.

• It does not appear that we will see significant reduction in medical malpractice, liability, or compliance liability.

"In fact, due to regulation and the oversight from multiple agencies at this point, you can assume the risk management for these functions will be more expensive, more time-consuming, and will not add to the quality or reduce the cost of health care delivery in this country," Thomas says.

Corporate-funded and commercial insurance are at risk in this arena, he says. There is a high probability current health insurance plans, such as PPO plans, will be extinct in 24 to 36 months, he believes. There will be opportunities for new insurance programs, however, as the majority of people will move to the federal plan and high-income individuals will buy additional plans above the federal coverage.

"It is extremely unclear whether having more insured people translates into more net revenue for under-funded hospitals in certain marketplaces, because of the indexing of the downward pressure of Medicare funding, which may have to be cut, and the indexing of commercial plans to Medicare," Thomas says. "While you picked up 20% on uninsured, the money may not offset the reduction on Medicare rates and the reduction in corresponding indexing due to commercial insurance. Where are you as a provider? The answer is: No one knows." ■

SOURCES

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Accreditation records can be released

Risk managers expect accreditation records to be confidential, and The Joint Commission (TJC) urges providers to fully disclose information about adverse events and deficiencies as part of the quality improvement process. But some risk managers are learning that those records are not as private as often thought.

A recent court case in Kansas was an eye-opener for those who assumed that accreditation records could not come back to haunt them in a civil or criminal investigation. The Headache & Pain Center in Leawood, KS, is under investigation for alleged federal offenses, and a federal prosecutor was able to access the organization's Joint Commission accreditation records, explains **Robert Guenthner**, JD, a partner with the law firm of Sonnenschein Nath & Rosenthal in Chicago, who has studied the case. The Joint Commission in Oakbrook Terrace, IL, resisted the prosecutor's request at first, stating that Illinois law prohibited the release of the information.

EXECUTIVE SUMMARY

A recent court case has risk managers concerned that accreditation records may be released by The Joint Commission and used against health providers in civil actions and criminal investigations. The records are not often released, but they can be in certain situations.

• The records may reveal past deficiencies that can be used against the provider.

• Corrective action must be thoroughly documented.

• Records are most likely to be released for federal fraud investigations.

The prosecutor obtained a court order from a federal court, and The Joint Commission complied. However, TJC convinced it to redact some sensitive information, such as patient names and all communication related to sentinel events. The order also included strict limits on the dissemination of the information, Guenthner explains.

The Joint Commission did not respond to a request for comment, but explains on its web site that certain information is kept confidential, while other, less sensitive data can be released to certain parties. *(See p. 54 for an explanation of what material is confidential.)* The Headache & Pain Center did not respond to a request for comment.

Federal law wins

Though such a court order is rare, the case nevertheless has prompted concern that accreditation records are not completely confidential. Guenthner says federal law trumps the Illinois peer review statute that TJC relies on to refuse records requests, but even then, TJC requires a federal court order, not just a subpoena.

"This is not a situation we have seen regularly, but this case in Kansas is getting some attention, and that may make the government more interested in using this approach," he says.

When TJC, or any other accrediting body, turns over records about a health care provider, there is substantial risk, says **Anthea Daniels**, JD, a partner with the law firm of Calfee, Halter & Griswold in Cleveland.

"If the prosecutor wants to show that you were aware of a particular issue and should have corrected it, those accreditation records can be extremely useful," she says. "They can say that a year ago you were informed by the accrediting body that [you] were not meeting the standard, and because this [is] from the group that is the final word on what is and isn't OK in health care, it is very hard to refute that. They have evidence that you were in the wrong — and that you knew it."

The situation becomes worse if the prosecutor can show that you did not address the issue. As with any internal records, the provider is in a bad spot if the records show you were put on notice of a defect and did not take corrective action.

"You want to be able to say yes, you were informed of the deficiency and be able [to] show that you corrected it immediately," she says. "If you can show that you addressed it right away, that lessens the impact quite a bit."

Guenthner notes that TJC usually notifies the provider when prosecutors or plaintiffs request accreditation records, so he says risk managers should be prepared for that call and have a response plan.

"Work with your own counsel to minimize the disclosures, because if there is a federal court order, you're not going to be able to stop the release of the documents," he says. "The best you can do is to see that certain sensitive information is not included."

Accreditation records could be sought under a False Claims Act case, says **Sara Kay Wheeler**, JD, a partner with the law firm of King & Spalding in Atlanta. For instance, prosecutors may allege that the service that was provided was of such poor quality that it should not have been billed.

"In that case, they may seek underlying documentation to show that the level of care was insufficient and that you knew that because you had been told by the accreditation agency," she says. "If they get access to those records, they can make a convincing case that you knew you shouldn't have billed for that care."

Civil cases not a concern

The Kansas case is a reminder that risk managers should consider the possible release of information whenever they provide sensitive material to anyone outside the organization, whether it is TJC, a state agency, an outside auditor, or a contractor, she says.

"The Joint Commission probably provides the greatest level of confidence with regard to confidentiality, but you have to consider the risk any time you're handing over proprietary information, potentially damaging data, or anything you would rather not have in a prosecutor or plaintiff's attorney's hands," she says. "Ask yourself how much you can depend on their confidentiality before you hand it over."

Andrew P. Gaillard, JD, a partner with the law firm of Day Pitney in Stamford, CT, notes that the Kansas case is an example of the most likely situation in which accreditation records would be released. Headache and pain treatment centers are prime targets for criminal investigations related to billing fraud, and accreditation records are most likely to be released in criminal cases rather than civil, he says.

"It has to be a broader investigation than the typical type of case where they look at bill-

ing records and talk with employees," he says. "They're not going to seek accreditation records unless they are looking very deeply into the provider's past activities."

Gaillard says federal prosecutors will almost always be able to get the accreditation records if they want them, but he says risk managers do not have to worry about the records being released in civil matters, such as a malpractice case.

"In any run-of-the-mill civil malpractice case, the accrediting body will be able to maintain confidentiality of those records under state law," he says. "You don't have to worry about plaintiffs' attorneys digging through your accreditation records for every routine malpractice case." ■

SOURCES

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RCA, other sensitive data kept confidential

The Joint Commission (TJC) states that this information received or developed during the accreditation process will be kept confidential:

• The Official Accreditation Decision Report, unless its submission is required by a government agency; is required by organizations with which TJC performs coordinating surveys; or is requested by an accrediting body with which TJC has a formal agreement;

• information learned from the organization before, during, or following the accreditation survey, which is used to determine compliance with specific accreditation standards;

• an organization's root cause analysis prepared in response to a sentinel event or in response to other circumstances specified by TJC;

• all other materials that may contribute to the accreditation decision (for example, medical records, surveyor notes);

• written staff analyses and Accreditation Committee minutes and agenda materials;

• the algorithms used in the Priority Focus Process;

• the Priority Focus Process information used in an organization's survey, other than that provided to the organization's staff prior to survey;

• an organization's self-assessment and related Plan(s) of Action;

• the identity of any individual who files a complaint about an accredited organization, except when the complaint is shared by TJC with a governmental entity, an organization with which TJC performs coordinated surveys, or accrediting organizations with which TJC has formal complaint-sharing agreements and the receiving organization has agreed to maintain the confidentiality of the complainant. In instances in which the receiving organization cannot assure the confidentiality of the complainant, any complainant-identifying information shall be redacted by TJC prior to sharing.

For more information on what information can be released by TJC, go to http://www.jointcommission.org/AboutUs/Fact_Sheets/08_pip.htm. ■

Document release could chill quality improvement

If providers worry that The Joint Commission (TJC) will release their accreditation records to prosecutors, they may become reluctant to share sensitive information with the accrediting body, cautions **Vickie Patterson**, an associate director in the Atlanta office of Protiviti, a risk consulting firm.

She says the federal government is focusing much more on health care investigations now, and she suspects TJC and other accrediting bodies may be forced to release records more often in the future.

"In the growing trend of transparency in health care operations, this is just another example of quality issues and remediation being made available to the public," she says. "One problem is that this exposure creates is that hospitals may see a

decrease in reporting and documenting of errors and corrective actions. The accreditation process initially was created to be educational for the organization, in addition to creating a certification process. The Joint Commission has continually tried to create an environment where the facilities felt they could learn and improve from the accreditation process, rather than it being punitive. Having records made available for investigations and prosecutions could result in organizations being less open and hindering the accreditation process."

Even though it is uncommon for accreditation records to be released, Patterson says providers are increasingly aware of the possibility, and she fears it will create a reluctance to fully report quality issues.

"My concern is that facilities may be less apt to report, because it can be held against them," she says. "Risk managers have to reinforce the message that you want full reporting and you have to be diligent about responding fully and quickly to any issues. You need to be able to show that when you were made aware of it, you addressed it immediately and then monitored for any recurrence." ■

SOURCE

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Radiology risks center on communication

In radiology, the real malpractice risk begins after the technicians have performed the imaging study and the doctor has interpreted the results. It's what happens to that information from that point on that usually determines whether a lawsuit will result.

Radiology malpractice is most often tied to communication issues rather than alleged flaws in conducting or interpreting the imaging study, notes **Robert Russo**, MD, FACR, a radiologist in Bridgeport, CT. He runs six imaging centers in southern Connecticut, and his practice is the only Joint Commission-approved full radiology system in New England. Plaintiffs also claim that radiologists missed a diagnosis, but failing to communicate results is a particular risk for radiology, because the physician is not the patient's primary caretaker.

"We have a responsibility to communicate our report to the patient's primary or referring physician, and that gap is really where the improvements can be made in risk management," he says.

Jeffrey Kimmel, JD, a partner with Salenger, Sack, Schwartz & Kimmel LLP in New York City, is a plaintiff's attorney handling malpractice cases, and he has litigated several cases of failure to diagnose breast cancer. He agrees that communication is the most common issue.

"Whether it's communicating with the patient or the referring doctor, it always seems that someone dropped the ball in conveying what was found and whether or not it was urgent, needed follow up, how much follow up was needed, whether more views were needed," he says. "The communication practices vary from office to office, and people rely on these imperfect methods of communication — a fax, an e-mail, a letter — and don't follow through to make sure that the information got to the right person."

EXECUTIVE SUMMARY

Malpractice risks in radiology primarily involve poor communication of test results rather than interpretation of the study. Risk managers should ensure that adequate systems are in place to avoid results being miscommunicated.
- Communication standards are available.
- Patients may have too much faith in mammograms.
- Automated systems can decrease some risks.

Follow the standards

The American College of Radiology has standards that specifically address how imaging results must be communicated. *(For the standards, go to http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/comm_diag_rad.aspx)* One of the key points in the standards is that the communication of critical results, such as a cancer finding, must be from doctor to doctor. Critical results require the radiologist to call the other doctor by phone, in addition to sending a full report.

"What a risk manager can do is to set up a system that meets those standards from the college, a system that ensures those results are reported every time and that sets off an alert if anything is about to be overlooked or slip through the cracks," Russo says. "There are commercially available systems that keep a log to track all the communication, which keeps you from forgetting to do something, but also creates a detailed documentation of how and when you met the communication standards."

(See p. 57 for examples of how radiology results can be miscommunicated.)

In a presentation on malpractice risks at the recent meeting of the Radiological Society of North America in Chicago, **Robert Albert Schmidt**, MD, a professor of radiology at the University of Chicago Medical Center, said most radiologists have not read the American College of Radiology standards.[1] "If you don't know what's there, guess who reads these things," he said. "Lawyers. Lawyers read these things all the time."

Schmidt pointed out that radiology malpractice cases, while still relatively uncommon, are growing as a percentage of all malpractice cases. In 1990, radiology cases made up 11% of all malpractice cases, Schmidt says. But that figure rose to 24% in 1995 and 33% in 2002.

Schmidt says part of the increase can be attributed, ironically, to the health care community's successful promotion of mammograms. The public has been convinced that mammograms are a near perfect screening tool for breast cancer, he says, so people are quick to file a lawsuit if a woman gets breast cancer after mammography.

Hospitals at risk

Peter Hoffman, JD, an attorney with the law firm of Eckert Seamans Cherin & Mellott in Philadelphia, points out that the same communication failures can occur within a hospital setting. Patients who come in for preoperative imaging studies or those who undergo testing during emergency care are at the same risks if those results are not properly conveyed, he says.

"There can be a real risk in the emergency department, because you sometimes have people leave before the radiologist can read the results, and if it is a critical result, then that person is gone — and you may not able to find him again," he says. "There also is the problem of outsourcing, in which the image is sent to a firm somewhere else in the world when you don't have a radiologist in-house all the time. That company's communication policies can make or break you."

Premature discharge of emergency department patients can increase the risk for radiology malpractice, cautions **Edward Carbone**, JD, an attorney with the law firm of Buchanan Ingersoll Rooney, in Tampa, FL, who has represented hospitals for 14 years. Although the hospital should have a reliable methodology for contacting that patient when the imaging results are read, the reality is that it becomes more difficult to communicate the results after the patient walks out the door, he says.

"When communication is so critical to this process, you will always be better off streamlining the communication as much as possible," he says. "When you have a choice, opt for the more direct line of communication rather than relying on trying to track down the person later."

Radiology also is getting closer scrutiny from federal regulators because of recent incidents in which patients were overexposed to radiation. *(See p. 57 for more information on that initiative.)*

Jeffrey Kroll, JD, an attorney in Chicago, says radiologists can be targeted in a lawsuit when there is a bad outcome, because they are seen as the last line of defense. They also can be accused of failing to conduct follow-up tests to ensure an accurate diagnosis, which the ACR standards say they should be done "when appropriate."

"That's where we get hung up on some of these cases," Kroll says. "People will argue about what is appropriate, and unfortunately, we see the referring physician pointing fingers at the radiologist, saying he was relying on what the radiologist told him. The radiologist can be left holding the bag."

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SOURCES

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Watch for these common radiology mistakes

Robert Russo, MD, FACR, a radiologist in Bridgeport, CT, advises risk managers to watch for these common ways in which radiology findings can fall through the cracks and never be reported:

• **Patient names are mixed up.** If a family is being treated by the same doctor, for instance, the report on the wife's CT scan can be put in the husband's file. Or if the patient's name is similar to another patient in the computer system, the findings may be reported to that person's doctor. When that doctor gets the report for someone who is not a patient and for a test that wasn't ordered, it may be ignored. The radiologist never knows that the report went to the wrong doctor.

Electronic medical records and automated filing systems will lower this risk, Russo says.

• **The patient provides the wrong doctor's name.** When asked for the primary physician or to whom the results should be sent, the patient may provide the wrong name for various reasons. The patient may have several doctors or may have changed physicians recently. The risk is higher when physicians with the same last names — spouses or father and daughter physicians, for instance — work in the same practice.

"Sometimes the patient says Dr. Jones, and we may assume they mean the Dr. Frank Jones that we get many referrals from. Our staff puts that down and asks the patient to check everything and confirm that it's correct, but they don't catch the error either," he explains. "So, the report goes to Dr. Frank Jones instead of Dr. Emily Jones."

• **The radiologist does not follow up on messages.** Getting in touch with the other physician to communicate results can be difficult, and it is common for the radiologist to have to leave multiple phone messages and send e-mails asking the doctor to call. With a busy practice, it can be easy for the radiologist to lose track of who has completed the loop and who hasn't. A formal tracking system, preferably automated, is required to avoid this error, Russo says.

• **A patient misses an appointment.** The radiologist must have a system in place for notifying the referring physician if a patient does not show up for a scheduled test. If a patient is referred for a chest X-ray because lung cancer is suspected but then never shows up, the referring physician may never realize it if that office has no reminder system in place. Russo's radiology practice always calls the referring physician to report that the patient did not show up or cancelled a requested study. ■

FDA increasing oversight of radiology

The federal Food and Drug Administration (FDA) in Washington, DC, announced recently that it will strengthen its oversight of three of the most potent forms of medical radiation, including computed tomography (CT) scans.

The announcement came after an FDA investigation into why more than 200 patients in four hospitals received excessive radiation exposure from CT scans used to detect strokes over an 18-month period. Patients at Cedars-Sinai Medical Center in Los Angeles, where the overdoses first came to light in 2009, received up to eight times as much radiation as intended. No one knew the patients had received such high radiation exposure until some patients lost their hair.

The FDA said in its announcement that it hoped to reduce unnecessary radiation exposure from three of the most popular medical imaging procedures: CT scans, nuclear medicine studies, and fluoroscopies. *(For more information on the FDA initiative, go to http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199904.htm)*

"These types of imaging exams expose patients to ionizing radiation, a type of radiation that can

increase a person's lifetime cancer risk," the FDA said. "Accidental exposure to very high amounts of radiation also can cause injuries, such as skin burns, hair loss and cataracts."

The agency said it is considering several moves to reduce the risk. For starters, the FDA may require manufacturers of CT scanners and fluoroscopic devices to incorporate new safeguards into the design of their machines that would prevent incorrect radiation settings or alert the user to an input error. Medical personnel training might have to be improved, and the FDA may require that devices capture and transmit radiation dose information to a patient's electronic medical record and to national dose registries.

The changes will have teeth. The FDA is planning to ally with the Centers for Medicare & Medicaid Services (CMS) to incorporate new safety practices into the accreditation process of imaging facilities and hospitals.

Much of the radiology community supports the enhanced oversight and safety improvements. The Medical Imaging and Technology Alliance, an association of manufacturers of radiological equipment based in Arlington, VA, issued a statement supporting the FDA action. The group went on to endorse mandatory accreditation of advanced imaging facilities and minimum standards for personnel who perform medical imaging exams and deliver radiation therapy treatments. The American Society for Radiation Oncology in Fairfax, VA, called for a central database for the reporting of radiation errors. ■

Tread carefully when reprocessing SUDs

Reprocessing of single-use devices is becoming increasingly popular among U.S. health care organizations, which are drawn to the potential cost savings and, more recently, the effort to go green by reducing waste. But do those benefits bring liability risks?

They can if the reprocessing program isn't set up and monitored properly. But careful attention from the risk manager can keep those risks to a minimum and should not dissuade health care providers from adopting this strategy, the experts say.

Reprocessing has been around for decades and was much more controversial years ago, when no one was certain about the safety of using reprocessed instruments and the potential liability if they led to patient harm. Now much of that doubt has been cast aside, and a recent commentary in *Academic Medicine* received attention for calling on providers to adopt reprocessing more widely as a way to go green.[1] The authors of the commentary, from the Johns Hopkins University School of Medicine in Baltimore, pointed out that more than 25% of U.S. hospitals are using reprocessing as a means of decreasing the tons of disposable waste generated annually. In 2008 alone, there was a 20% increase in hospital utilization of reprocessing services offered by one leading reprocessing service, and associated cost savings of $138,142,000 nationwide. This represented 4,300,000 pounds (2,150 tons) of medical waste diverted from local landfills, they noted.

The authors also concluded that research has shown that reprocessed medical devices do not present an increased health risk when compared with new devices, though they call for further research. (*The commentary is available online at no charge. Go to http://journals.lww.com/academicmedicine/Fulltext/2010/03000/Commentary__A_Call_to_Go_Green_in_Health_Care_by.10.aspx)*

The cost savings can be substantial. Ascent, a leader in the reprocessing of medical devices in the United States, based in Phoenix, announced recently that its hospital partners realized hundreds of millions of dollars in cost savings in 2009. On a per-hospital basis, some hospitals saved more than $600,000 per year. Serving 1,800 leading hospitals, Ascent tracks savings realized by its customers year-over-year, and cost savings resulting from Ascent's reprocessing programs were up more than 20% in 2009 and were up more than 50% versus 2007.

EXECUTIVE SUMMARY

Reprocessing of single-use devices is gaining in popularity, partly as a green initiative. Liability risks can be kept to a minimum if the program is structured carefully.

- Reprocessing can decrease waste and save significant money.
- Choosing to reprocess brings some liability risks.
- Outsourcing can reduce liability risks, but not eliminate them.

Members of the VHA health system based in Irving, TX, saved $42 million in 2009 from reprocessing, says **Tina Norris**, senior director of purchased services with VHA. About 600 VHA members reprocess.

Liability was a concern for VHA from the start, Norris says. Though VHA believes reprocessed instruments do not pose any risk to patients, she says it was important to structure the contract with the reprocessing vendor so that the hospital was protected if a reprocessing failure led to a claim.

"We dive into the workings and the processes of the supplier," Norris says. "We want to see that their quality assurance is at the highest level, and that they are testing each device as it is finished. We feel confident that the process our supplier uses is top notch and is safe for our members."

Norris notes that deciding to reprocess is a significant undertaking. It is not as simple as finding a reprocessing vendor and starting to send equipment out. The program must be monitored closely for quality controls, she says.

The question of patient safety has been minimized but still exists from a legal standpoint, says **Angela Nolan Clarke**, JD, an attorney with the law firm of McGlinchey Stafford in Houston.

"Reprocessing has been shown to be safe for patients based on what we know to date," she says. "That's where it gets tricky. If I were sitting down with a risk manager, I'd say you need to decide whether you want to do it at all. But the next question is what devices do you want to reprocess, because the challenges and the risks can be different."

There are three classes of devices that are reprocessed, and Clarke says that she advises caution with Class III items, because they have the least amount of research showing them to be safe when reprocessed.

"You'll feel more comfortable about Class I and Class II devices, but it can be a leap to reprocess Class III," she says. "You might not feel as comfortable there, and for good reason."

Many hospitals outsource the reprocessing, partly in hopes that such an arrangement would insulate the provider from liability related to the reprocessing, notes **Richard Law**, JD, also an attorney with McGlinchey Stafford in Houston. That probably is not the case, he says.

"It's not likely that you would be completely protected, but you would have the ability to go back after the reprocessing company and show that they were not in compliance with government regulations and meeting the standards for reprocessing," Law says.

Clarke says it is very important that a reprocessing program include an adverse event reporting process. Any adverse events that could be related to the reprocessed items must be reported and thoroughly documented, she says.

Law also points out that there has been some debate over whether to get informed consent from the patient before using a reprocessed item. Law says risk managers must decide whether patients will be asked for permission, but be prepared for many of them to decline.

"I don't think most patients would care much if you didn't say anything, but once you ask them you have to be prepared for a lot of them to say no, they want a brand new item if they have a choice. That's going to affect your cost savings in the long run," Law says.

REFERENCE

1. Kwakye G, Pronovost PJ, Makary MA. A call to go green in health care by reprocessing medical equipment. *Academic Medicine* 2010; 85:398-400. ■

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 health care for hospital personnel to use in overcoming the challenges they encounter in daily practice.

COMING IN FUTURE MONTHS

- RAC audits to increase
- Best practice for background checks
- Nurses dispensing drugs
- Preventing drug theft by staff

CNE QUESTIONS

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

17. Which of the following is one reason Gina Kastel, JD, a partner with the law firm of Faegre & Benson in Minneapolis, says the Patient Protection and Affordable Care Act (PPAC) should be of concern to risk managers?
A. The act includes significant new fraud and abuse prevention provisions.
B. The act includes sweeping malpractice tort reform.
C. The act levies a tax on accredited hospitals.
D. The act discourages formal compliance programs.

18. What does J.R. Thomas, president and CEO of MedSynergies, a company based in Irving, TX, that provides business services to health care providers think will be the effect of PPAC on health care liability issues?
A. All liability risks will be sharply curtailed.
B. Compliance liability will be drastically reduced but there will be no effect on medical malpractice and other liability issues.
C. It does not appear that we will see significant reduction in medical malpractice, liability or compliance liability.
D. Compliance liability will increase but medical malpractice liability will decrease.

19. According to Robert Russo, MD, FACR, a radiologist in Bridgeport, CT, what is the most common cause of malpractice claims in radiology?
A. Communication failures
B. Improper reading of imaging results
C. Failure to promptly schedule requested imaging
D. Doing the wrong imaging study on a patient

20. What does Angela Nolan Clarke, JD, an attorney with the law firm of McGlinchey Stafford in Houston, advise regarding reprocessing of single-use devices?
A. She advises reprocessing all classes of devices with no reservations.
B. She advises against reprocessing any devices.
C. She advises reprocessing only Class III devices.
D. She advises caution with Class III items because they have the least amount of research showing them to be safe when reprocessed.

ANSWERS: 17. A 18. C 19. A 20. D

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

Survey: Hospitals not up to speed on 'meaningful use'

Only about 52% of surveyed hospitals use encryption technologies

According to a survey released in January by Falls Church, VA-based CSC, only two-thirds of hospitals have identified gaps in their current systems to meet the requirements for meaningful use, as set forth by the Office of the National Coordinator for Health Information Technology, Department of Health and Human Services (HHS). While it is true that the "interim final rule" was not published until Jan. 13, 2010, in the *Federal Register*[1], experts have had a good idea of what "meaningful use" would consist of, at least as early as last spring as HHS issued guidance on the Health Information Technology for Economic and Clinical Health (HITECH) Act passed as part of the American Recovery and Reinvestment Act of 2009 (ARRA).

Additional findings include the following:

- Most hospitals (98%) have a policy in place to limit the disclosure of protected health information, but only 52% employ encryption technologies to render data unreadable or unusable in the case of unauthorized access.
- Smaller hospitals have lower readiness scores, especially for use of required applications and quality reporting.
- 54% are using the latest software version of their electronic health record (EHR) product, which indicates upgrading might be required to meet the criteria for meaningful use.
- Although 89% report on core quality measures, only half capture the majority of the required data from their EHR system.
- Only 40% report that there is clear and broad awareness of the new civil and criminal penalties under the ARRA.

The HITECH standards revealed last spring on privacy and security (especially breach notification) and the attendant penalties for violators garnered the greatest attention among compliance officers and risk managers, and according to CSC hospitals have the highest readiness scores for privacy and security protection. But this is not a time to relax; with the publication of the meaningful use standards required for EHRs, "the other shoe" has now dropped.

Although the privacy and meaningful use standards were not formalized at the same time, they are inextricably linked. Consider this language in the *Federal Register:*

"The health outcome policy priorities identified in the Medicare and Medicaid EHR Incentive Programs proposed rule are: improving quality, safety, efficiency, and reducing health disparities; engage patients and families in their health care; improve care coordination; improve population and public health; and ensure adequate privacy and security protections for personal health information."[1]

Or these comments in the "Privacy and Security Standards" section concerning "certified" EHR technology ("certified" technology is technology that meets the meaningful use standards):

"We believe it is necessary for Certified EHR Technology to provide certain privacy and security capabilities. In that regard, we have aligned adopted certification criteria to applicable HIPAA Security Rule requirements and believe that in doing so, such capabilities may assist eligible professionals and eligible hospitals to improve their overall approach to privacy and security. In addition, some may find that the capabilities provided by Certified EHR Technology may facilitate and streamline compliance with federal and state privacy and security laws. We believe that the HIPAA Security Rule serves as an appropriate starting point for establishing the capabilities for Certified EHR Technology."[1]

In fact, the document goes on to say that the adopted certification criteria "assure that Certified EHR Technology is capable of supporting eligible professionals and eligible hospitals comply with HIPAA requirements to protect electronic health

information residing within Certified EHR Technology and, where appropriate, when such information is exchanged."[1]

What's more, this linkage is a two-way street: The HIT Policy Committee has recommended that CMS and Medicaid withhold meaningful-use payment (the HITECH Act offers incentives for compliance) until any confirmed HIPAA privacy or security violation has been resolved.

In other words, if your facility's EHR is not certified, it may not adequately address the privacy and security aspects of HITECH; on the other hand, if there are HIPAA violations in your facility, you could not only face HIPAA-related penalties, but you also could prevent your hospital from reaping the benefits of meeting meaningful use standards.

Know where you stand

Perhaps the first step towards meaningful use compliance, says **Carlos Nunez**, MD, chief physician executive at Picis, is to develop a realistic approach. This is already happening, he blogged after attending the HIMSS conference. "This year's sessions have revealed that a lot of attendees are more comfortable admitting the reality of the situation; that they are just now . . . understanding the challenges that this will bring," he wrote. "I overheard an IT executive from one of the most prestigious and well-regarded health centers in the world claim, 'If we're not sure that we are going to be ready by 2011 (the Phase I date), I can only imagine what others are facing.'"

Vendors such as Picis "need to approach each hospital partner with an understanding that each one will be in a different state of readiness," Nunez continues. There will never be a one-size-fits-all solution for each step along the way to 2015 (the Phase III date)."

"I'm not at all surprised by the fact that many hospitals find themselves at least partially unprepared," Nunez tells *HRA*. "Up until the latter part of last year, nobody knew what [the government] would do. In December, many of the things they had been expecting had changed, and underneath this, most CIOs were starting to realize there's a lot here, and they're just not sure they can get all the pieces in place."

Allison Viola, MBA, RHIA, director, federal relations for the American Health Information Management Association (AHIMA), agrees that the challenge is significant. "We at AHIMA will be submitting our comments officially, but basically we feel the criteria to achieve full use is extremely aggressive given the nature of what's being required," she says. "There's a lot of manual data collection to report — particularly HIT functionality measures, and we envision that a lot of that work will fall on HIM professionals." AHIMA, she says, "will try to get [the government] to look at alternative options or consider ways to ratchet this down a little bit."

"There is definitely time to identify gaps and become compliant so you can receive the incentives," counters **Erica Drazen**, managing partner, emerging practices healthcare group, for CSC in Waltham, MA. "The question is, how quickly they can they get there? One of the things that are going to happen for sure is there will be a shortage of people to do this — vendor employees, consultants, as well as people in the hospital; that will be a major challenge."

In addition, "They've upped the ante on privacy and security, with requirements like audit trails of all disclosures," says Drazen. "To share information with patients and other providers will be challenging for most organizations, as these reports have not been designed to be read by patients."

How to move forward

Viola says facilities that are not yet in compliance need to get going. "We would encourage hospitals to start getting teams in place, pay attention to what is going on with the whole certification process, and start the dialogue with their vendors — reviewing their contracts and potentially looking at new vendors if the current vendor is not certified," she says. "If you have a hybrid environment and are predominantly paper-based, you probably want to get moving on this, because by 2015 you will start to see a reduction in payments if you do not meet the requirements." As a first step, she recommends "getting a task force or committee together of multi-stakeholders within the hospital or provider organization, and start nailing down what each of these measures mean."

Drazen recommends you review the list of standards and pick out those that have the highest priority. "Also, start negotiating with your vendor; if they are not going to be certified on the same time frame, you're out of luck. You and they have to be certified on a schedule as aggressive as meaningful use. So, for example, you have to be certified for stage II requirements for 2013, so look at your vendor and see if they meet all the requirements for stage I, which would mean they're on course for stage II."

Nunez, on the other hand, questions whether it's better to do the wrong things quickly or the right things slowly. "A CIO told me that one of

the big consulting firms said to him they advised some of their clients not to rush into this, but to do it slowly and deliberately so that you're ready by the time the penalties kick in; you might not get incentives, but at least no penalties," he shares. "I read a study recently that said the average hospital would get between $6 million and $8 million if they met all the requirements — but you could be spending tens or even hundreds of millions in IT projects to get to meaningful use."

A lot depends on the progress you have made to date, he continues. "If as a hospital or a health care system you've been part of a process to implement meaningful use and you've been thoughtful and taken a long-term look at things, then you're probably really close to getting toward meaningful use," says Nunez. "If you're a Mayo Clinic, or a Mass General, if you have integrated systems and an efficient automated work flow, you'll probably get there soon. However, if for whatever reason you've not undertaken it, or have not been successful, or have chosen the wrong vendors, and you're just now really looking at a ramp-up effort, you may not be ready by 2011 or 2013. If that's the case, you may need to take a step back and say, 'Are we rushing for a couple of million dollars, or should we take time and start on a path that makes sense for us and our patients, so at the very least we do not get penalized?'"

If you decide to take what Nunez calls the "baby steps" approach, "at the very least you should look at the roadmap of the Office of the National Coordinator," he recommends. "We know what the requirements are for 2011; and we have some idea of what will be required for 2013 and 2015, although right now the descriptions are at a very high level. To the credit of the Office of the National Coordinator, what they've done really well is spelled out a vision; they say they want to get there in three phases, and they initially set the bar low with incentives to move up to better performance."

In other words, he continues, if you are not in good shape at present, "that first baby step to take is an honest assessment of where you are and where you can be in five years." He recognizes that it is a difficult process. "I've seen so many different hospitals and health systems that have tried to implement systems — some of which were the biggest companies — and they failed miserably, while the very same EHR systems have done very well in other hospitals and health systems. If your hospital is ready, the HITECH provisions of ARRA are laid out, as well as what the measures will be. If not, be honest with yourself about where you are and where you want to be in five years."

REFERENCES

1. Department of Health and Human Services Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule. *Federal Register*: January 13, 2010 (Volume 75, Number 8) [Rules and Regulations] [Page 2013-2047]. ■

Will Medicaid take full advantage of HITECH?

Will funding from the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act (ARRA), propel state Medicaid programs forward with the use of electronic health records (EHRs)? Or will state fiscal crises or other unforeseen problems prevent the hoped-for progress?

The answer probably is a little of both, but efforts are redoubling now that the Centers for Medicare & Medicaid Services (CMS) actually is releasing funds to Medicaid programs.

The HITECH funding "provides momentous opportunities, significant funding, immense expectations, tight time frames, and huge financial and human resource demands on state Medicaid programs, CMS, and Medicaid providers," says **Patricia MacTaggart**, a lead research scientist/lecturer at George Washington University's Department of Health Policy in Washington, DC. "The potential is great for real transformation in health care, health care delivery, and health care administration."

There is 90% federal funding for administrative activities, including oversight and promotion of health information exchange, and 100% federal funding for provider incentives. However, for providers to get incentive payments in 2010 for adopting, implementing, and upgrading certified EHR technology, states must have a process and infrastructure for administering and disbursing the incentive payments to Medicaid providers. At the same time, duplication of payments made through Medicare must be avoided.

States are now sorting through the Office of the National Coordinator's Interim Final Regulation relating to HIT standards, implementation specifications, and certification criteria, and CMS' proposed rule on the Electronic Health Record Incentive Program for Medicare and Medicaid programs, often referred to as the "meaningful

use" Notice of Proposed Rulemaking.

"They are identifying and clarifying numerous governance, legal, policy, technical, and business process complexities, while educating their stakeholders, including governors, state legislators and their own staff, on what must be done, by when, and how many state dollars will be needed," says MacTaggart. "They are balancing doing it quickly with doing it well, and they are doing it with limited staff in an economic environment that is stretched."

As for the proposed meaningful use regulation, MacTaggart says CMS "did a great job of clarifying many things and requesting comments on areas where there is more than one option being considered."

It will be important for states and providers to review the proposed language, understand the terminology, and comment on feasibility related to operational issues, time lines, and interdependencies with other regulations and activities. These include certification and standards of EHRs, and the commonalities and differences between Medicare and Medicaid. ■

HITECH Act timeline

Pay attention to deadlines to ensure compliance

On Feb. 17, 2009, the Health Information Technology and Economic and Clinical Health Act of 2009 (HITECH) was enacted. On that date, tiered civil monetary penalties were put into place for violations following the enactment, and state attorneys general were given the authority to enforce the act.

On Feb, 18, 2010, all business associates were to be compliant with new regulations.

Future deadlines for compliance include:

• **Jan. 2, 2011:** Initial deadline for complying with new accounting for disclosure rules for entities implementing electronic health systems after January 1, 2009.

• **Feb. 18, 2011:** Department of Health and Human Services required to impose civil monetary penalties in cases of "willful neglect."

• **2013:** Extended deadline for older systems to comply with the new accounting for disclosure rules.

Although these are the deadlines published in the initial act, it is important to stay on top of changes and new deadlines, points out **Heather P. Wilson**, PhD, principal, Weatherbee Resources, a Hyannis, MA-based compliance and hospice consulting firm. "Throughout this process, HHS has missed deadlines, and health care providers have found themselves with little time to implement changes." ■

Breach notification process spelled out

HITECH is very specific about actions to take

Although prior privacy requirements called for home health agencies to notify patients when a breach of privacy was discovered, the Health Information Technology and Economic and Clinical Health Act of 2009 (HITECH) specifically identifies time frames and content of notifications.

Once a home health agency discovers a breach of unsecured protected health information, each individual whose PHI has been or is reasonably believed to have been accessed, acquired, used, or disclosed, must be notified no later than 60 days after discovery.

Notifications must include:

• a brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known;

• a description of the types of unsecured protected health information that were involved in the breach (such as whether full name, Social Security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

• any steps individuals should take to protect themselves from potential harm resulting from the breach;

• a brief description of what the covered entity involved is doing to investigate the breach, to mitigate harm to individuals, and to protect against any further breaches;

• contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, web site, or postal address.

All of the notifications must be made in writing, and they must be written in plain language.

The notifications can be mailed or, if the individual has approved electronic communications, sent by e-mail.

Special circumstances, such as death of the individual, incorrect mailing address, or urgent need to contact individual also are addressed in the requirements. ■

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

Nursing Home Resident's Bedsores Lead to Death; $18 Million Jury Verdict in New York

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News: A 76-year-old retired butcher and truck driver with dementia was admitted to a nursing home. During the man's stay, he suffered from dehydration and also developed several bedsores requiring hospitalization. During his hospitalization, the man underwent a diverting colostomy, a treatment for infected bedsores. Unfortunately, however, exacerbated bed sores led to the man's death 14 months after being admitted to the nursing home.

Background: After finding that more advanced care was required to treat a 76-year-old man suffering from Alzheimer's disease, a family admitted the man to a nursing home. Due to his condition, the nursing home used restraints to keep the man from wandering off. While a resident at the nursing home, the man suffered from dehydration and bedsores requiring hospitalization. The bedsores eventually became infected with E. coli. Nine months later, the man was discharged from the nursing home and transferred to another facility. At the time of the transfer, the once-250-pound man had lost over 100 pounds and was suffering from more than 20 bedsores, which progressed to state-IV bedsores, also known as decubitus ulcers. The man's condition required five additional hospitalizations, and he underwent repeated debridment of infected tissue and a diverting colostomy. Nevertheless, the infection spread and ultimately led to organ failure and the man's death.

The man's estate brought suit against the nursing home. The estate claimed that the man was in relatively good overall health at the time of admission, able to walk on his own, and that the bedsores and weight loss were a result of staff negligence. Information was set forth that the man had only been moved by the nursing home staff once, at most, every four hours, when medical standards required restrained patients to be moved at least once every two hours. The claim also stated that the man was allowed to reside in his own feces and suffered from dehydration and malnourishment.

The nursing home impleaded the hospital and contended that the man's nutrition was adequately monitored, that bedsores were unavoidable given the man's condition, and that the hospital allowed the bedsores to further exacerbate to the point of infection.

The hospital countered by claiming that the man's condition and subsequent death were a result of the nursing home's negligent care. The hospital provided evidence that it had taken necessary action to prevent further infection and was ultimately found by the jury to have acted in accordance with the standard of care.

The estate sought damages for 13 months of pain and suffering, as well as punitive damages. Following a four-week trial and two days of deliberation, the jury awarded damages to the family in an amount of $3.75 million for pain and suffering and $15 million in punitive damages. A lawyer for the plaintiff indicated that the punitive dam-

ages were awarded based on the fact that the nursing home had attempted to cover up the neglect. Specifically, records illustrated that nursing staff consistently notated "G" for "good skin condition." These "Gs" were eventually written over with "Bs," indicating "areas of broken skin." An FBI agent who served as an expert witness for the estate determined that more than 100 alterations were made to the record before it was provided to the man's family. The estate's recovery was ultimately reduced due to a high/low agreement for $750,000/$75,000 that was entered into by the parties prior to trial. This was the first time in New York history that a jury had awarded punitive damages in a case against a nursing home.

What this Means To You: This case represents a myriad of all that can and will go wrong when there is noncompliance with regulatory requirements and standards of care. It is difficult to comprehend how failure to provide adequate and appropriate care within a health care setting was tolerated in such a manner. This case involves not only clinical staff, but it also involves the organization's medical and administrative leaders as well. Health care leadership in acute and long-term care is responsible for quality of care monitoring and oversight of the delivery of care within the organization.

Alzheimer's disease is not a precursor for decubitus ulcers, systemic infections, malnutrition, weight loss, or a diverting colostomy. It would be difficult, if not impossible, to justify to any jury Alzheimer's disease as the primary factor in the harm and subsequent death of an ambulatory 76-year-old with dementia. What speaks vividly to a jury is the health care acquisition of more than 20 bedsores, a 100-pound weight loss, malnutrition, and dehydration. Use of restraints without systematic and continuous reassessment is not acceptable. The same is true for the monitoring of skin integrity. What screams to a jury and all health care consumers is the act of altering medical records to disguise or delete evidence of neglect and/or substandard care.

The Joint Commission (TJC) defines a decubitus ulcer as a "breakdown of skin and subcutaneous tissue due to prolonged, unrelieved pressure over a bony prominence, often associated with malnutrition, paralysis, or physical deformity." In this case, the development of numerous ulcers, due to the use of restraints to prevent wandering (resulting in lack of mobility and skin pressure relief), failure to assess, reassess, prevent, report, and appropriately treat developing ulcers, and lack of adequate nutrition and hydration, placed the resident at risk for deterioration and death — and placed the nursing home at risk for difficult-to-defend litigation.

The Joint Commission recognizes that a late-stage Alzheimer's patient may typically be "incontinent, often bedridden, and may have difficulty with seizures, swallowing, infections, and communication." This recognition does not, however, excuse a facility from providing the best care possible to avoid unnecessary deterioration, complications, or harm for a resident. TJC provides, in its National Patient Safety Goal on Pressure Ulcers, information on pressure ulcer risk assessment tools and preventive methods. Prevention actions include, but are not limited to: skin inspection, skin cleansing, use of moisture barriers and massage, nutritional support, use of appropriate positioning, transferring and turning techniques, a plan to maintain or increase mobility and activity levels, use of repositioning devices, staff educational programs on assessment, prevention, and treatment protocols, and hand-off communication that includes relevant information regarding the resident's risk of developing a pressure ulcer, as well as the treatment and status of any existing pressure ulcers. Such actions are low in capital cost, high in benefit, and supported by federal and state agencies through regulatory requirements.

The indication of E. coli as a source of infection in the ulcers represents a failure to meet the preventive action of skin cleansing and works to substantiate the plaintiff's claim of having allowed the resident to "reside in his own feces." This only adds to the difficult-to-defend issues in this case.

Amendment of a record for accuracy and completeness may be beneficial if it is done in a legitimate manner and in accordance with an organization's medical record policy and procedure. Drawing a line through an incorrect entry and explaining the correction is appropriate; writing over letters, words, or numbers lends itself to the appearance of alteration, and alteration is unacceptable, indefensible, and could be considered criminal.

This is a tragic case. The jury saw it as such, evidenced by their award of $15 million in punitive damages for the first time in New York history in a case against a nursing home. The Centers for Medicare & Medicaid Services (CMS) is poised to monetarily reward health care providers who excel in all aspects of health care services and penalize those organizations who fail to achieve top rankings in the standards of care. As health

care leaders, we must learn from the examples presented here. We must empower staff to report care concerns and assessments; we must provide the tools and resources necessary to ensure and sustain do-no-harm care. In an era of low reimbursement rates, ever-increasing regulatory requirements, and high medical malpractice costs, we all must find creative and effective ways to achieve and deliver excellence.

REFERENCE

1. Supreme Court, Second Judicial Circuit, Kings County, New York, No. 40307/04. ■

Delay in Shunt Leads to Hypoxia; $22M Verdict

News: At birth, a baby boy was diagnosed with a congenital heart defect preventing blood flow to his lungs. Two days later, a B-T shunt was placed, and the child was discharged a few days later. About two weeks after birth, the baby was brought to a local hospital hypothermic, mottled, and with low oxygen saturation levels. Seven hours after the baby was admitted, a pediatric cardiologist performed a cardiac catheterization to diagnose the issue, and eventually a replacement shunt was inserted. About seven months later, the baby was diagnosed with a stroke, and when he was 3 years old, underwent an amputation of his left leg. He also suffered developmental delays as a result of prolonged hypoxia. The jury found in favor of the plaintiff and awarded $22, 327,241.

Background: A baby boy born with a congenital heart defect, called pulmonary atresia, underwent surgery to place a Blalock-Taussig (or BT) shunt. The BT shunt is used to temporarily direct blood flow to the lungs. After discharge, the baby presented at a local hospital providing pediatric cardiology care as hypothermic, riddled with spots or patches, and with oxygen saturation levels in the 50% range, when normal ranges are between 95% and 100%. While in the emergency department, the baby was classified as a four out of four for acuity, and his oxygen levels fell into the teens, a condition also known as hypoxia.

A pediatric cardiology fellow performed an echocardiogram that uncovered slow blood flow through the shunt. Based on his findings, the physician recommended the boy for surgery. The attending physician, however, did not see the boy until 4 hours later and ultimately determined that a cardiac catheterization procedure was necessary. Following the catheterization, a pressure dressing was applied to the boy's left leg.

Following the subsequent emergency shunt replacement surgery, the boy's leg continued to be mottled and discolored due to spots and blotches. The boy was diagnosed with a stroke and eventually underwent an above-the-knee amputation of his left leg as a result of the stroke. The boy also suffered developmental delays due to prolonged hypoxia.

The boy's family sued the hospital, three physicians, and two nurses, claiming medical malpractice. The plaintiff's attorney alleged that the shunt replacement surgery should have been done shortly after presenting and that the cardiac catheterization procedure was unnecessary based on the diagnosis. In addition, the plaintiff claimed that the dressing placed on the boy's leg was extra tight and that the hospital staff failed to properly evaluate and monitor the boy's leg following the catheterization.

The defense contended that their actions fell within the standard of care and that the cardiac catheterization was necessary in order to properly diagnose the shunt occlusion. According to the defense, the echocardiogram tape was inadvertently erased and could not be produced at trial.

The boy needs assistance with everything from dressing to feeding himself. While he is able to walk with the help of a prosthetic and attend school, the boy's mother had to quit her job in order to care for him.

The jury agreed with the plaintiff and found that the hospital and staff were negligent by: failing to make a timely diagnosis of the issues regarding the shunt; improperly subjecting the boy to an unnecessary procedure; improperly applying pressure to the dressing on the boy's left leg; and failing to remove the dressing in a timely manner. The jury also found that the hospital and staff failed to monitor the boy's pulse and improperly destroyed an echocardiogram.

What This Means To You: The congenital defect of pulmonary atresia (PA) is also known as the "blue baby syndrome." Common symptoms of pulmonary atresia include cyanosis within the transitional first day of life, rapid or difficult breathing, lethargy, irritability, and pale, cool, or clammy skin. Oxygen and perhaps ventilation may

be used initially to assist with respiratory function. Diagnostic studies to aid in the confirmation of PA include chest X-ray, EKG, echocardiogram, or cardiac catheterization. The Blalock-Taussig (B-T) shunt is a temporary procedure used to direct blood flow to the lungs and relieve cyanosis. Ultimately, surgical intervention will be required to improve blood flow to the lungs on a permanent basis.

In this case, the infant boy was diagnosed with PA at birth. Two days later, a B-T shunt was placed. About two weeks later, the child presented to a hospital ED with low oxygen saturation levels, mottling, and hypothermia, and was classified as 4/4 acuity. The attending physician did not evaluate the child until four hours post-echocardiogram and recommendation for surgery. Seven hours post-admission, a heart catheterization was performed. This was followed by emergency shunt replacement surgery. This case represents an issue of timeliness and failure to rescue vs. actual intervention and appropriate treatment. There was failure to either recognize adequate perfusion or the signs and symptoms of hypoxia. The interventions provided to the baby boy at birth and thereafter may have been appropriate, but the delay in intervening in a timely manner is at the heart of the matter. This brings to mind several questions: were the signs and symptoms of hypoxia properly identified and communicated? Was the acuity and severity of the situation properly communicated and understood? Was the sense of intervention urgency communicated and understood? Was follow-through monitored? Did assessment and reassessment occur? Was there adherence to an appropriate chain of communication and command? Were solutions to problem(s) identified, initiated, and monitored? Given the jury verdict in this case, I would venture to say the answer to all these questions is "no."

Low oxygen saturation rates require immediate attention and intervention. A saturation rate 45% to 50% below normal range in a child requires rapid response; an emergent response is absolutely necessary when those stats drop into the teens. With a known history of PA and B-T shunt placement, this 2-week-old infant with symptoms of hypoxia required emergent assessment and intervention. Long-term effects and damages from prolonged hypoxia not addressed in a timely manner, especially in infants, children or young adults, often leads to expensive verdicts. Consideration of life expectancy rates and the need for lifelong continued assistance with activities of daily living contribute to the verdict dollar determination.

Following the heart catheterization, this young boy continued to display signs of circulatory issues in his left leg, as evidenced by persistent mottling and discoloration. The pressure dressing on his left leg may have been improperly applied. The left leg site and dressing should have been assessed on a frequent basis for post-procedure bleeding and circulatory constriction. Evidence of monitoring left leg status post-heart cath was critical. The inability of the hospital to produce the echocardiogram that substantiated decreased blood flow through the shunt demonstrated carelessness. Absence of monitoring evidence and failure to produce films or records leaves little to defend. And regardless of all the facts presented in the case from both plaintiff and defense perspectives, there is a young boy who has suffered a stroke at a very early age, incurred developmental delays, and will live with those negative outcomes the rest of his life.

Continuous medical and clinical staff education in assessment, documentation, and communication skills is required for successful outcomes for the patients we serve and for survival in the world of litigation. The Joint Commission describes the goal of assessment in its introduction to Standard PC.01.02.01 as determining *"the care, treatment, and services that will meet the patient's initial and continuing needs. Patient needs must be reassessed throughout the course of care, treatment, and services."* Failure to properly assess, and reassess continuing care needs on a frequent and as-needed basis, is failure to serve our patients, their families, and our health care organizations. Failure to provide evidence of care through appropriate, clear, and concise documentation leaves us with little to no support of our efforts in providing care when faced with litigation.

REFERENCE

1. Circuit Court of Illinois, Cook County Judicial Circuit, No 02L16398. ■

Healthcare Risk Management

2010 Reader Survey

In an effort to learn more about the professionals who read *HRM*, we are conducting this reader survey. The results will be used to enhance the content and format of *HRM*.

Instructions: Fill in the appropriate answers. Please write in answers to the open-ended questions in the space provided. Return the questionnaire in the enclosed postage-paid envelope by **July 1, 2010.**

1. Please fill in all the areas for which you are responsible for risk management in your facility or system.

- O A. acute care
- O B. outpatient services
- O C. same-day surgery
- O D. home health services
- O E. rehabilitation services
- O F. extended care facility
- O G. hospice

In future issues of *HRM*, would you like to see more less coverage of the following topics?

	A. more coverage	B. less coverage	C. about the same amount
2. compliance	O A	O B	O C
3. malpractice	O A	O B	O C
4. patient safety	O A	O B	O C
5. patient restraints	O A	O B	O C
6. informed consent	O A	O B	O C
7. patient confidentiality/privacy	O A	O B	O C
8. patient falls	O A	O B	O C
9. medical errors	O A	O B	O C
10. root-cause analysis	O A	O B	O C
11. sentinel event reporting	O A	O B	O C
12. accreditation issues/audits	O A	O B	O C

13. Do you find the *Legal Review & Commentary* insert in *HRM* helpful?

O A. yes O B. no

14. Including *HRM*, which publication or information source do you find most useful, and why?

_____

_____

15. Do you plan to renew your subscription to *HRM*?

- O A. yes
- O B. no If no, why not?_____

_____

16. Are the articles in *HRM* written about issues of importance and concern to you?

- O A. always
- O B. most of the time
- O C. some of the time
- O D. rarely
- O E. never

17. How would you describe your satisfaction with your subscription to *Healthcare Risk Management* newsletter?

- O A. very satisfied
- O B. somewhat satisfied
- O C. somewhat dissatisfied
- O D. very dissatisfied

18. Which best describes your title?

- O A. risk manager or risk management director
- O B. VP or assistant administrator
- O C. director/manager of quality
- O D. medical director or director of nursing
- O E. other_____

19. Please indicate all of the activities for which you have primary management responsibility.

- O A. risk management
- O B. compliance
- O C. legal
- O D. quality or utilization review
- O E. other_____

20. Which area at your facility triggered the most incident reports in 2009?

- O A. emergency department
- O B. medical
- O C. obstetrics
- O D. operating room
- O E. other _____

21. *HRM* has been approved for 15 nursing contact hours using a 60-minute contact hour by the American Nurses Credentialing Center's Commission on Accreditation. If you participate in this CNE activity, how many hours do you spend in the activity each year?_____

Please rate your level of satisfaction with the following items.
A. excellent B. good C. fair D. poor

22. Quality of newsletter	○ A	○ B	○ C	○ D
23. Article selections	○ A	○ B	○ C	○ D
24. Timeliness	○ A	○ B	○ C	○ D
25. Length of newsletter	○ A	○ B	○ C	○ D
26. Overall value	○ A	○ B	○ C	○ D
27. Customer service	○ A	○ B	○ C	○ D

28. On average, how many people read your copy of *HRM*?

○ A. 1
○ B. 2
○ C. 3
○ D. 4
○ E. 5 or more

29. What is the bed size of your facility/system?

○ A. fewer than 200 beds
○ B. 200 to 400 beds
○ C. 401 to 600 beds
○ D. 601 to 800 beds
○ E. more than 800 beds

30. On average, how many articles in *HRM* do you find useful?

○ A. none
○ B. 1-2
○ C. 3-4
○ D. 5-6
○ E. 7 or more

31. What do you like most about *HRM* newsletter?

32. What do you like least about *HRM* newsletter?

33. Please list the top three challenges you face in your job today.

34. What issues would you like to see addressed in *HRM* newsletter?

Contact information _____