



Healthcare RISK MANAGEMENT



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HMA lawsuits, indictment highlight whistleblower risk

Allegations brought by insiders claiming kickbacks, sham business deals

The eight False Claims Act lawsuits being pursued against Health Management Associates (HMA) illustrate the risk that hospital executives take when they aggressively seek increased revenue without adequately assessing the potential for fraud charges, say healthcare fraud experts who are watching the case closely.

The government has intervened in eight False Claims Act lawsuits against the Naples, FL-based hospital chain. It alleges that HMA billed federal healthcare programs for medically unnecessary inpatient admissions from the emergency departments at HMA hospitals and paid remuneration to physicians in exchange for patient referrals, the Justice Department announced recently.

The government also has joined in the allegations in one of these lawsuits that **Gary Newsome**, HMA's former CEO,

directed HMA's corporate practice of pressuring emergency department physicians and hospital administrators to raise inpatient admission rates, regardless of medical necessity. (See the stories on p. 39 and p. 40 for more on the allegations.)

HMA operates 71 hospitals in 15 states: Alabama, Arkansas, Florida, Georgia, Kentucky, Mississippi, Missouri, North Carolina, Oklahoma, Pennsylvania, South

Carolina, Tennessee, Texas, Washington and West Virginia.

HMA's practices violated the Anti-Kickback Statute, which prohibits offering, paying, soliciting, or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid, and other federally funded programs, the government claims. The Stark Statute prohibits a hospital from submitting claims for patient referrals made by a physician with whom the hospital has an improper financial arrange-

"...you have to realize that everybody who works in your healthcare practice is a potential government investigator."

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Legal Review & Commentary

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ment, the government says.

Everyone can blow the whistle

One of the most important lessons for risk managers from the HMA case concerns the risk posed by whistleblowers, says **John G. Martin, JD**, an attorney with the law firm Garfunkel Wild in Great Neck, NY. Under the False Claims Act, whistleblowers can get rich by turning in providers committing fraud.

The volume of whistleblowers has increased exponentially in recent years, Martin says. He has heard reports that some U.S. Attorney's offices receive as many as five false claims allegations each day.

"In addition to government watchdogs reviewing your bills, you have to realize that everybody who works in your healthcare practice is a potential government investigator," Martin says. "Once they learn that if there is anything questionable and they might get rich off of it, they're all looking for something to investigate. The idea that if the government is not looking

Executive Summary

Health Management Associates, a hospital chain based in Naples, FL, is facing several whistleblower lawsuits. The allegations suggest that the chain might have underestimated the potential fraud charges from an aggressive effort to increase revenue.

- ◆ The whistleblowers include top executives and a compliance officer.
- ◆ Some of the allegations involve "sham" co-management agreements with physicians.
- ◆ An executive was indicted for allegedly altering or forging a document related to the case.

at some policy or practice, you're OK, that's no longer valid in the healthcare field. Everyone is looking at it."

An HMA effort to encourage admissions and keeping scorecards on physician performance was at the heart of some of the False Claim allegations, but Martin cautions that the concept is not invalid. Many providers have a similar program to track "productivity" of physicians. The problem, he says, appears to be how HMA carried it out.

"It has to be done completely on the up and up, and vetted by an attorney or an experienced compliance officer," Martin says. "So many things that

are natural to a business person in another area of work are forbidden in healthcare. Rewarding productivity is completely uncontroversial in any other field, and you can do it in healthcare, but only if you're very careful about it."

Vet any revenue plans

Risk managers should insist that any program intended to make more money be analyzed for potential violations of the law, Martin says. Healthcare regulations are far more complex than the strictures placed on other businesses, and healthcare execu-

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Editorial Questions
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tives should not be overconfident about their ability to assess compliance, he says.

Having your plan reviewed by counsel will greatly reduce the repercussions, even if the government decides later that you were in violation of a law or regulation, Martin says. The effort to ensure legality goes a long way and can mean the difference between merely paying back money and being subject to a full-fledged fraud investigation with criminal charges, he says.

It appears the HMA leadership had a chance to respond to concerns posed by executives about the legality of the revenue improvement efforts, Martin says, but the lawsuits suggest they tried to get rid of the people who complained. Disclosing the ill-conceived plans and reimbursing the government would have resulted in much less damage to the company, Martin says.

Martin also warns strongly against any type of cover-up.

"Covering something up is like waving a red flag in front of the U.S. attorney," says Martin, who was a U.S. attorney for five years and a state prosecutor for 18 years. "Nothing got my blood boiling more than someone who covered up or somehow obstructed the investigation. I don't think people understand how that lights a fire under the U.S. attorney. It convinces them that there is something here that must be prosecuted."

Oversee documents carefully

The HMA case also points to a lack of internal controls on responding to subpoenas and fraud investigations, says **Jonathan Feld, JD**, an attorney

"Covering something up is like waving a red flag in front of the U.S. attorney."

protect their institutions," Feld says. "We don't know yet, but it appears to be either a lapse that led to allegations of intent to defraud, or the executive did in fact insert the document intending to defraud investigators. Either way, it shouldn't have been allowed to happen."

Feld notes that such charges of obstruction can arise from sloppy or misguided efforts by those involved, rather than actual intent to deceive. Investigators can see obstruction where none was intended, notes **Henry R. Fenton, JD**, co-founder of the law firm Fenton Nelson in Los Angeles.

"If a risk manager makes it difficult for an investigator to communicate with employees or represents that an employee does not want to talk when that is not completely accurate, those things are going to be considered obstructing the investigation," Fenton says. "Any charge of obstructing is completely separate from the underlying allegations, so you've created a new problem."

SOURCES

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HMA accused of scheme to increase admissions

Some of the lawsuits against Health Management Associates (HMA), a for-profit hospital chain based in Naples, FL, concern allegations that it encouraged doctors to admit patients who did not need inpatient care, as a way of increasing reimbursement revenue.

In a recent court hearing, prosecutors revealed the allegations made by HMA whistleblowers. One of the

lawsuits claims that HMA has a formal strategy for increasing revenue that included posting scorecards for physician admissions. The goal was to admit at least half of the patients over 65 years old who entered the emergency department. Scorecards for physicians who hit that mark were color-coded green, those who were close to the goal were yellow, and underperformers were red, according to the lawsuit.

HMA declined to comment on pending litigation other than to say it was cooperating with the Justice Department investigation. "HMA associates and physicians who practice at our facilities are focused on providing the highest-quality patient care in all of our hospitals," according to a company statement.

The lawsuits point to the company's former chief executive, Gary D.

Newsome, as the one responsible for the strategy to increase admissions and revenue. Newsome's attorney issued a statement denying the allegations. Newsome joined HMA in September 2008 and soon after traveled to North Carolina to meet with local hospital officials, several of the lawsuits allege. At that meeting he explained that he was instituting new protocols and customized software that would increase admissions at HMA hospitals, according to a federal suit filed by Michael Cowling, a former division vice president and chief executive of an HMA-owned hospital in Mooresville, NC.

Cowling alleges that administrators were directed to use the customized software program to monitor the daily percentage of patients being admitted and then post the physicians' score-cards.

Cowling claims that he reported to Newsome physician concerns that the new protocols were clinically inappropriate and would result in unneces-

sary tests and admissions. The lawsuit claims that Cowling said the doctors would not participate, but Newsome responded by saying, "Do it anyway."

A lawsuit by Craig Brummer, MD, a former medical director of emergency departments at two HMA hospitals, includes examples of how the system prompted physicians to admit patients who did not need inpatient care, including an infant who was admitted for fever when the record shows the temperature at admission as 98.7 degrees.

Some of the lawsuits claim that executives who questioned or resisted the HMA policies were fired. Jacqueline Meyer, a regional administrator for EmCare, a company that provided emergency department physicians to several HMA hospitals, claims that she was fired after refusing to follow HMA's directives and fire doctors who admitted fewer patients than HMA wanted.

Court filings indicate that Ralph D. Williams, an accountant with 30 years'

experience in hospital management, became concerned after he was hired as the chief financial officer for an HMA hospital in Monroe, GA. Williams asked an outside consulting firm to review the hospital's increased inpatient admission rate, according to his lawsuit. Williams says he presented the critical report to a division executive, who told him to burn it. Williams was fired soon after and filed a *qui tam* lawsuit against HMA.

In addition to the lawsuits, a former vice president with HMA has been indicted on a charge of falsifying records to impede one of the federal investigations into HMA's billing practices. If convicted, Joshua S. Putter faces a maximum penalty of 20 years in federal prison.

According to the indictment, on or about Oct. 7, 2008, Putter knowingly falsified, or made false entry in a document, with the intent to impede, obstruct, or influence an investigation. ♦

HMA execs claim kickbacks to physicians

The whistleblower lawsuits against Naples, FL-based Health Management Associates (HMA) include claims from two former C-suite executives that the company paid millions in kickbacks to physicians who participated in joint ventures and co-management agreements.

Court documents indicate that the complaint was filed in 2010 by executives at Lancaster (PA) Regional Medical Center and Heart of Lancaster Regional Medical Center, affiliates of HMA. The complaint was unsealed recently and contains numerous allegations pertaining to HMA's relationships with physicians in 2008 and 2009. The whistleblower complaint was filed by former Lancaster Regional CEO George Miller and former CFO Michael Metts in 2010.

Miller was CEO of Health Management's Heart of Lancaster from

June 2008 through May 2009 but also served as CEO of Lancaster Regional from June 2008 until January 2009. Metts was systems CFO and compliance officer for Lancaster Regional, Heart of Lancaster, and 13 related clinics from June 2008 through December 2008. He later served as CFO and compliance officer at Lancaster Regional from December 2008 through September 2009.

The two executives claim HMA arbitrarily discounted the true value of physicians' shares of HMA joint-ventured facilities, which resulted in investment rates that were substantially less than fair market value (FMV). HMA offered referring physicians the opportunity to invest in the facility "substantially below and without reference to FMV," the complaint says. The favorable joint venture plans were used as a way to get physician investors to

refer more patients to HMA facilities, the lawsuit alleges.

"Although HMA refers to its ownership of hospitals as 'joint ventures,' HMA's ultimate goal was to have potential referring physicians invest in HMA hospitals by purchasing shares in a newly-created LLC which owned the hospital," the complaint says.

The whistleblowers also allege that HMA offered physicians a "robust" return on investment and explained that increasing referrals by only one or two patients per day would improve their return.

Several examples of specific transactions are cited in the lawsuit. In one, Metts says HMA presented a joint venture proposal to physicians at Heart of Lancaster. HMA said the wholesale value of Heart of Lancaster was \$62.4 million, but the lawsuit claims the company applied arbitrary discounts total-

ing 35% to reach an offering price of \$40.5 million.

The lawsuit claims that HMA intentionally undervalued Heart of Lancaster to induce referring physicians “to participate in the joint venture by offering them an interest in the facility at a price far less than its market value.”

Health Management executives devised the Lancaster Regional joint venture to lure in a particular physician group of family physicians and internists, the lawsuit claims, because the group referred 35% of its patients to Lancaster Regional and the rest to a competitor. To seal the deal with the

practice, the lawsuit alleges that HMA executives paid the doctors \$500,000 per year in a “sham co-management agreement.” HMA executives and the physicians were aware that the physician group would not actually provide co-management services, the lawsuit alleges. ♦

‘Copy-and-paste’ fraud targeted by CMS and OIG

“Copy and paste” is a feature common to almost all computer programs that allows the user to quickly select text and reproduce it elsewhere instead of typing it again. Though useful, the Department of Health and Human Services’ Office of Inspector General (OIG) is warning that copy and paste can lead to fraudulent billing, and the Centers for Medicare and Medicaid Services (CMS) is vowing to pursue any providers who abuse the feature.

The OIG recently released a report critical of hospitals’ use of copy and paste in electronic health record (EHR) documentation, based on an online questionnaire to 864 hospitals and interviews with hospital staff, including a demonstration of EHR technology at eight hospitals.

OIG found that only about one-quarter of audited hospitals had policies regarding the use of the copy-and-paste feature. Also, 61% of surveyed hospitals “shifted the responsibility to the EHR user to confirm that any copied-pasted data were accurate.”

Additionally, the audit found that 51% of surveyed hospitals reported that they are unable to customize the copy-and-paste feature in their EHR technology by restricting its use or disabling it. Only 25% of hospitals had policies on the use of the copy-and-paste feature.

The audit also found problems with what OIG calls “overdocumentation” in EHRs, which it describes as “inserting false or irrelevant documentation to create the appearance of support for billing higher level services.” This prob-

lem can occur when an EHR automatically fills in fields for built-in templates or when a system generates “extensive documentation on the basis of a single click of a checkbox, which if not appropriately edited by the provider, may be inaccurate,” the report says.

The OIG report urges that audit logs always be kept and stored to bet-

to develop a comprehensive plan to address fraud vulnerabilities in EHRs ... and develop guidance on the use of the copy-paste feature in EHR technology.” (See p. 42 for more information.)

Responding to the audit report, CMS issued a statement saying it will work “to develop a comprehensive plan to detect and reduce fraud in EHRs.”

Using the copy-and-paste feature should not be considered bad practice, but it must be done carefully enough that the user doesn’t veer into fraud territory, says **Robert Hitchcock**, MD, FACEP, a practicing ED physician and an Emergency Department Practice Management Association (EDPMA) board member. He also is vice president of T-System, a regulatory consulting company based in Dallas.

Hitchcock notes that most EHR systems include macros that can generate a significant amount of documentation with one click which enable the physician to “chart by exception.” That charting technique is legitimate and can improve efficiency, he says. However, this technique requires taking the time to amend the record however necessary so that the information is accurate for

“Copying data from one patient record to another can include identifiable information, and that’s a privacy violation.”

ter track EHR access and changes. It also recommends that the Office of the National Coordinator for Health Information Technology and CMS “strengthen their collaborative efforts

Executive Summary

The Department of Health and Human Services’ Office of Inspector General (OIG) is warning that some electronic health record (EHR) documentation features can result in fraud. The Centers for Medicare and Medicaid Services says it will pursue “cut-and-paste” fraud.

- ◆ Most EHR systems allow and even encourage copy and paste as an efficiency feature.
- ◆ Some systems make it difficult or impossible to disable the feature.
- ◆ Only about one-quarter of hospitals have a policy on cut-and-paste fraud.

that patient.

Even more troublesome are EHR features that encourage “chart cloning” in which the record is automatically filled with information that is not reviewed by the user and might have no relevance to that particular patient visit. Chart cloning can result in upcoding and documentation for services not provided, Hitchcock says.

“Poor use of these features can bloat the medical record and introduce charges for services that did not happen on that date or possibly ever,” Hitchcock says. “Copying data from one patient record to another can include identifiable information, and that’s a privacy violation.”

Hitchcock cautions that auditors’ interest might be piqued, which can cause them to dig deeper into individual records, if your EHR has these features enabled:

- The EHR automatically generates codes that are inconsistent with your documentation.
- The system has prompts that suggest how to obtain higher reimbursement.
- The EHR automatically inserts information that inflates the extent of the patient visit or includes care that

was not provided.

Federal regulators will be able to find and pursue large cases of fraudulent billing because of these pitfalls in EHR systems, says **Andrew Urbaczewski**, PhD, chair and associate professor of the Department of Business Information and Analytics at the University of Denver. But that federal interest doesn’t mean that providers should junk the automation features of EHRs altogether, he says.

“One way that fraudsters have traditionally operated is by using the same X-ray or report and showing it to patients, and make it part of their record,” he says. “However, physicians who are practicing medicine legally and ethically should have little fear of being incorrectly labeled as a fraudster. Shortcuts for frequently used items in the patient care workflow exist to help providers spend more time with patients and less time hung up in the EHR system.”

The real risk for providers who use copy and paste is that the provider might copy and paste notes and inadvertently leave in items from other medical records, Urbaczewski says. That action would create privacy issues or incorrect data. Well-meaning pro-

viders also might produce too much information in the record, which makes the note needlessly long, perhaps drawing attention away from the crucial facts in the patient record. (*See the story below for more advice on avoiding fraud with EHRs.*)

“The provider must remember that ultimately the responsibility for the medical record lies solely with him or her, in its entirety, and should take care to carefully note copied and pasted material by changing its appearance in some way, such as when pasting information from an outside consultant, and note the source,” Urbaczewski says. “Ultimately, the EHR interface for the provider should be designed with data fields and links to where copying and pasting can be avoided, making systems safer for patients, providers, and less prone to fraud in that manner.”

SOURCES

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- **Andrew Urbaczewski**, PhD, Department of Business Information and Analytics, University of Denver. Telephone: (303) 871-4802. Email: andrew.urbaczewski@du.edu. ♦

OIG report says EHRs ripe for fraud

Hospitals are trying to prevent fraud in their electronic health records (EHRs), but they are not doing enough, according to a report released recently by the Department of Health and Human Services’ (HHS) Office of Inspector General (OIG).

The report looked at the extent to which hospitals that received EHR Medicare incentive payments between January 2011 and March 2012 implemented certain fraud safeguards recommended by Office of the National Coordinator for Health Information Technology (ONC) contractor RTI International. ONC coordinates the adoption, implementation, and

exchange of EHRs, and it contracted with RTI to develop recommendations to enhance data protection; increase data validity, accuracy, and integrity; and strengthen fraud protection in EHR technology.

Hospitals are not ignoring the issue. Among other actions, all hospitals were using recommended user authorization and access controls, and nearly all had recommended audit functions and data transfer safeguards in place. But the OIG report says those steps are not enough. OIG recommends that healthcare providers also keep audit logs operational whenever EHR technology is available for updates or viewing, and it

recommends they develop specific policies on the use of the copy-and-paste feature in EHRs.

The report recommends that HHS strengthen efforts to develop a comprehensive plan to address fraud vulnerabilities in EHRs and develop guidance on the use of the copy-and-paste feature in EHR technology.

These were some other findings from the report:

- Nearly all hospitals with EHR technology had recommended audit functions in place, but they might not be using them to their full extent.
- Ninety-six percent of hospitals reported that their audit logs remain

operational at all times despite reporting barriers, including limited human resources, a lack of vendor-provided audit log user guides, and inadequate training on audit log functionality. Audit logs monitor user activity and are an important tool against fraud in EHRs. OIG notes that they are so important that one-third of the recommended safeguards concern audit log operation and content.

- Hospitals' control over audit logs might be at odds with their RTI-recommended use as fraud safeguards. RTI recommends that EHR users not be allowed to delete the contents of their audit log so that data are always available for fraud detection, yet nearly half of hospitals (44%) reported

that they can delete their audit logs. Although these hospitals reported that they limit the ability to delete the audit log to certain EHR users, such as system administrators, one EHR vendor noted that any software programmer could delete the audit log. RTI recommends that the ability to disable the audit log be limited to certain individuals and that EHR users, such as doctors and nurses, be prevented from editing the contents of the audit log because these actions can compromise the audit log's effectiveness.

- Hospitals reported they have the ability to disable (33%) and edit (11%) their audit logs, although they reported restricting those abilities to certain EHR users, such as system administra-

tors or EHR vendors.

- OIG interviewed four EHR vendors, and all four reported that the user cannot disable audit logs in their products. One vendor noted that a programmer could disable the audit log.

- Most hospitals reported analyzing audit log data, but only to ensure privacy of patient data rather than detecting and preventing fraud and abuse. Hospitals cited barriers to analyzing audit logs, including limited human resources, a lack of vendor-provided user guides for audit log functionality, inadequate training on audit logs, and the inability to interpret audit log data.

The full OIG report is available online at <http://oig.hhs.gov/oei/reports/oei-01-11-00570.pdf>. ♦

No need to disable ctrl-c/ctrl-v in EHRs

The government's pledge to ferret out copy-and-paste fraud is causing some hospitals to ask their electronic health record (EHR) vendors to disable the common "control-c/control-v" feature altogether. But don't rush to that extreme remedy.

First, it's not so easy to do. That common copy-and-paste command usually is built into the local computer environment — the Microsoft operating system on your computer, for instance — rather than the EHR technology itself. A skilled programmer might be able to block the feature, but it is not as easy as calling your vendor rep.

Blocking the feature also is not necessary to avoid fraud, says **Robert Hitchcock**, MD, FACEP, a practicing ED physician and an Emergency Department Practice Management Association (EDPMA) board member. He also is vice president of T-System, a company based in Dallas that provides consulting on regulatory issues.

"There was a knee-jerk reaction to turn this thing off, and that was coming from the risk folks at the

hospital, not from the clinicians," he says. "The better move is to educate people about the risks. There are places where these tools are appropriate and even beneficial."

Retyping information anew for each patient visit actually can introduce errors into the record, Hitchcock notes. His own policy on copy and paste is that it should not be used at all in the history and physical portion of the visit documentation, but otherwise it can be used judiciously.

Require validation of copied data

Another good move is to work with vendors to ensure that features are less "copy and paste" and more like "copy, validate, and paste," Hitchcock says. The EHR should minimize the automatic transfer of data or the automatic generation of data in forms. Instead, it should require the clinician to view that information and confirm it as correct before entering it in the new record.

Hitchcock also suggests providers take a good look at why these

features are so enticing to clinicians. The move to electronic documentation has greatly increased the data entry demands for physicians, while at the same time making common blocks of data available for easy retrieval, he says.

"The demands of using an EHR are so great that you almost have to use some sort of crutch or shortcut," Hitchcock says. "More importantly, the primary use of the data generated in these visits is for billing and coding purposes, not for medical record documentation and communication of care to the next provider. The way to get a ton of information in the record that CMS requires is through this copy-and-paste functionality."

Also note that the OIG found hospitals were not adequately using the audit function built into most EHRs, says **Jeff Helton**, PhD, CMA, CFE, FHFMA, assistant professor of healthcare management at the School of Professional Studies at Metropolitan State University of Denver. "Everyone is mostly concerned with staying compliant with HIPAA, rather than looking for

opportunities to ensure the integrity of the medical record," Helton says. "If a risk manager were to routinely look at the audit log in an EHR, you could see how much the cut-and-paste function is being used, who is using it, and how much you are at risk for fraud."

Indiscriminate use of copy and

paste most often will result in sloppy records and nonsensical entries for a patient rather than upcoding and outright fraud, Helton says. However, any incorrect entries can lead to fraud charges if the government investigates.

Helton's message for providers is, "You can use cut and paste, but use it

with caution."

SOURCE

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Hospitals struggle to resolve brain-death issue with families

Hospitals in two states recently were in the difficult position of having to disagree with a family about terminating life support for patients declared dead. In one case the family refused to accept that a young girl was dead, and in the other the family struggled with a state law that seemed to require keeping a woman on life support even if her family and physicians wanted to end it.

Both cases suggest that the public — and some lawmakers — still need to be educated about how death is determined and the futility of continuing life support, says **Craig B. Garner, JD**, formerly chief executive officer at Coast Plaza Hospital in Norwalk, CA, and now an attorney and adjunct professor at the Pepperdine University School of Law, Malibu, CA.

The first case involves 13-year-old Jahi McMath, who died after surgery at a California hospital but the family refused to allow termination of her life

support. The family eventually won the right to remove her from the hospital. The other case centered on Marlise Muñoz, a pregnant 33-year-old woman

both cases, see the story on p. 45.)

Many states have adopted laws restricting the ability of doctors to end artificial life support for terminally ill pregnant patients, Garner notes. Twelve have laws that automatically invalidate a woman's advance directive if she is pregnant, which means that a woman must remain on life-sustaining treatment until she gives birth.

Garner notes that though the medical community, and to some extent the legal community, has largely come to terms with the definition of death in recent years, families still might resist what seems the only reasonable action to clinicians. Ethical debates about such cases among clinicians and risk managers are rare these days, but the general public and grieving families are a different matter.

"They may see reflexes and actions from the respirator, and that can make it very difficult for them to accept the explanation that the patient is dead," Garner says. "The hospital has to counter the notion of miracles and the idea that sometimes these patients do wake up."

Stories about "Lazarus" patients waking up after being declared dead are always apocryphal or can be explained by the diagnosis being wrong to begin with, Garner says. Once clinicians are certain that the patient meets the death criteria, without a doubt, then there is no hope for the patient coming back and families must be educated about that certainty, he says.

"The hospital has to counter the notion of miracles and the idea that sometimes these patients do wake up."

whose husband wanted to remove her from life support, but the hospital was stymied by a Texas law that seemed to require the continuation of support if the fetus was alive. (For more details on

Executive Summary

Two recent cases show that hospitals are continuing to struggle with the termination of life support for patients declared brain dead. The cases suggest that hospitals should emphasize educating families about how death is determined.

- ◆ One case involved a family trying to maintain life support, while the other had a family trying to remove it.
- ◆ Both cases posed difficult legal and public relations problems for the facilities.
- ◆ Neither case changes the clinical definition of death.

Hospitals must proceed gently, of course, and allow for some time delay if the family is waiting for someone to appear at the bedside, for example. But if the family seeks to prevent the termination of support, Garner says the hospital is on solid ground if it has properly determined the death.

"The family will have to go to court to try to stop the hospital, but the hospital really doesn't have to do anything at that point," Garner says. "The hospital is doing what they deem appropriate for the patient, according to accepted clinical guidelines. That doesn't mean you would rush to terminate support

while the family is saying no, but the legal obligation really is on the family."

The best solution is to have the lead physician begin educating the family member about the process as soon as it appears the patient will not survive, Garner says. The Texas case was even more difficult for the clinicians, Garner suspects, because they wanted to terminate support and so did the grieving husband. Administrators at the hospital must have felt restricted by the law even if they disagreed with it, and they were put in the awkward position of denying the husband's wishes.

"Whenever possible you want to

work the family and help them through this process, to be an ally instead of opposing their wishes," Garner says. "That is going to be the likely outcome if you take the right approach with families early on and help them understand, but the Texas case shows that this can still be a difficult issue for everyone sometimes."

SOURCE

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Two struggles with brain death: One to keep support, one to let the patient go

Two cases show the struggle that hospitals and families still can have with the definition of death, and the legal fights that might ensue.

In a highly publicized case, 13-year-old Jahi McMath was admitted to Children's Hospital Oakland (CA) on Dec. 9, 2013, for an adenotonsillectomy, uvulopalatopharyngoplasty, and a submucous resection of bilateral inferior turbinates, all intended to improve her breathing and sleep. She suffered bleeding and cardiac arrest while in recovery, and blood flow to the brain was lost for an undisclosed period of time. Court records show that on Dec. 12, 2013 she was declared brain-dead by doctors at the hospital. Her family was informed that, because her brain had died, she was legally dead and life support systems would be removed.

The family refused to accept that conclusion and petitioned Alameda County Superior Court Judge Evelio Grillo, JD, to order an independent second opinion. Paul Graham Fisher, MD, the chief of child neurology at Stanford University School of Medicine, was appointed by the court and he reaffirmed the diagnosis of

brain death.

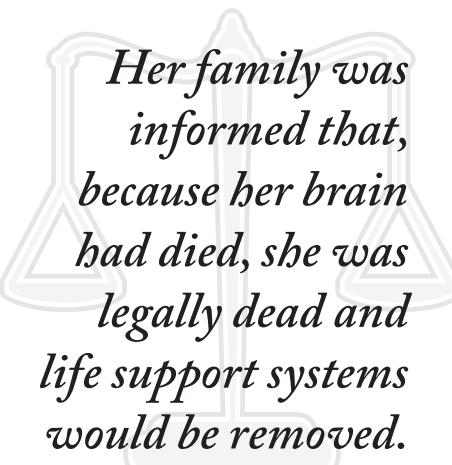
McMath's mother claimed that declaring McMath dead under the Uniform Determination of Death Act violated her freedom of religion and privacy. The Alameda County

then released her body to the custody of her mother. The family has since issued statements saying McMath is on life support at an undisclosed facility.

Marlise Muñoz was a pregnant 33-year-old paramedic in Fort Worth, TX, who died from a suspected pulmonary embolism on Nov. 26, 2013. Her husband, also a paramedic, relayed that Muñoz did not want life support in such an instance, but the hospital refused to terminate it and cited a Texas law that limits the application of advance directives in pregnant patients.

The Muñoz family filed suit in state court and argued that the law did not apply because the patient already was dead, and that the fetus had suffered from oxygen deprivation and was suspected to be non-viable. On Jan. 24, 2014, Judge R. H. Wallace Jr., JD, ruled that the hospital must disconnect life support for Muñoz by Jan. 27. While not ruling on the constitutionality of the state law, Wallace found that the law did not apply to deceased patients such as Muñoz.

Muñoz was disconnected from life support on Jan. 26, 2014. ♦



Her family was informed that, because her brain had died, she was legally dead and life support systems would be removed.

Superior Court granted an extension to keep McMath on a ventilator until Jan. 7, 2014, but refused the family attorney's request for hospital staff to insert tracheostomy and feeding tubes.

On Jan. 5, 2014, Children's Hospital released McMath's body to the Alameda County coroner, which

OSHA offers new resource for worker safety

A federal agency has launched a new online resource to help hospital leaders protect their employees from getting hurt when lifting patients, handling combative patients, during exposure to chemicals, and being exposed to other common hazards of working in healthcare.

Successful strategies to improve patient safety and worker safety "go hand in hand," said **David Michaels**, assistant secretary of labor for the Occupational Safety and Health Administration (OSHA), during a news conference announcing the new site, osha.gov/hospitals. The site contains fact books, self-assessments, and best practices to guide hospital managers.

The initiative does not include any new requirements for hospitals,

but Michaels said that improving safety requires a transformation of the workplace culture in the industry. "We urge all hospital executives that are ready to protect workers, enhance patient safety, and save money to go to our website, take the self-assessment, compare your hospital with benchmarks from high-performing hospitals," Michaels said.

OSHA says of the 250,000 work-related injuries and illnesses reported in U.S. hospitals in 2012, almost 60,000 resulted in employees missing work, costing hospitals \$2 billion in nationwide workers' compensation losses.

Representatives from the Lucian Leape Institute, the National Patient Safety Foundation and the Joint Commission Center for Transforming

Healthcare participated in the announcement.

Public Citizen, a consumer advocacy organization, issued a statement applauding the creation of the site. Their group released a report in 2013, called "Health Care Workers Unprotected," finding healthcare workers suffer more injuries than those in any other industry. (*That report is available online at <http://bit.ly/1kCzRUM>.*) Employers across all healthcare settings reported nearly 654,000 workplace injuries and illnesses in 2010, which is about 23% more than the next most injury-prone sector, manufacturing. (*For more on how risk managers can address employee safety, see Healthcare Risk Management, February 2014, pp. 16-19.*) ♦

Record number of fraud cases in past year

Federal prosecutors filed a record number of healthcare fraud cases last fiscal year, perhaps reflecting the greater emphasis the government has placed on combatting the crime costing taxpayers billions of dollars per year.

According to Justice Department statistics obtained through a Freedom of Information Act request by a Syracuse University-based nonprofit group that tracks federal spending, staffing, and enforcement activities, prosecutors pursued 377 new federal healthcare fraud cases in the fiscal year

that ended in October 2013. That was 3% more than the previous year and 7.7% more than five years ago.

Southern Illinois led the nation on a per-capita basis in such cases filed, with the government pursuing 10.1 prosecutions per 1 million people, which was more than eight times the national average. Southern Illinois U.S. Attorney **Stephen Wigginton**, JD, said he was surprised that his office was the top healthcare fraud prosecutor, but he noted that every U.S. attorney enjoys discretion in prioritizing which crime issues to

combat, taking into account regional demographics and the U.S. attorney general's desires.

Wigginton said he placed special emphasis on going after healthcare defrauders since he began overseeing his district more than three years ago. Since then, Wigginton's office has increased such investigations each year.

Last year, more than 30 people were indicted for allegedly scamming a Medicaid program meant to allow individuals to stay in their homes instead of entering a nursing home. ♦

HHS releases guides for health IT safety

A new set of guides and interactive tools to help healthcare providers more safely use electronic

health information technology products, such as electronic health records (EHRs), are now available

online.

The Office of the National Coordinator for Health Information

Technology (ONC) recently released the Safety Assurance Factors for EHR Resilience (SAFER) Guides. These guides are a suite of tools that include checklists and recommended practices designed to help healthcare providers and the organizations that support them assess and optimize the safety and safe use of EHRs.

The release of the SAFER Guides follows the implementation of the HHS Health IT Patient Safety Action and Surveillance Plan, which was issued in July 2013, said **Jacob Reider**, MD,

chief medical officer at ONC, in announcing the guides.

"A basic premise of the Health IT Safety Plan is that all stakeholders have a shared responsibility to make sure that health IT is safely implemented and that it is

used to improve patient safety and care," Reider said. "The SAFER Guides combine the latest applied knowledge of health IT safety with practical tools that will help providers — working closely with EHR developers, diagnostic service providers, and others — effectively assess and optimize the safety and

safe use of EHR technology within their organizations."

The SAFER Guides complement existing health IT safety tools and research developed by the Agency for Healthcare Research and Quality (AHRQ) and ONC. AHRQ's Patient Safety Organizations (PSO) have explicitly identified health IT as a high priority area because of the enormous impact EHRs are having on patient safety. PSOs are charged to help their members improve patient safety, and the SAFER

Guides give them an evidence-based tool to do so.

Developed by leading health IT safety and informatics researchers, each SAFER Guide addresses a critical area associated with the safe use of EHRs through a series of self-assessment

checklists, practice worksheets, and recommended practices. Each SAFER Guide has extensive references and is available as a downloadable PDF and as an interactive Web-based tool.

The SAFER Guides are available online at <http://www.HealthIT.gov/saferguide>. ♦



“... all stakeholders have a shared responsibility to make sure that health IT is safely implemented ...”

COMING IN FUTURE MONTHS

◆ Changing marijuana laws affect policies

◆ Hospital reduces safety events 83%

◆ Malpractice coverage for physician assistants?

◆ Medication event huddles improve safety

CNE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- describe the legal, clinical, financial and managerial issues pertinent to risk management;
- explain the impact of risk management issues on patients, physicians, nurses, legal counsel and management;
- identify solutions to risk management problems in healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.

CNE INSTRUCTIONS

Nurses participate in this CNE program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Scan the QR code below, or log on to www.cmeicity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be emailed to you instantly. ♦



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1. According to John G. Martin, JD, an attorney with the law firm Garfunkel Wild, who can potentially be a whistleblower and instigate fraud charges against a healthcare provider?

- A. Only upper level executives with personal knowledge of fraud.
- B. Only those employed in a compliance position within the organization.
- C. Only patients who claim damages based on fraudulent billing on their behalf.
- D. Anyone who has knowledge or suspicions of fraudulent activity.

2. In the whistleblower lawsuit against Health Management Associates (HMA) filed by two former C-suite executives, how do they allege that the company paid millions in kickbacks to physicians?

- A. The two executives claim HMA arbitrarily discounted the true value of physicians' shares of HMA joint-

ventured facilities, which resulted in investment rates that were substantially less than fair market value (FMV).

- B. They claim that HMA arbitrarily inflated monthly payments to the physician practice for services rendered at the hospital.
- C. They claim that HMA provided money to the physicians through a complex scheme intended to pay the doctors' malpractice premiums through joint venture but instead funneled money to the practice.
- D. They claim that HMA entered into an agreement for business consulting services with the physicians but, in fact, no services were rendered.

3. What does Robert Hitchcock, MD, FACEP, advise is the proper use of "cut and paste" in electronic health records (EHRs)?

- A. It should not be used at all in the history and physical portion of the visit

documentation, but otherwise it can be used judiciously.

- B. It should be used only in the history and physical portion of the visit documentation, but nowhere else.
- C. It should be used only for "well patient" visits with no diagnoses or test abnormalities.
- D. It should never be used in EHRs.

4. In the case of Marlise Muñoz, a 33-year-old woman who died after a suspected pulmonary embolism, why was life support not terminated immediately when clinicians deemed it appropriate?

- A. She had no advance directive.
- B. Her husband opposed the termination and took legal action.
- C. A second opinion on her brain death conflicted with that of the primary caregivers.
- D. A Texas law required that life support be continued for pregnant patients.

Legal Review & Commentary

A Monthly Supplement to **HEALTHCARE RISK MANAGEMENT**



Botched genetic testing yields massive verdict of \$50 million

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News: A young child was diagnosed with an unbalanced chromosomal translocation, a chromosomal abnormality resulting in the need for 24-hour care throughout his life. Before his birth, his parents had requested prenatal genetic testing to detect the genetic disorder, but they were informed by the hospital and laboratory responsible for the testing that the fetus tested negative for the abnormality. In actuality, the fetus had the chromosomal abnormality. Two years after giving birth to the young boy, the parents brought suit against the hospital and the genetic testing facility, and they alleged wrongful birth. At the conclusion of a seven-week trial, the jury returned a

verdict against the hospital and laboratory. It held both joint and severally liable for \$50 million.

...the fetus did have the genetic abnormality and was subsequently born needing lifelong 24-hour care.

Background: After a couple received news from their local hospital's genetic counselor that the fetus the wife was carrying tested negative for a hereditary chromosomal abnormality, the married couple decided to carry out the pregnancy. The husband was aware, based on genetic testing he had done previously, that he was a carrier for a chromosomal abnormality specifically involving the translocation of chromosomes 2 and 9. While the father was a carrier for the disorder, he expressed no phenotypical traits and was told there

was still a 50% chance that he would pass this abnormality on to his child. Transmitted to an offspring, this abnormality results in a child requiring 24-hour care along with various other serious health complications throughout the duration of their lives. Additionally, this disorder does not necessarily result in a shorter lifespan but rather a generally normal lifespan for the affected person. Sadly, the genetic results provided to the couple were incorrect; the fetus did have the genetic abnormality and was subsequently born needing lifelong 24-hour care.

The parents were understandably baffled as to how this situation could have happened. While consulting with the genetic counselor for a local hospital, the couple had decided that they would not carry out the pregnancy if the child tested positive for the chromosomal abnormality. A specific genetic test thus needed to be ordered on a blood sample obtained from the fetus. Also, and importantly, a detailed family history of the mother and father was supposed to be submitted with the blood sample. This family history information, including symptoms and characteristics of how the abnormality presented itself in affected family members of the father, was especially critical.

Also included in this history should be the nomenclature of the abnormality, or the “GPS” coordinates of the abnormality, so that the genetic laboratory technicians know specifically where to look for it. These kinds of details are vital to genetic testing for chromosomal abnormalities because they ensure that the laboratory testing the blood samples, as well as the genetic counselors, is sure about what the results indicate. In this case, the mother and father arranged for the family history to be faxed to the genetic counselor in advance of their appointment, and they brought in a hard copy as well.

However, the genetic counselor at the hospital failed to provide the laboratory conducting the genetic testing with the necessary family history paperwork. Upon receiving the blood sample from the genetic counselor, the laboratory failed to inquire as to why the necessary family history paperwork was missing. Consequently, the laboratory technician carried out testing on the blood sample but did not specifically analyze the areas on chromosome 2 and 9 that caused the genetic abnormality in question. To make matters worse, the technician analyzing the blood sample was a trainee and per the protocol of the laboratory, a supervisor is required to review all reports generated by the trainees to ensure accuracy. However, the report was not reviewed by a supervisor prior to sending it out to the hospital’s genetic counselor. Thus, the genetic counselor then informed the parents, incorrectly, that the fetus did not have the chromosomal abnormality.

After realizing their newborn was in fact tragically affected by the chromosomal abnormality, the parents and the child, through his court-appointed guardian *ad litem*, brought suit for wrongful birth against the hospital that employed the genetic counselor and the laboratory responsible for providing the

results of the genetic testing. At the conclusion of the eight-week trial, the jury deliberated for one and one-half days before finding the hospital and laboratory jointly and severally liable for \$50 million dollars. These damages include the extensive 24-hour care required to adequately take care of the young child through adulthood.

What this means to you:

Discussions about genetic testing with patients are never easy because of the serious ramifications the results pose. In this case, the married couple’s decision to carry out the wife’s pregnancy depended on the results of the genetic testing. It is imperative that the greatest care be taken when consulting, discussing, and eventually reporting genetic testing with patients. All necessary information must be supplied to the genetic testing laboratory to ensure that the results are reported accurately based on accurate information. The genetic counselor did not take the time to ask the testing laboratory staff the right questions to ensure that they had the information needed to complete the ordered test accurately. (Note that genetic counselors generally are neonatologists.) Likewise, the laboratory failed to notify the hospital about the missing information or inquire as to why it was missing. With the life of the fetus dependent upon the results of this test, all steps available to avoid result discrepancies should have been taken.

Also, training of new employees must be supervised closely. From intake coordinators, to residents and fellows, it is that supervisors responsible for overseeing training remember to double-check and review a trainee’s work. In this case, failure to properly review a trainee’s report resulted in the reporting of genetic testing results with absent family history information. Had a supervisor reviewed these results, the super-

visor would have realized that the laboratory was missing the necessary information to focus the genetic testing on the particular areas of chromosome 2 and 9. By ensuring proper supervision of trainees, mistakes like this one can be caught ahead of time and corrected.

Additionally, it is essential for hospitals and physicians (neonatologists) to order their genetic testing through a reputable genetic testing laboratory that remains in good standing with all required compliance agencies. By doing so, the hospital and physician ensure to the best of their knowledge that accurate reports are being provided to patients. Also, it is not uncommon for some medical professionals to order more than one genetic test by separate companies to further verify the validity of genetic testing results. While this might not be an option for everyone, it might be advisable to ensure that the results are 100% accurate and consistent.

Healthcare professionals must be keenly aware of how genetic testing results impact crucial life decisions for families. For this reason, the role of a dedicated genetic counselor is significantly important. In this case, the hospital made cuts to their budget, which in turn limited funding allocated to the maternal fetal medicine clinic. Due to the budget cuts, the maternal fetal medicine clinic employed a genetic counselor from a neighboring hospital once a week. This situation proved to be problematic because it likely produced an overly burdensome workload for the counselor. In contrast, similar medical centers in the county employ their genetic counselors full-time, which allows for a more reasonable workload and a better guarantee of daily follow-up with patient’s matters. While it is often difficult to control major budgetary decisions, it is important to ensure that current employees have a reasonable workload to ensure proper patient

follow-ups.

At times, healthcare professionals have little choice in deciding which laboratory to use when ordering genetic testing because of patents on DNA testing. This situation can become problematic when doctors and hospitals need to order a specific genetic test. Most recently, the United States Supreme Court handed down a decision in June 2013 determining what exactly can be patented regarding DNA testing and sequencing in the *Association for Molecular Pathology v. Myriad Genetics* case. In that case, a genetic testing company obtained patents for the isolation of certain DNA segments and methods used to determine the propensity for developing cancer based on analysis of mutated DNA segments. These

patents limited medical professionals and patients because only a specific company was able to process a certain genetic test to determine cancer propensity in patients. Furthermore, the out-of-pocket price for these tests could be thousands of dollars because the companies holding the patents had no competition in the market, which would have helped to reduce the price for these tests. Proponents of these patents argue that patents encourage investment in biotechnology and help to promote the sharing of ideas that otherwise would be kept secret in isolated research labs. On the other hand, opponents of the patents claim that the patents actually prevent research innovation because the patents by their very nature prevent projects based on patented DNA.

Ultimately, the United States Supreme Court held that a DNA segment cannot be patented even if it is isolated because it is naturally occurring in nature. However, DNA segments that are not naturally occurring — for example, modified DNA such as DNA synthesized from messenger RNA — still may be patented. While this decision was definitely a relief to healthcare providers, researchers, and patients, there might be issues in the future with modified DNA patents. The question remains as to exactly how much modification is sufficient to allow for a patent.

REFERENCE

Case No. 10-2-43289-2 KNT, Superior Court of King County, King County, Washington, Dec. 10, 2013. ♦

Negligent prescription results in fatality and verdict of \$2.25 million

News: A young woman died from fatally low oxygen levels after being prescribed a narcotic pain relief patch after treatment for pancreatitis. This pain relief patch caused her oxygen levels to fall well below normal, which resulted in a lack of oxygen to the brain. The woman had received treatment from a hospital for pancreatitis and was discharged after five days. However, after suffering from additional abdominal pain and fevers, the woman was prescribed a pain relief patch, which depresses the respiratory system even further, especially if the patient has a fever. In this case, the combination of the patch and the woman's fever resulted in a fatally low oxygen saturation level and a fatally depressed respiratory system. Her parents brought suit against the hospital for negligently prescribing the medication while knowing that

she was suffering from fevers. After three trials, a jury returned a verdict against the hospital for \$2.25 million, which included loss of consortium damages.

Background: After experiencing severe abdominal pain, a young woman went to her local emergency department and was diagnosed with pancreatitis. She was promptly admitted to a nearby hospital for treatment. The patient remained in the hospital for five days and was discharged. Once at home, she began to experience increasing abdominal pain. Three days after being discharged from the hospital, the woman returned to the emergency department. She was diagnosed again with pancreatitis and again admitted to the nearby hospital for treatment with antibiotics. Throughout her stay

in the hospital and on the day she was discharged, the woman had a fever. Unfortunately, she was not provided additional antibiotics upon discharge from the hospital, and she still was suffering from an intra-abdominal infection.

Upon discharge, the hospital neglected to provide the woman additional instructions on how to care for herself after going home. Specifically, the hospital failed to provide the woman with proper instructions emphasizing that she might be particularly vulnerable as she was still suffering from a fever. Tragically, the narcotic pain relief patch prescribed to alleviate her abdominal pain resulted in a fatal decrease of her oxygen saturation levels. The day she was discharged from the hospital, her oxygen saturation levels had dropped to as low as 48%. When she was discharged,

her levels had risen to 88%; however this level still was considered low. Fentanyl can further exacerbate low oxygen levels as it has a depressive effect on the respiratory system. Sadly, the young woman was found unconscious 18 hours after being discharged. Despite multiple attempts to resuscitate her, she was pronounced dead.

Five days after her death, the family filed a wrongful death lawsuit against the hospital and the treating physician for medical negligence for failing to provide the woman adequate medical care. The jury found the hospital and physician guilty of medical negligence, but jury members could not reach a verdict as to whether or not the negligence was the proximate cause of the woman's death. A second trial was granted with a subsequent verdict for the hospital; however the presiding judge ordered a third trial after defense attorney misconduct. After the end of the third trial, the jury found the hospital and physician guilty of medical negligence and awarded the family \$2.25 million, which included \$1.25 million for loss of consortium damages.

What this means to you: Pain relief patches often are prescribed to treat ongoing pain. Great care must be taken while a patient is using this medication because of the significant side effects, namely addiction. In this case, fentanyl is particularly sensitive to increases in body temperature from a fever or even exercise. When there is an increase in body temperature, the fentanyl patch releases additional medication into the patient's system through the skin, which in turn causes depression of the respiratory system. Here, the young woman already was suffering from decreased oxygen saturation levels, which combined with the effects of fentanyl, left the woman particularly vulnerable to a

fatally low oxygen levels. Physicians must be extremely mindful of all aspects of their patient's conditions in relation to prescribed medications. It is always important to take the time to read through the warnings for medications and possible side effects to ensure the patient will be safe. Fentanyl in particular is considered a high-risk medication and comes with a black box warning that alerts physicians to the specific risks of prescribing the drug to patients. Unlike oral narcotic analgesics that are effective for three to four hours, fentanyl remains on the skin and is active for 72 hours. This time element is especially critical to keep in mind if your patient is going to be taking the medication at home without the supervision of a healthcare professional.

Additionally, a well-established protocol for patient discharge is vital to ensure that the patients and their caregivers are well informed about the needed care after discharge. A patient with an oxygen saturation level of 48% qualifies for ventilator assistance, not discharge from the hospital. She should not have been released until her levels were within a normal range of 95-100%. Her nurse should have alerted the physician of her abnormal oxygen levels and stopped the discharge. If the physician disagreed, the nurse has the responsibility to go up the chain of command within the hospital and advocate for the patient.

It is also the nurse's responsibility to provide discharge instructions to every patient. These instructions include a review of the medications to be taken at home, the dose, the side effects, and a review of when to seek medical attention. Had the nurse or the physician taken the time to explain the risks of the fentanyl patch, including its respiratory depression effects, the outcome for this patient likely would have been quite different.

A significant turning point in the litigation for this case was the second trial in the case. By that point, the hospital had received a verdict in their favor. However, a third trial was ordered by the judge as a result of misconduct of the hospital's attorney. Specifically, the attorney made a number of improper objections during the trial, asked various improper questions that were ruled unacceptable by the judge, and made improper comments in front of the jury. Despite being warned by the judge on more than one occasion, the attorney persisted with improper courtroom behavior and demeanor. While sitting at the bench, the judge noted that this trial was the first new one he had ordered because the attorney's behavior was so offensive.

It is important for healthcare professionals to seek out law firms who are committed to zealously defending their clients. However, there is a line drawn between a zealous defense and improper tactics and behavior. Given that there are very high stakes in medical negligence and malpractice cases, it is extremely vital to select a law firm that has an established history of reputable behavior, both in and out of the courtroom. It would be wise to consult with other legal professionals to determine what kind of overall reputation a particular attorney or law firm has. This kind of due diligence will be invaluable when a verdict is on the line. Here, the failure of the defense attorney to heed the judge's warning about his behavior resulted in a third trial. Not only did this third trial cost the hospital a significant additional expense, but it cost the hospital an undisputed verdict in its favor.

REFERENCE

Case No. D-101-CV-2009-04090, First Judicial District of Santa Fe County, County of Santa Fe, New Mexico, Dec. 13, 2013. ♦